PRACTICAL ISSUES ARISING FROM THE USE OF TELEMEDICINE APPLICATIONS; An evaluation of equipment used for colour imaging in teledermatology, automated weight monitoring and patient-operated 12-lead ECG recording in arrhythmia.

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Abstract

Three telemedicine applications which depend on relatively simple telephone technology to transfer data in the care of patients managing chronic conditions at home are investigated in order to evaluate their application from the users' perspectives.

Part one provides an evaluation of four mobile cameraphones, of varying quality, such as those commonly used to photograph patients for remote diagnosis. The cameraphones are compared with a digital camera, two videophones and an ISDN6 conferencing facility, in their ability to replicate colour and shape. The effects of uploading the images to a laptop computer and of transferring an image by MSN messaging are also evaluated.

Part two provides an evaluation of electronic weighing scales connected via a wireless gateway to a landline telephone for the purpose of remote weight monitoring in patients with chronic heart failure. Self-reported experiences of patients, carers and specialist nurses are explored and outcomes compared with previously published opinion. The idiosyncratic nature of health care is highlighted as a main factor in the success or failure of the system.

The third application is a patient-operated 12-lead ECG unit which transmits data via a home landline to a call centre, where it is displayed as an ECG trace and a report is given by specialist clinicians. Self-reported experiences of patients with arrhythmia reveal systematic phenomena which hinder the effectiveness of the device and which are related to human, not technological, failings. ECG traces obtained by unskilled lay persons on paediatric patients are compared with the ECG traces obtained by skilled and experienced paediatric nurses on the same patients.

The results show that in the case of the cameraphones the technology is less accurate than normally assumed. In the case of the weight monitoring and ECG equipment however it is more usually human factors which cause a disappointing outcome.

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Author's declaration

The author takes responsibility for all the material contained within this thesis and confirms this is her own work.

G.Johnston

Introduction and overview of thesis.

The thesis addresses the evaluation of three telemedicine applications used in the management of three different chronic conditions, in which a domestic telephone system via either a landline or mobile network is the medium of data transfer. The applications are;

- mobile cameraphones used in acquiring images of patients
- a remote weight monitoring device connected via a wireless gateway to the normal telephone line, for use by patients with chronic heart failure.
- a patient operated 12-lead ECG unit in which the data are transmitted via a normal landline telephone.

To aid comprehension of the whole, a flowchart is presented in figure 1. The studies seek to contribute to the body of evidence by exploring some common assumptions and exposing the truths as experienced by patients, their carers and clinicians. A review of the growth of telemedicine applications based on relatively simple telephone technology, and the need for evidence in the field, is presented in **chapter 1**. It is followed in **chapter 2** by a description of the development of the overarching methodological strategy which encompasses the disparate methods relevant to each study. The specifics of each method are described within the individual study to which they relate. The studies are grouped, according to the telemedicine application they refer to, in three main parts.

Part One investigates the use of mobile cameraphones, a digital camera and three examples of real-time imaging equipment which are commonly used to transfer visual data in telemedicine applications, mainly within the clinical specialities of tissue viability and dermatology. **Chapter 3** provides a review describing the use of the equipment to date, discussing the relationship between the quality of the image and successful telediagnosis or monitoring. The rationale for the studies is explained. C**hapter 4** describes a study which compares the image quality in terms of colour accuracy afforded by the digital camera and four mobile phones, ranging in cost and quality from very lowest to the highest available at the time. POTS, ISDN2 and ISDN6 video telephony are also briefly addressed, as it the effect of transmitting an image from one device to another via the messaging facility. They are followed in **chapter 5**, by a study which presents a comparison of the distortion present across the face of the mobile phones and digital camera used in the previous study.

Part two investigates the use of a landline telephone and wireless gateway to monitor patients with chronic heart failure. The telephone receives data, via the wireless gateway, from electronic weighing scales and transfers it to a central call centre staffed by specialist heart failure nurses and cardiac clinicians. **Chapter 6** provides the context for the study from the literature available and **chapter 7** describes a study in which interview data compare and contrast the perception of patients, spouses and clinicians with each other and with the reality of events occurring throughout the study. It raises questions regarding the ability of the system to fulfil expectations, exposing barriers to successful implementation and suggesting manoeuvres which may facilitate it. Limited data relating to quality of life and state/trait anxiety scores are offered in **chapter 8** and findings are supported by a vignette of one patient's experience in an unusual scenario. **Chapter 9** offers an appraisal of the limitations of the evaluation study, a reflective account of the research process and a summary of the conclusions and recommendations arising from the complement of data.

Part three describes a study in which a landline telephone transfers the audible signal of a patient-operated ECG machine to a central call centre, where it is converted to an ECG trace and a clinical report made available within a few minutes. The background and a review of previous work are presented in **chapter 10,** following which **chapter 11** describes a study which compares the patient/spouse experience with that of the clinicians, via the medium of interview. **Chapter 12** is presented as a vignette of one particular patient, whose experience contrasted the success of the telemedicine equipment against the failure of the administrative structure encompassing it. **In chapter 13**, the quality of ECG traces obtained from paediatric patients, either by an untrained operator such as the parent, or sometimes by the child themselves, is compared with the quality of the traces achieved by a professional paediatric nurse trained in ECG monitoring obtained using traditional methods. Some limited verbal comment, reported from parents, is included to raise awareness of the appeal that such a service would have for them. **In chapter 14** the limitations of the ECG studies are described, together with the conclusions and recommendations arising from the studies, and an overview of the researcher's perspective is provided by a reflective summary of the research process.

Finally, **chapter 15** summarises the evidence from all studies and discusses the implications for the successful implementation of telemedicine initiatives. A flowchart of the thesis content is given in figure 1-1 on the following page.

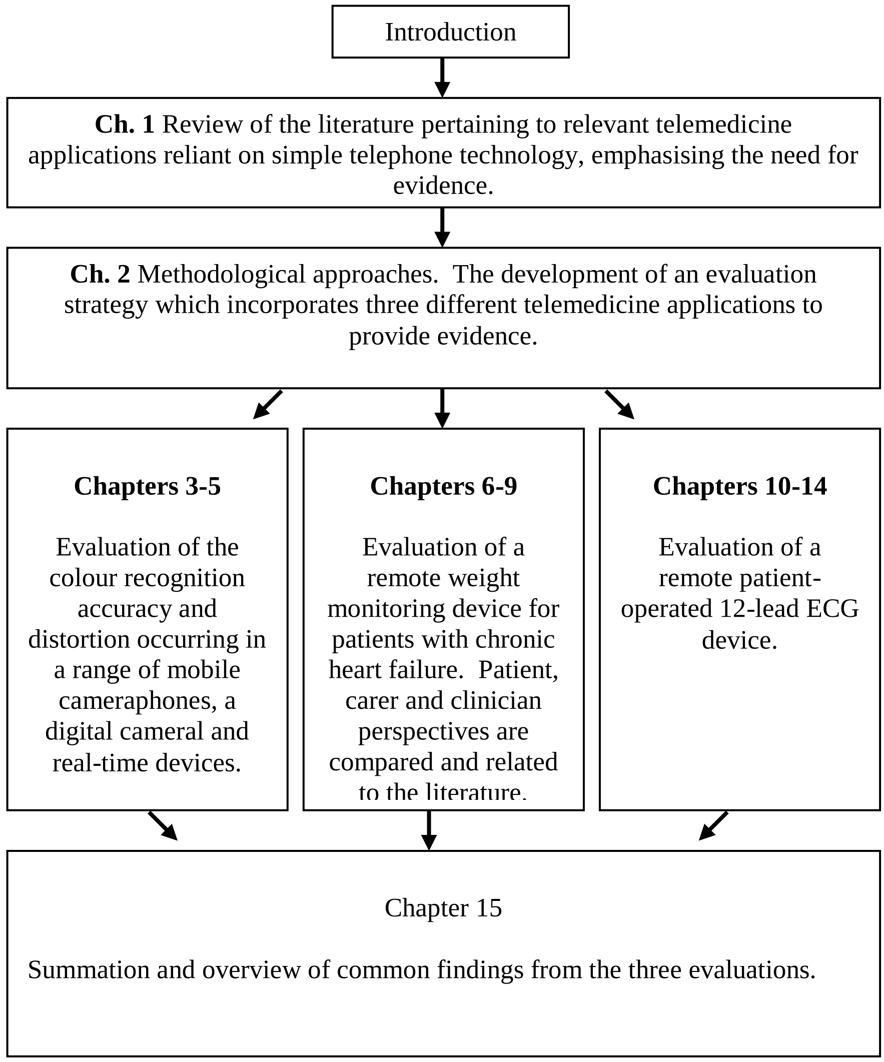

Fig 1-1 Flowchart and outline of thesis contents.

CHAPTER 1: A literature review of telephone-based applications in telemedicine

1.1 The use of telephonic communication in telemedicine. Although there is no definitive recording of the first use of telephonic communication in telemedicine, it has had far wider application, and for far longer, than is generally recognised. Since the inauguration of the American public telegraph service in 1844, it is entirely possible that there was some unrecorded communication relating to medical matters during the early years. Zundel claims "it is known that the telegraph was used during the Civil War to transmit casualty lists and order medical supplies," although her source is not revealed. (Zundel, 1996 p 72). Following Alexander Graham Bell's patenting of the telephone in 1876, it is probable that many unreported telephone conversations of a medical nature occurred, although the distance over which a telephone conversation could occur was comparatively restricted. It was over thirty years before the telephone relay was invented (Brown, 1910) which substantially increased the distance possible between telephone connections. In testing his invention, Brown transmitted the sound of heartbeats over several miles of telephone line and claimed that a correct diagnosis could be achieved by that method. Developments in telephony continued and seventeen years later, in 1927, the first emergency service was established, when London residents were advised to dial "0" if they had an emergency, later developing into the "999" emergency service we know today (Firenet: [cited 2008 Oct 20] [1]).

Since that time, even though innovations in technology have led to the telephone communication systems being used to transmit far more than simple sounds, the simple telephone conversation still has a role which is greater than the merely administrative, particularly in communications between health care professionals and patients receiving therapeutic care. In a randomised trial of 613 patients the authors claimed significantly improved outcomes for patients suffering from depression who had received systematic follow-up by telephone (Simon, VonKorff, Rutter and Wagner, 2000), and in 2003 the authors of one systematic review had found that telephone consultations can be efficient and effective in other areas of patient management, such as "facilitating health promotional

[1] Available from:- http://www.fire.org.uk/advice/999history.htm

interventions, in triage, and in promoting access and delivery of routine health care to people with chronic disorders" (Car and Sheikh, 2003 p 966). They claimed additional advantages in staff training, possible cost savings and public satisfaction, although there had been some concern raised by clinicians about medical and medico-legal risks. In contrast, Meyer and colleagues (Meyer, Raman, Hemmen, Obler et al., 2008) in their study relating to patients with acute stroke, found that fewer correct treatment decisions and more incomplete data resulted from a telephone consultation alone, than from an alternative telemedicine facility. In this case the alternative facility was web-based, but it cast doubt on the efficacy of the telephone alone versus a consultation including additional facilities. In 2004, an initiative to establish a system of telephone support for families caring for palliative care patients at home was reported to have provided a feeling of security and lessened the isolation experienced by those families (Wilkes, Mohan, White and Smith, 2004).

Telegraphic transmission provided an additional facility to the telephone call , as demonstrated in 1929, when a description and picture of transmitted dental X-rays appeared in the publication Dental Radiography and Photography (Anonymous, 1929). Facsimile (FAX) transmissions have also been employed as an additional diagnostic aid, having been used routinely for the remote diagnosis of X-rays since 1947 and the results reportedly being comparable to a face-to-face diagnosis (Gershon-Cohen, 1952). It should be noted that the quality of detail visible on the original dental radiographs of 1929 and Gershon-Cohen's radiographs in 1947 was vastly inferior to the detail visible from modern X-ray equipment and those results may well not apply today, however fax is still used to transmit documents and pictures such as ECG tracings, either between healthcare professionals or, increasingly, between patients operating home monitoring devices and the commercial companies interpreting the data[2]. ECG recordings can also be captured and transmitted as sound without the need for mediation by fax, as in the Broomwell Healthwatch system of home monitoring in which the 12 lead ECG is said to require nothing more than a normal phone (BroomwellHealthwatch, 2010).

[2] For examples, see:- http://www.broomwellhealthwatch.com
http://www.hommed.com

Although two-way interactive television had been in use for consultation and education purposes since the late 1950's (Benschoter, 1967, Wittson and Benschoter, 1972) it is widely accepted that the first commercially available "picture phone" was unveiled at the Bell Telephone Pavilion at the 1964 World's Fair. Since that time technological developments have allowed a variety of videophones to emerge, all of which are employed in a wide variety of telemedicine initiatives. For example Videophones were found to be useful in a pilot project relating to the secure access to patient records over the internet (Vasudevan, 2001) and The Eastern Montana Telemedicine Network provided two-way videophone communication to parents of newborn children who were hospitalised (EMTN, 2002). The Regional Medical Centre at Lubec used POTS (Plain Old Telephone Service) videophones to assist communication between nurses and patients (Edwards and Patel, 2003) and in a study involving patients receiving palliative care patients and their families commented that the "visual features of the phone enhanced the care that they received". (Miyazaki, Stuart, Liu, Tell et al., 2003 p75). However Miyazaki and colleagues had conducted a related study at the same time in which the use of the videophones was related to antenatal care. In that case the authors found that videophone communication was used mainly for booking appointments and arranging home visits. Although conducted on very small numbers (six patients and three staff provided evidence via an exit interview) it does suggest that this equipment may be better suited to some clinical circumstances than to others. The reported success of a system in which POTS videophones were used to provide a connection between schoolchildren and elderly residents living in long term facilities (Troen, 2006) may suggest that its strengths lie in psycho-social support rather than the purely medical.

In contrast to the reported successes, the use of a POTS videophone in a child abuse prevention programme was not an unmitigated success (Inouye, Cerny, Hollandsworth and Ettipio, 2001). The authors concluded that logistic and technical difficulties caused low patient and clinician acceptance, and satisfaction was low due to the type of equipment and picture quality. The especially sensitive psycho-social aspect of child abuse may have some bearing on the findings, but interestingly, in reviewing the development of telepsychiatry, one author found that the service users were more comfortable with mediated services than the professionals were (Mclaren, 2003). This supported the findings of an earlier author who, in trialling a psychiatric service by videophone, found that some patients preferred the video consultation because they reported finding it far easier to tell the psychiatrist the things they wanted to say (May, Ellis, Atkinson, Gask et al., 1999).

Employing more sophisticated technology, single and multiple ISDN (International Services Digital Network) lines have been confirmed as accurate and rapid vehicles for transferring echocardiogram (ECG) images (Widmer, Ghisla, Ramelli, Taminelli et al., 2003, Milazzo, Herlong, Li, Sanders et al., 2002), and the use of a videoconference camera, connected via a single ISDN line and the patient's television set, for real-time audiovisual connection with the hospital, has been described in the care of patients with advanced chronic obstructive pulmonary disease (Vontetsianos, Giovas, Katsaras, Rigopoulou et al., 2005). Videoconferencing has, in the main, been shown to be a useful alternative by which to provide a variety of services where geographical distance is an issue, particularly in psychosocial interventions. The added advantage of the potential to reduce costs to patients and the health service is frequently cited, as in the case of a videoconferencing facility which communicated between a department of emergency medicine and a number of local correctional facilities, in which the authors claimed that 38% of patients avoided a journey to the emergency department (Ellis, Mayrose and Phelan, 2006). In addition to clinical benefit and cost saving, there appears to be a number of other advantages. For example in investigating videoconferencing as a tool to aid stroke victims, the authors found that it not only allowed participants to access the rehabilitation service more readily, particularly the patient education aspects, but that participants were also using it to increase their social network (Lai, Woo, Hui and Chan, 2004).

Videoconferencing has also been shown to be useful as a multi-purpose tool in a telepaediatric burns service, not only as a medium for patient consultation but also for educating and supporting the occupational therapists involved in the patient management locally (Smith, O'Brien and Jakowenko, 2006, Smith, Kimble, O'Brien, Mill et al., 2007). Although the study reports only potential cost savings for the health service and participant satisfaction for the clinicians accessing the educational content, it must be assumed that the videoconferencing process is effective, as it was still in operation in 2009, albeit with the support of digital photographs received via email (personal email from Dr Smith). Smith and colleagues also made claims of cost-savings in the use of videoconferencing for the telepaediatric mental health service described above (Smith, Stathis, Randell, Best et al.,

2007) and in a similar discipline related to mental health other authors found it a promising method to bring appropriate cognitive behavioural therapy to patients with obsessive-compulsive disorder (Himle, Fischer, Muroff, Van Etten et al., 2006). More recently it has been described with regard to its contribution to undergraduate and postgraduate dental education (Reynolds, Eaton and Mason, 2008).

In a study comparing the accuracy of pre-recorded video images with face-to-face consultations in the assessment of ENT conditions (Smith, Perry, Agnew and Wootton, 2006) the authors reported 81% concordance between diagnoses from face-to-face consultations and those made from videoconferencing using pre-recorded video footage, in patients with ear, nose and throat conditions. The evidence was later supported by a retrospective audit, confirming that there were no missed diagnoses or ongoing ENT related problems (Smith, Dowthwaite, Agnew and Wootton, 2008).

Most of the telemedicine evaluation has relied on demonstrating an acceptable comparability with a face-to-face consultation. However a study into videoconferencing with associated facilities used in paediatric and perinatal cardiology rather surprisingly showed significantly higher levels of parental satisfaction, in terms of explanatory advice compared to a face-to-face consultation (Weatherburn, Dowie, Mistry and Young, 2006). Videoconferencing has also been claimed by some authors to have the potential to enhance paediatric and perinatal cardiology services (Dowie, Mistry, Young, Weatherburn et al., 2007), thus supporting the claim related to tele-psychiatry, that a telemedicine consultation may in some aspects be superior to the face-to-face consultation.

Moving away from the designated landline telephone connections, mobile phones and cameraphones have also been used in a number of telemedicine applications. Ishida and colleagues (Ishida, Yonezawa, Maki, Ogawa et al., 2005) described a respiration monitoring system which automatically sends episodes of apnoea during sleep via a mobile phone to the hospital, and in another study the authors concluded that capturing and transmitting plain X-ray films of musculo-skeletal trauma via a mobile cameraphone enhances clinical care (Archbold, Guha, Shyamsundar, McBride et al., 2005), although again numbers were small and the evaluation largely subjective.

1.2 The need for evidence

Telemedicine is now claimed to have applications in a growing number of medical specialities, such as; cardiology, home care, radiology, emergency care, surgery, dermatology, psychiatry, oncology, pathology, ophthalmology, haematology, ENT, nephrology and pre-hospital care, as well as in professional education, patient education, research, public health and healthcare administration. Despite the growing number of telemedicine studies however, some authors have commented on the lack of high quality evidence, one commenting that, "Despite enthusiasm and development of such new projects, conventional clinicians need further longer term observation to grasp the advantages and pitfalls before more widespread use of telemedicine becomes commonplace" (Pal, 2001 p189). Hailey and colleagues supported this view by saying "Although further useful clinical and economic outcomes data have been obtained for some telemedicine applications, good-quality studies are still scarce" (Hailey, Ohinmaa and Roine, 2004 p318). Hjelm expressed a similar view, writing "As yet there are limited data on the clinical effectiveness and cost-effectiveness of most telemedicine applications… objective information about the benefits and drawbacks of telemedicine is limited" (Hjelm, 2005 p60).

Not all calls for more substantial evidence related to telemedicine in the abstract. In 1995, according to McLaren and Ball, there was a need for "methods for evaluating the impact of ***particular*** technologies…" (McLaren and Ball, 1995 p1390) but the paucity of evidence still appeared to be an issue until relatively recently. For example Louis and colleagues acknowledged that telemonitoring had a role in the management of patients with heart failure, but went on to say that "adequately powered multi-centre, randomised controlled trials are required…" (Louis, Turner, Gretton, Baksh et al., 2003 p583). It has already been mentioned that evidence relating to the impact of illness on the families of patients is scarce and in the care of patients with implanted cardiac defibrillators, it was noted that "Further research into the unique needs of partners … would be significant in developing practice and theory" (Albarran, Tagney and James, 2004 p210). Two years later the lack of high quality evaluation was still being remarked upon, for example in relation to home-based telemedicine interventions in chronic diseases it was noted that, "There are still significant gaps in the evidence base" (Hersh, Hickam, Severance, Dana et al., 2006 pV).

In some studies however, the initial promise of a beneficial telemedicine application was seen to remain unfulfilled, as in the case of an internet-based videophone support for a young boy with attention-deficit hyperactivity disorder (ADHD), who was hospitalised for bone marrow transplantation (Bensink, Shergold, Lockwood, Little et al., 2006). Clear examples of reduced inherent anxiety and distress were given in this single case, but the evaluation was subjective and as of October 2008 the system had not been adopted, or even trialled more widely because, according to Dr. Bensink, "Internet access at the bedside for all patients" was a main issue (personal correspondence from Dr. Bensink).

A similar situation occurred following the study by Dr. Troen, previously mentioned on page 6, which investigated the use of videophones as intergenerational connections for quality of life issues. The programme continued for four years. It ceased because, according to Dr. Troen "the individual in charge of the project at the Senior Citizen facility left and no other social worker wanted to continue the project" (personal email correspondence from Dr. Troen). Dr. Troen went on to say that he had learned from his experiences of this telemedicine application that there were certain essential elements without which the initiative would founder. Those elements were all concerned with people (users and providers) and not with the equipment. They included training, continual reinforcement, and the importance of selecting the right people (people who "care") to lead the project from the outset. It would appear that many telemedicine applications, regardless of how beneficial or effective they might be, are reliant for their success or failure on the individuals involved, and the following studies seek to illuminate not only the effectiveness of the equipment used but also the human perspective and contribution to its successes and failures. Although the internet has been touched upon, and is one of the largest and fastest-growing uses of telephone networks in telemedicine, it is not a major part of the telemedicine applications evaluated in these studies and therefore will not be addressed.

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CHAPTER 2: Methodological approaches

Introduction. This chapter describes the identification and subsequent logical development of one initial research idea into a research strategy. It resulted in a participant-oriented evaluation study covering three telemedicine applications, all of which use relatively simple telephone technology in the support of patients managing chronic conditions at home. During the process it became apparent that there was a need to achieve better understanding of the practical realities experienced by the users of these telemedicine applications, both to foster a more effective approach to the adoption and continued use of the technology, and also to enable more meaningful evaluations to be carried out in the future. To that end, those evaluations sought to expose the discrepancies in the participants' experiences, not only between the individual participants, but also between the participants and some generally recognised "facts".

2.1 Stage 1. Identification of a simple research problem. The researcher had read with interest a number of telemedicine studies which claimed to indicate that correct diagnoses could be achieved from the images of wounds, captured using mobile cameraphones or digital cameras and subsequently relayed to relevant experts for evaluation at a distance. However the researcher noted that some of the studies contained inherent weaknesses which had not been properly addressed and was concerned that such weaknesses may lead to an inappropriate reliance being placed on the use of photographic images with potentially harmful results. The literature is reviewed more fully in chapter 3, but to give an example, in some studies which compared diagnoses made by two or more clinicians from pictures diagnostic agreement was accepted as evidence that the diagnosis was correct. This is questionable on a number of counts, as;

- In this, and many other studies, patients were not followed up to verify that the diagnoses had in fact been correct. It is possible that both diagnoses might have been incorrect and this is particularly the case if a photographic anomaly created an appearance which deviated from the original subject.
- A high percentage of agreement was used as evidence that this procedure was a viable alternative to a face-to-face consultation, appearing to suggest that a 4%

misdiagnosis from images was an acceptable price to pay for a telemedicine service which would be cheaper and more time-efficient.

A further example was that many authors expressed the belief that as mobile phone technology improved and the number of pixels increased, the resulting images would be more accurate and thus accuracy of diagnosis would also improve. The researcher felt very strongly that these assumptions were unreasonable, on the grounds that;

- Although a greater number of pixels ensure better resolution it will have no significant impact on the quality of the image obtained unless the photographer is aware of the other contributing factors of photography, such as lighting, movement, distortion etc. The final appearance of sharpness of image, which may be blurred due to "camera shake" or subject movement, is termed the definition.

- The number of pixels does not reduce the distortion of shape, which is due partly to the curvature of the viewing screen, but largely to incorrect photographic angle.

- It assumes that all operators will have at least the same level of photographic ability as the researcher. If the method is adopted widely in the monitoring of patients in the home, possibly by the patients themselves, this is unlikely to be the case.

- Mobile cameraphone images are often subject to software "enhancement," intended to make the resulting photographs more attractive to potential users. Any manipulation of an image is prone to the dangers of inaccurate replication of the original.

- An increase in software enhancement is generally associated with an increase in cost, and cost was one of the features that authors had assumed indicated quality.

It appeared therefore that there were a number of questions requiring answers. So, following a format which had become familiar to the researcher over many years of teaching, a template was used to clarify the nature and purpose of inquiry. This resulted in a research design framework, shown in figure 2-1 overleaf, of a quasi-experimental investigation into the comparative quality of images obtained from a variety of equipment commonly used in teledermatology. A review of that framework revealed the nature of the study as being both evaluative and exploratory, the purpose being to identify any areas of concern regarding image quality which might point to a need for rigorous scrutiny from a clinical perspective. That scrutiny should subsequently inform clinical practice as to the scope of safe use of mobile cameraphones for diagnostic or monitoring purposes.

2.2 Stage 2. The emergence of a wider problem and common aims. Deeper exploration of the problem might not have occurred except that coincidentally during the early phase of clarification of this study the researcher was invited to consider also evaluating two telemedicine devices intended to monitor heart conditions. One was a set of automated weighing scales which enabled weight changes to be monitored daily by an outside agency, in the case of patients with chronic heart failure. The second was an ECG unit which patients used to record their own 12-lead ECG trace whenever they experienced pre-specified symptoms. Both devices relied on the provision of a fixed landline telephone in order to transfer data to an "expert" for remote evaluation.

On reviewing previous studies relating to ECG monitoring in the home and to the remote monitoring of patients with chronic heart failure, the researcher recognised that these also included some assumptions, or at best generalisations, which might not hold true in all circumstances. They are explored more fully later, but to illustrate the point, some studies claimed that remote weight monitoring reduced readmissions and improved patient wellbeing. However in those studies the monitoring of weight was performed by the patient and reported to a nurse during a regular telephone phone call. During that telephone call, which was initiated by the nurse, the patient provided a range of clinical information, of which weight was only one part. There was no evidence to show that the patient-reported weight monitoring was accurate, or that any benefit derived from the weight monitoring at all, rather than from the simple fact of regular phone calls which served to remind the patient of self-care behaviour in terms of diet, activity, etc.

Research Design Framework 1 ~ Mobile Phones and Comparative Image Quality.

Problem ~ Weaknesses of arguments and findings in studies of mobile phone diagnosis.
- .Assumption of being right simply because observers agree
- Assumption that the more expensive the equipment the more accurately it will perform.
- Number of pixels is important for resolution, but cannot be assumed for colour or distortion.

Units of Analysis?
- Staff involved in evaluating dermatological conditions and/or tissue viability.

Units of Inquiry?
- Colour – replication of a matrix of colours from an image (% score of correct identification.)
- Area – comparison of area measured at different points on the image (% difference.)
- Detail – assessment of clinical features. (Subjective)

(Future study to be determined depending on results of experimental study)
- Clinical studies to assess relevance of colour reproduction
- Clinical assessments. Eg diagnoses or evaluation of the progression of disease
- Confidence of above. (High confidence level when the evaluation was actually incorrect is potentially particularly dangerous to patients.)
- Statements from participants. (What is it about the image that makes diagnosis or evaluation easy, difficult or impossible.)

Topics?
- Use of photographic equipment in the diagnosis or evaluation of disease in dermatology/tissue viability
- Accuracy of reproduction & potential implications of accuracy and inaccuracy.
- Potential effect on patients and working practices & cost implications

Nature of Effect?
- Match between image and original object = findings in other studies supported, even though the reasoning might have been faulty
- Mismatch between image and original object = potential patient mis-diagnosis?
- Better matching relates to increased cost of equipment = previous recommendations safe
- Better matching does **not** relate to cost of equipment = previous recommendations **un**safe.

Variables?
- Type of diagnosis (whether based on colour as in erythema, or on size as in ulcer healing)
- Staff (training, experience, eyesight etc)
- Equipment. (Mobiles, cameras, video, etc)
- Imaging conditions (quality of lighting, minimal movement, perpendicular projection)
- Viewing conditions (ambient light & temperature, glare reduction.)

Major themes?
- Relevance of the findings of quasi-experimental study to clinical practice?

Purpose?
Evaluation and policy development.

Fig 2-1 Research Design Framework for mobile phone study.

The implication in many studies was that the patient would be told what to do and would do it, however no reason was offered as to why an unusually high percentage of patients had refused to participate, why there was a high incidence of non-compliance, or why some “were lost to the study.” Nor was evidence offered to support the decision that some participants were dismissed as “ineligible” because their heart failure was “too severe,” or they had dementia, or they had no partner at home. It was assumed that the system would not be appropriate for them, but it could be argued that these patients were those in most urgent need of an automated system as they did not have the skills or ability to do this for themselves. Furthermore, due to the nature of chronic heart failure, which is associated with age and with cognitive dysfunction, it is likely that all sufferers would ultimately fall into the “ineligible” categories. The results of such studies often implied that remote monitoring afforded better health and substantial cost saving, quoting comparison of bed-days and hospitalisation events. However the comparison of percentages relate only to those heart failure patients who were otherwise physically and mentally fit, who had a carer living at home and who chose to participate. Had the reduction in bed-days and hospitalisations been presented as a percentage of all heart failure patients, the results may well have appeared a lot less dramatic.

In considering the 12-lead ECG unit used in the home, a patient-operated version had not previously been investigated. Similar equipment had been shown to be of use when operated by visiting doctors or nurses and this had been used to indicate the cost-benefits of such a scheme. There was no evidence to suggest that patients either would or would not be able to perform this task nor was there an indication to what extent other treatment provided by the visiting clinician had contributed to the outcome. A patient-operated one-lead ECG apparatus had been shown to be cost-effective, but the one-lead ECG equipment is worn like a wristwatch, and it does not require any physical preparation before use. The 12-lead unit however requires the removal of clothing, some education and a degree of dexterity in order to operate it. This was a strong indication that a fuller exploration of users’ experiences would be required if it was considered worth pursuing as a useful diagnostic tool for patients in the home at the time an arrhythmia occurred.

One major concern in incorporating the heart monitoring aspect into the original research idea of image replication in mobile phones, was that the automated weighing scales and the

ECG unit required a fixed landline telephone, as neither was approved for use with a mobile telephone. Being particularly interested in the mobile phone aspect, the researcher queried why not, asking the question of representatives of the telemedicine company, and of a number of general practitioners and consultants who were interested parties in the heart monitoring research. All respondents offered the same two reasons, these being that;

- the quality and reliability of mobile phone communication signals were not yet good enough. A recurring point was that the signal is compressed during periods of busy transmission and thus the quality of the information, particularly the ECG trace, might suffer from loss of data. It was feared that the signal would not get through at all or be severely delayed, and thus would be an unacceptable danger to patients using either piece of equipment.

- there was no need to transmit the data from a mobile phone as these patients did not normally venture far from their home.

In order to verify the truth of the reasons given, the researcher first sought advice from a senior representative of a large mobile phone company. It transpired that uncompressed data transfer would not present a problem as mobile phone signals can be tagged with a unique identifier and transmitted as a priority, thus minimising delay and signal compression. The argument against the use of transmission via mobile phone also presupposes that medical data would be transmitted over the general network, although in America specific networks have been developed for the transference of just such data. The representative indicated an interest in pursuing this line of enquiry with a view to commercial development, but the researcher felt that the equipment should be evaluated as it was intended to be used in the first instance, whilst building into the evaluation the identification of any need for the facility to be mobile. If a need was discovered during that evaluation, then a further study could follow. However the meeting had confirmed that once again prospective users of telemedicine held firm convictions which were not necessarily correct, but which were obstructing the progress of unprejudiced inquiry.

The three telemedicine applications being considered (the mobile camera phone for image transfer, the automated weight monitoring system and the remote diagnosis of ECG data) undoubtedly had a number of features in common, i.e.,

- regular monitoring or early diagnosis of a chronic condition, hopefully resulting in better care and reduce costs.
- claims of increased access to expert resources which were in short supply
- concern with accessing that expert opinion from a remote location
- reliance on relatively simple telephone technology to transfer data from the home to that expert service.

However it was beginning to emerge that by far the most sinister commonality was the inference that the evidence on which policy (and therefore clinical practice) was based, was at best unproven and at worst false, in its assumptions. Incorrect assumptions might lead to a promising telemedicine application being vetoed without trial, but even more worryingly they might lead to an inappropriate telemedicine application being adopted in clinical practice. Not only might that be harmful, but the very fact of its adoption could be used as evidence in support of its expansion, thus reinforcing any misconception which might originally have existed. So whilst the evaluation of three separate telemedicine applications would provide valuable information about the nature and scope of those individual applications, a second aim had emerged. That aim was to expose the potential impact of mistaken assumptions or beliefs on the timely and effective adoption and continued use of telemedicine applications, so that future initiatives might more accurately address the problems they were intended to solve. Thus the recognition of assumption and the potential importance of its consequences had produced a unified central research aim in which the three specific applications, through useful evaluation in their own right, had assumed the role of tools by which to achieve that aim.

Figure 2-2 on the following page shows a diagrammatic representation of the relationship between the individual evaluations and the aims of the study as a whole. It also clarifies the trail of evidence required to achieve the final outcome. Thus the aims and objectives can be defined as follows;

2.2.1 Aims and objectives of the study.

Aims:- To Illuminate the factors which act to encourage the successful implementation of telemedicine strategies and,

To expose barriers which act to delay or deter the successful implementation of a telemedicine strategy

Objectives:- To evaluate the individual telemedicine applications

To identify differences in beliefs and opinions between user groups

To identify differences between users' views and published material

This characterised the end of the second stage. The next stage was to define the parameters within which the details of the investigation could later be constructed.

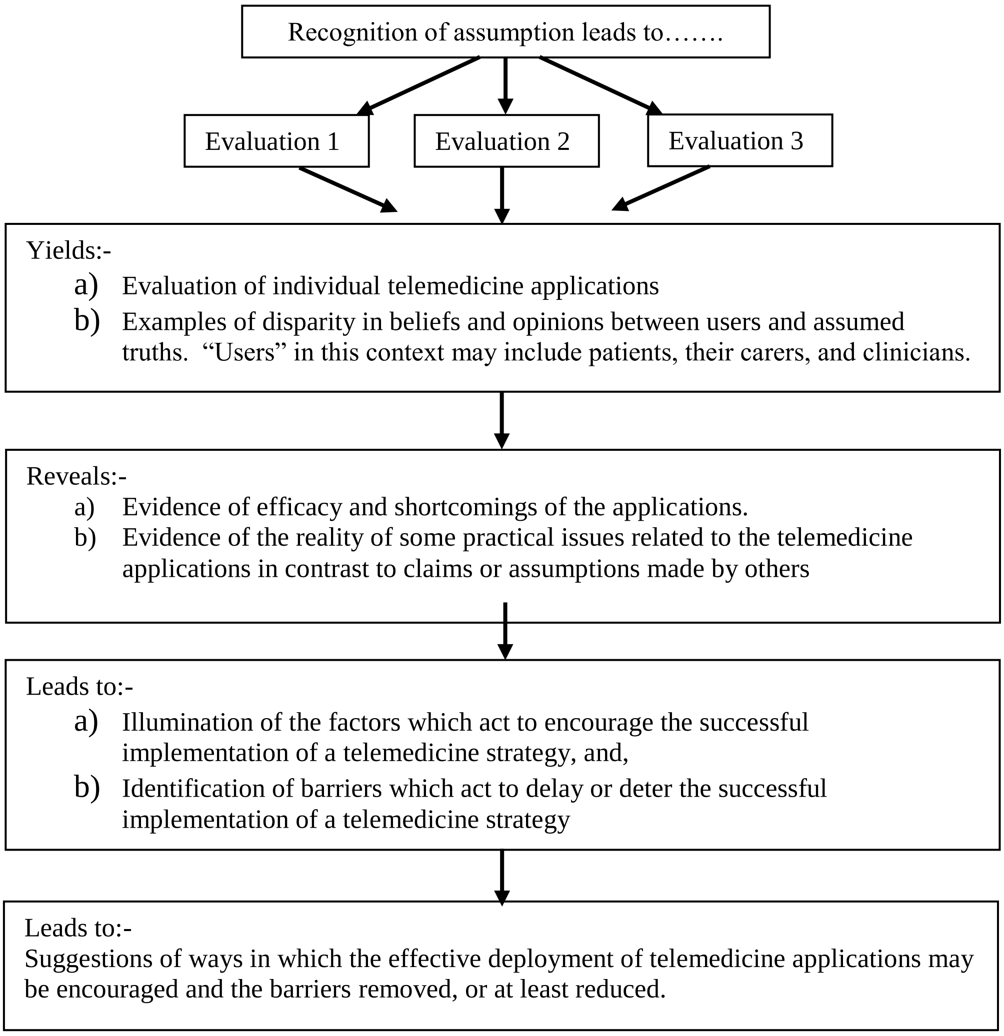

Fig 2-2 The relationship between the individual evaluations and the overall aims of the study.

2.3 Stage 3. Defining the parameters of the research strategy. Much of the research strategy relating to the comparison of mobile phones was under the control of the researcher. The researcher was limited by time constraints related to the availability of daylight conditions, the availability of the observers and the availability of the telemedicine coordinator at the distant hospital. The two studies relating to the monitoring of heart conditions however were under the influence of external factors.

Funding had been sought and obtained from the Department of Health and so certain features of the research were already established with the intention of evaluating the items of equipment for future use within a specific health authority. Twenty-five sets of each of the telemedicine applications had been acquired, together with the use of the monitoring service, for a period of six months. A team of clinical and managerial staff had already been defined and the researchers were brought in to steer the research. The team therefore comprised the clinical lead, who was a GP currently in general practice locally, cardiac nurses who were working in hospitals, general practice and in the community, the manager with special remit for cardiology, and the researchers. The detail of the research strategy had therefore to fulfil the requirements of a number of interested parties and also meet the constraints of the limited budget available. Team meetings were held in order to identify and discuss elements of the evaluation that the various team members felt should be included.

2.3.1 Outcomes of meetings relating to weight monitoring. The initial meetings with the health care provider team and the heart failure nurses gave a vague indication that comparative data were required, but that it had not been defined or even contemplated to any great extent. These meetings centred on practical minutiae, such as how the list of weights for each patient would be communicated to the nurses, how often, and where the focus of responsibility would lie in the event of a patient's weight exceeding pre-defined limits. It was clear that the nurses saw the weight monitoring initiative as being inflicted on them, rather than something they would control and drive, and the early meetings raised more questions than they answered. The telemedicine company was approached in an attempt to clarify the available choices in relation to working practice.

A few non-negotiable variables existed, which were that participants;

- had to be fluent in English, as no other language was offered in the call centre.
- had to be able to stand on the scales without support.
- had to have a landline telephone.

In contrast, there were numerous negotiable variables. To give a few examples;

- What results were sent (All daily weights for every patient or only those weights which had exceeded pre-defined limits, or even only those which exceeded pre-defined limits for a specified period of time)
- How the results were sent. (E-mail, fax, mail, telephone)
- Where the results were sent. (to the specialist nurse, GP, consultant, patient / any combination of those.)
- How often the results were sent. (Daily, weekly, or only when there was an adverse event.)
- Action to be taken. (Whether the telemedicine staff should merely alert the patient's nurse or doctor and leave it to them to take the appropriate action, or whether the telemedicine staff should themselves initiate remedial action by contacting the patient and providing advice on medication etc.)

When asked to specify their selection from the list of variables, the nurses made very different choices. The differences and the reasons offered are discussed in chapter 7, but disparity, it seemed, was already in evidence. Given that the fundamental theme was to address the nature and scope of disparity and to see how that impacted on care, the decision was taken to allow each nurse their choice of working practice as far as possible.

Recognising the requirement for comparative data however, the researchers insisted that the selection of patients and the administrative procedure of receiving and operating the telemedicine equipment should be identical for every patient.
The processes of defining the data required and teasing out the operational details of the research strategy occurred in the fourth stage and is described in section 2.4

2.3.2 Outcomes of meetings relating to ECG monitoring. Not surprisingly the managers stressed the need for evidence of cost effectiveness, whilst the clinicians debated the clinical scenarios in which they perceived a need for this equipment. The managers offered evidence from the past six months, relating to the number of patients having made multiple unplanned visits to emergency services complaining of either arrhythmia or chest pain, without having obtained a diagnosis. The cardiologists on the other hand, saw a potential use for this equipment in the case of post-operative patients, at least in the first few weeks after being discharged to their home. The decision was made to investigate the use of the equipment in patients with arrhythmia, on the basis that;

- post-operative patients should be excluded as they often had abnormal anatomy of the heart, due to the operation. The equipment had not been proven on abnormal anatomy, but this was noted for a possible additional study.

- chest pain may be related to factors other than the heart and thus the limited supply of equipment might be given to patients who did not necessarily have a heart condition.

- it was the policy to send patients with post-operative chest pain straight back to hospital without delay, and in the nurses' opinion there would not be an opportunity to record an ECG at that time whilst waiting for an ambulance.

There was a clear requirement for an evaluation study which provided comparative evidence relating both to costs and to healthcare outcomes, between patients using the telemedicine equipment and those who did not. The process of defining the precise nature of that evidence occurred in the fourth stage and is described in the next section.

2.4 Stage 4. Teasing out the details of the research strategy. This process occurred during the same time period for both items of equipment and the two groups reached similar, but not identical, conclusions. Minor discrepancies, when brought to the attention of both teams, often resulted in ideas being embraced. The prime example of this is that the ECG team had not considered including the effect on partners of arrhythmic or heart failure patients in the evaluation, but agreed it was a good idea when raised by the researchers and supported by the heart failure nurses.

Conducting an evaluation which, in the opinion of all the relevant parties, addressed all the important issues, was a matter of prime importance. The researchers asked the clinical teams to perform three tasks which would result in the operational details of the research plan. The first task was to define the broad clinical research question which, since the intention was to conduct an evaluation was quickly agreed to be "To what extent is this telemedicine system of value, or potential value, in caring for patients with this chronic condition?" (Heart failure was the chronic condition specified in the first study and intermittent undiagnosed arrhythmia in the second.)

The second task was to define the concept of "value." Discussion led to the concept of "value" being defined by its relationship to the individuals involved. Thus it emerged as :-

a) Value for patients and carers related to :-

- Benefit or detriment to health of patients
- Benefit or detriment to socio-psychological aspects of life for patients and partners.

b) Value for staff related to improvements in patient care or working practices.

c) Value for healthcare providers related to value for money.

The third task was to operationalise the research, in other words specify the data that would provide evidence on each concept defined. At this stage differences occurred in the development of the two studies and they are described separately.

2.4.1 Operationalising the research. ~ CHF study. This required a careful balance between what was wanted by the clinicians (health outcomes), what was wanted by the healthcare providers (cost / benefit assessment) and what was practical in terms of the financial and time constraints imposed. The constraints imposed in trying to achieve this balance were not always immediately understood by members of the team and the discussions and resultant outcomes are explained under the relevant heading below.

2.4.1.1 Benefit or detriment to the health of patients. Some team members had the pre-conceived notion that the research would replicate other studies and provide a statistical analysis relating to changes in hospital admissions derived from comparisons between experimental and control groups. Given that only twenty-five sets of weighing scales were available, the comparative data gathered would not provide very robust statistical evidence, as numerical comparisons of this nature require a greater number of participants in each group than the funding allowed for. The telemedicine company were approached to provide double the number of weighing scales and supporting services than the original funding allowed. They agreed to do this at no extra cost, whilst at the same time giving assurance that the records would be available to the researcher, who was free to publish whatever outcomes arose.

The heart failure nurses were keen to obtain feedback from the patients as they felt that there were many facets to healthcare that could not be quantified so easily. They did however recognise that the funding available would not allow for the time and travel required to conduct interviews with all patients, but that it was possible, with the extra equipment now available, to gather:-

- Subjective data from interviews with a small sample patients, carers and staff to provide reported health changes and identify other hitherto unrecognised issues that might arise.

- Quantitative data from patient notes relating to incidence of time to respond to decompensation, number and duration of hospitalisations.

2.4.1.2 Benefit or detriment to social and psychological aspects. This was the subject of similar discussion, mainly between the nurses, who expressed the strong opinion that “reassurance” and “worry” were important issues both for patients and for their carers.

Exploration of the issue led the team to decide that “anxiety,” or more accurately “changes in anxiety” was the topic of choice for investigation, as a reduction in anxiety may reduce the tendency towards depression, which is a common comorbidity of heart disease. “Quality of Life” assessment was a very familiar concept to the clinicians, and they assumed it would be incorporated as a matter of course. The only discussion was on which instrument to choose, and that centred on the apparent trend in recent studies to use newer instruments than, for example, the Minnesota “Living with Heart Failure” questionnaire. Since telemedicine is a rapidly expanding subject of research, it was thought better to have a study comparable to work which would follow, rather than work which may become outdated. Acting on advice from a researcher with many years of experience in the topic, the pragmatic decision was taken to use the MacNew Quality of Life assessment tool, as trends indicated that this might become the standard in the future and it had an instrument being piloted for carers, which others did not.

Although there was now sufficient equipment available to allow the analysis of comparative data the team were in unanimous agreement that there was a strong case for the collection of patient views. The nurses had expressed the firm belief that in chronic heart failure, changes in psychosocial state were influenced more by complex extraneous factors than by a single medical intervention, and it was important to differentiate between causes. They also gave accounts of patients being distressed because they either felt slightly unwell, or had noticed a small weight change and were not sure of what action to take. On the one hand they “didn’t want to bother the nurse” but on the other hand they “didn’t want to cause trouble by needing to go into hospital.”

Following the discussion on the relevance of worry, reassurance and anxiety, it was suggested that a patient diary might be useful, in order to capture those occasions. Thus the required data were identified as:-

- Comparisons of MacNew Quality of Life scores
- Comparisons of Spielberger State / Trait Anxiety scores
- Interviews with a sample of participants and their partners or carers.
- Diaries of patient experience

2.4.1.3 Value for staff related to an improvement in patient care or working practices.

Although it was possible to identify differences in the way each nurse used the weighing scales by observing the administrative data from the telemedicine company, it would be a meaningless exercise without a rigorous investigation of the reasoning behind those differences. The nurses explained that their work situations were very different, that external influences regulated their practice and that they were keen to explore the impact of those influences. It was apparent that, if those influences did indeed impact on practice within the sphere of heart failure care, it was important to recognise them and consider the implications.

The two sources of evidence were therefore defined by the evidence required, and were:-

- Interviews with CHF staff to gain insight into the implications of introducing automated weight monitoring into their practice

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- Comparison of the administrative choices they make in using the equipment.

2.4.1.4 Value for money. Managers and nurses alike felt that emergency hospitalisation due to decompensation was one of the highest costs to the health service in this group of patients and also one of the most easily preventable by vigilant weight monitoring. Thus a simple comparison of the number and duration of hospitalisations between experimental and control groups was all they required. The researcher felt that this was an over-simplified view, which would ignore subtle changes in the patterns of use of NHS resources by patients. For example a reduction in the number of phone calls patients made to the heart failure nurses due to reassurance from the staff at the telemedicine centre, or a change in outcomes such as an unplanned phone call or extra home visit by the nurse due to an alert from the telemedicine service, would probably not be recognised through quantitative comparison, because the six month period specified for the study would be too short for such changes either to take effect or to occur in such numbers as to be noticed. These changes, though subtle in quantitative effect, would in all probability be noticed by the patients and the nurses however. Therefore it was agreed that the researcher should collect:-

- Comparative data on interactions with healthcare resources from medical notes.

- Interview data of perceptions of change in the use of resources from the patients, their partners and the nurses.

The final debate addressed two questions which had cropped up during previous discussion. The first was whether patients who were classified as 1 on the New York Heart Association (NYHA) scale should be invited to participate. Previous studies already mentioned in the literature review had excluded this group as being too mild to require such frequent monitoring. The clinicians agreed with this view and so only patients in classes II-IV were deemed eligible. With hindsight this was the incorrect decision, and that point is discussed further in chapter 7.

The second question addressed the logistics of recruitment and the means by which patients would receive the electronic weighing scales. The nurses were concerned that patients would need assistance to install the equipment and this, together with the extra task of obtaining informed consent would place an unacceptable burden on their time. There was little option in the method of recruitment, which had to be done by the heart failure nurses as until informed consent had been received the researcher could have no details or contact with the patients identified. However in the case of patients needing assistance to install the equipment, the researcher felt that this was an issue which should be explored and not simply circumvented at outset. Therefore the decision was taken that the company would administer the scales according to their normal practice of sending them, with installation instructions, via parcel delivery. Any problems related to installation would be noted as a research finding.

Reflecting on the major elements of the evaluation strategy thus agreed, the researcher noted that in order to elicit a full representation of each participant's experience of the previously defined concepts of "value," it was necessary to collect;

a) inter-group data, in order to compare the experiences of those participants having access to the telemedicine equipment (the experimental group) with those participants not having access to the telemedicine equipment but continuing with normal care (the control group), and also to compare the experiences of patients with those of staff.

b) intra-group data to compare experiences of individuals in each group in order to find out;
   - if any of the benefits or detriments reported in the literature were realised, and if so whether changes occurred over time, either due to the progressive nature of the disease or to learning / familiarisation related to the technology, and,
   - if findings demonstrated patterns of similarity, or if they were idiosyncratic in nature.

This reflection completed the design process and resulted in the production of a flowchart, seen in figure 2-3 on the following page.

Patients with CHF

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Clinical judgement identifies 100 patients who need weight monitoring

↓

Informed consent and randomisation

50 to receive telemedicine plus normal care | 50 to receive normal care only

0 months, baseline assessment:-
Patients:- State/trait anxiety & QoL questionnaires. Interviews with 5%
Partners:- As above
Staff:- Interviews

3 months, intermediate assessment
Patients:- State/trait anxiety & QoL questionnaires. Interviews with 5%
Partners:- As above
Staff:- None

6 months, final assessment
Patients:- State/trait anxiety & QoL questionnaires. Interviews with 5%
Partners:- As above
Staff:- Interview
Ancillary data from medical records & company records

Fig. 2-3. Flowchart of the Chronic Heart Failure study

2.4.2 Operationalising the research ~ ECG study. The process of defining firstly the research question and subsequently the concept of value resulted in discussions which often mirrored those that occurred with the CHF team. There were however inevitable differences which arose as consequence of the clinical condition concerned and the way the telemedicine equipment was intended to be used. As a result of this it proved impossible to separate discussion of the benefit or detriment to health from the psychosocial aspects and so the two concepts are considered together. Another notable difference was that although inferences might be drawn from a change in the number of emergency visits to hospital, there was no easily identifiable members of staff whose working practices would be affected by a patient-operated ECG. The concept of “value for staff” was therefore omitted at this stage.

2.4.2.1 Benefit or detriment to the health of patients and psychosocial aspects. The value to patients and carers was initially perceived in a very similar manner to the CHF study, in that a statistical analysis of medical outcomes between experimental and control groups would provide the necessary comparative data. However in this case the number of items of equipment could not be doubled, so quantitative evidence would not be as robust. Also, a comparison of the number and duration of hospitalisations was not appropriate, as this equipment was intended to achieve a diagnosis from within the home environment and, if successful, might actually result in a hospitalisation for treatment, rather than avoid one. This would not, of course, be an unplanned admission and would hopefully signal the end of unplanned attendances, but as the time period had again been specified as six months this was not likely to be demonstrated within the time span available.

Furthermore, the number of possible actions and outcomes was much greater in this case than for patients with CHF and due to the difference in the urgency of the symptoms there was much less time in which to make the decisions. In daily weight monitoring the patient could take hours to ponder whether or not to report a weight increase to the nurse, without serious adverse effect. Due to the sporadic and alarming nature of arrhythmic events however, the patients have to decide very quickly whether to call their GP, call NHS Direct, phone for an ambulance, or simply do nothing and wait for the episode to pass. Add to that the opportunity to record one’s own ECG and obtain specialist advice by telephone, and it will be obvious that the comparison is not a simple one.

All of those actions have the potential to provide life-saving advice or to cause life-threatening delay, if chosen in preference to any of the alternative actions. Moreover it is entirely possible that participants might choose to take more than one course of action, for example if they were not satisfied with the advice received from one source, if they were experiencing delay outside their control, or if the clinical symptoms worsened. The importance of making the right decision, and making it quickly enough to be effective, places an additional burden of anguish on patients and carers, and it is possible that this burden in turn can exacerbate symptoms. Although the anxiety and quality of life scores would enable a comparison between experimental and control groups, as well as a "before and after capture of event" comparison, it was felt that it was important to allow the patients and their partners the opportunity to share their experiences through interviews, thus revealing any ancillary issues that might have arisen during the course of the study. The problem with that was that in situations involving multiple choices, multiple actions, and a degree of alarm such as would occur in patients undergoing an arrhythmic episode, it is unlikely that patients would recall the events with the same clarity as experienced at the time. Therefore patient diaries in the form of brief notes following each arrhythmic event were added to the list of data to be collected, the list comprising:-

- The pathway of the action(s) taken
- The clinical outcomes resulting from the choices made above
- State / trait and quality of life anxiety scores
- Interview data and notes in patient diaries.
- Invited comment or interview with staff members.

2.4.2.2 Value for money. The managers and lead clinician were keen to conduct what they called an "economic evaluation," but accepted that this could not be achieved within the time and budgetary constraints imposed. They agreed that the identification of potential changes in the pattern of use of NHS resources would be an acceptable compromise. That, together with data relating to the clinical outcomes and any advantage or disadvantage from the patient's perspective, would enable them to consider the cost / benefit balance of the equipment and to decide if further economic analysis was necessary.

The evidence selected to evaluate this concept was therefore virtually identical to that required in the evaluation of the benefit or detriment to the patient, and comprised:-

- A comparison of number of arrhythmic events between experimental and control groups
- A comparison of the pathway of action taken between experimental and control groups. (Medical and telemedicine records, patient reports.)
- A comparison of the clinical outcomes resulting from the above.
- A simplified comparison of the use of healthcare resources arising from the data specified above.
- Interview data and patient diaries to reveal other benefits and/or detriments from the perspective of the participants.
- State / trait anxiety and quality of life scores to reflect any psychosocial benefits afforded by the equipment to patients and carers.
- Interview data or comment from staff involved in the care of those patients.

The evaluation strategy formulated is best demonstrated by the flowchart in figure 2-4 on the following page. Following the production of an explicit research strategy, the administrative details of recruitment and informed consent were discussed. It was agreed that a member of the health care provider team would interrogate the data base to identify and invite as participants all patients who had had one or more unplanned hospital visit due to episodes of arrhythmia within the past six months. On acceptance, potential participants would be invited to meet with the researcher for a full explanation of the research and a demonstration of the equipment, prior to being required to give signed consent.

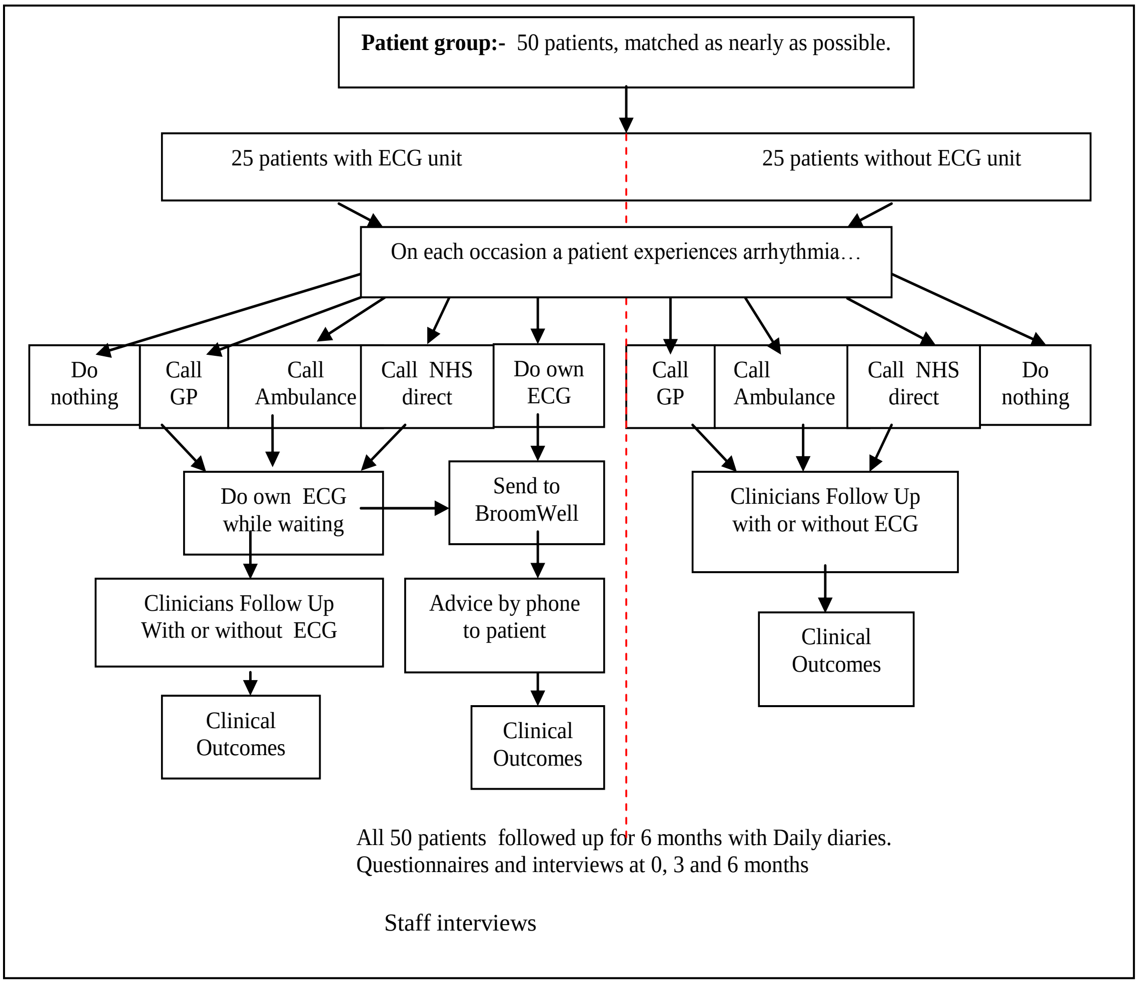

Fig 2-4 Flowchart of ECG study

2.5 Stage 5. Revisiting the research framework. Prior to submitting the two proposals for the approval of the relevant ethical committee, the researcher again reflected on the three studies to see how they fit together within a single design framework relating to the harmony, or lack of it, between the theoretical aspirations of telemedicine applications and the practical realities of it. In other words, would the studies address the need to explore the disparity between belief and reality as required by the researcher, whilst at the same time yielding the evaluation required by funding bodies and other interested parties?

The research framework was revisited by means of a template of questions already described in figure 2-1 on page 18, this time incorporating all three evaluations. The result can be seen in figure 2-5 on the following page, which shows that all prospective users in each of the three cases might hold theoretical assumptions or arguable beliefs which could potentially impact on the findings. The strong underpinning of data collected directly from the users concerning their experiences was an inevitable requirement, both of the evaluations conducted on behalf of the health service and of the investigative strategy required by the researcher.

Clearly a greater number of studies based on widely differing telemedicine applications would provide a greater portfolio of evidence than the single circumstance of an investigation into the use of mobile phones. The differences would provide the breadth that was required for the findings not to be dismissed as idiosyncratic to a single instance, whilst the commonalities would give coherence to the inquiry. This exercise had therefore confirmed the appropriate research strategy. However, during the early stages of conducting the research, difficulties arose which caused a revision of some of the practical facets of the methodology, and these are described in the next section.

Research Design Framework Revisited

Problem 1:- What is the "truth" of the users' experiences of the three telemedicine devices, compared to the truth as perceived by other users and to claims made for similar services elsewhere?

Problem 1:- Mobile cameraphones used for clinical photography– how do they perform?.
- How do mobile camera phones compare in image quality? Are more expensive models better?
- How do mobile cameraphone images compare in quality with those from other equipment?
- Does the choice of equipment affect clinical evaluation?

Problem 2:- Does the weight-monitoring telemedicine system work for the users involved?
- How are benefits and/or detriments of the device perceived and expressed by the users?
- How do the users' perceptions compare with each other and with documentary evidence available?
- How might differing opinions impact on how the telemedicine equipment is used, if at all?
- How does all of the above compare with claims made by others?
- Are there situations in which a mobile telephone connection would have been advantageous?

Problem 3:- Identical to problem 2 above but related to the ECG monitoring device.

Units of Analysis? All users directly involved. ie patients, carers and clinicians.

Units of Inquiry? Data which identify the practical realities and permit comparison with other studies, ie
- Quasi-experimental tests in colour comparison & distortion of images from mobile phones.
- Assessment of clinical application by users, including comments where relevant.
- Interviews & focus groups with a sample of patients, carers and health care professionals.
- Medical records
- Questionnaires
- Other documentation eg from telemedicine company, communications from the users.

Topics? Matters arising from the above.
- Anything the user feels is important
- Confirmation or negation of assumptions and generalisations relevant to each piece of equipment.
- Improvement in healthcare (or not.) eg reduction in unplanned admissions etc.
- Differences in quality of life and anxiety levels between groups and changes over time

Nature of Effect?
- Similarities and/or differences in views of users
- Similarities and/or differences in evidence with published or generally accepted recommendations

Variables? All users and the equipment in general.
- The patients (physical and mental capabilities, stage of disease etc)
- The carers (different relationships with patient, different coping mechanisms or priorities?)
- The clinicians (different opinions & working practices.)
- The equipment
- System of use of the equipment in case of automated weighing scales.

Major themes? Benefits (or detriments) of the telemedicine applications
Effectiveness of the system and features which facilitate or obstruct it.

Purpose? Evaluation and policy development.

Fig. 2-5 Research Design Framework Revisited

2.6 Stage 6. Methodological approaches reviewed. The methodology, when considered in its entirety in order to scrutinise the validity of the approach, revealed a number of interesting features. A research design comprising multiple methods had been derived largely because a pragmatic approach had been taken to the collection of the data identified as being relevant in the "operationalisation" stage previously described. Employing a number of methods may permit alternative sources of evidence to support or refute each other in the investigation of the topics of interest. Thus simple numerical scores indicating a change in "Quality of Life," which might lead to conclusions about the telemedicine equipment, could perhaps be strengthened by identifying specific examples of how the participants identified and perceived this change and also the strength of feeling they encompassed. Alternatively, the conclusions might just as easily be refuted by participants who indicate that the change was due to other factors and not necessarily related to the telemedicine equipment. To give a further example, the interview material of a limited number of participants, which is invariably context-laden and also subject to the personal interpretation of the researcher, may give rise to conclusions which might be strengthened (or refuted) by a greater number of participants showing similar (or dissimilar) patterns of change in questionnaire scores. The choice of using a number of methods was therefore shown to be a sound one.

Whilst a mixed method approach has been described as providing "strengths that offset the weaknesses of both quantitative and qualitative research" (Creswell, 2007 p 9) and appears to describe this design perfectly, it would be erroneous to claim that this was the intention at the outset. To suggest an "approach" of any kind is to infer that the design plan adhered to a predetermined model, and as already explained the features of this design arose inevitably out of pragmatism. Therefore, rather than a "mixed-method approach", it was simply a mixture of methods which had arisen from the largely positivist and constructivist paradigms embraced.

Whilst recognising that the study design had both qualitative (interview) and quantitative (questionnaire score) aspects, it is acknowledged that a polarised distinction between the terms "qualitative" and "quantitative" is rarely completely accurate, and that research practices lie somewhere on a continuum between the two (Newman, 1998). A more specific explanation of that view was offered by Trochim, who pointed out that all quantitative data are based on qualitative judgements and all qualitative data can be described and manipulated numerically (Trochim, 2006). This point is emphasised here because judgement may be compromised, either in patients who are known to have some degree of cognitive dysfunction due to the nature of their disease or in patients whose condition gives rise to alarm. It might, for example, result in misinterpretation of the questions posed, or in the participant recording their intended responses incorrectly in the questionnaire material. Neither the errors in responses nor the misinterpretation would be recognised from the quantitative data alone, and that possibility further supports the need for multiple methods.

In addition to using the quantitative and qualitative data to cross check the validity of each, the intention was also to use both quantitative and qualitative data to compare the experiences of experimental and control groups. The quantitative data would provide a comparison in terms of differences in the nature and number of healthcare resources utilised, changes in anxiety and in quality of life. The qualitative data would be used to illuminate the nature and extent of those differences by means of the thematic analysis of interview material, an analytical method advocated by many authors as providing particularly rich data due to its ability to encompass meaning of spoken words in the context that they were expressed. (Krippendorff, 1980, Bauer, 2000, Krippendorff, 2004)

It was also the intention to use both forms of data to reflect any changes that occurred over time, thus revealing any implications that might be due to increased familiarity with the equipment, adjustment of working practices or changes in the stage of the disease process.

Thus the design afforded elements of;

a) **A cross-sectional study,** in which a comparison of data from the experimental and control groups of patients and partners might elicit;
    - differences in anxiety and quality of life scores, and the number and duration of interactions with the health care services.
    - any benefits and difficulties related to the practice of weight monitoring by each method, which might provide insights to inform "best practice."

b) **A longitudinal study** in which any impact on health and wellbeing in the case of patients and their partners, and on the working practices and deployment of health care resources in the case of staff, could be identified over time as the telemedicine system became incorporated into the daily self-care regime of the patients. In particular, such impacts would be identified if participants in the control group could subsequently become participants in the experimental group, time and resources permitting.

Findings which demonstrated the immediate effects of the telemedicine applications and also the consequences of longer term use, was what the fund holders required, and so provided additional corroboration in favour of the design employed.

The methodology thus adopted has features which resemble a number of research methodological models, but does not correspond completely with any specific one. For example, in recognising that the different views held by the nurses were to some degree the result of the particular system of operation in which they were employed, it became clear that all participants were operating within a variety of "systems." Most patients were within a family or spousal relationship system, the family unit was interacting with a complementary system whose central point of focus was the specialist nurse, and the specialist nurses were operating simultaneously from their own individual niche within the healthcare system. To further complicate matters, the health system comprised numerous "mini-systems" in which the nurses interacted not only with other healthcare professionals such as GPs, consultants and other nurses, but also with policy makers and indeed with the policies themselves which shaped their working practices. Although to some extent the research addresses differences between some of those systems, it will be evident from the complexities described that the design exploits a much broad ranging exploratory approach than is encapsulated by a systems approach.

Similarly, the "systems" described above could also be said to fulfil the function of "cases" as "a conceptual umbrella for multiple sub-studies" (Yin, 1993). Again, on the surface the concept of the case study might be a good fit in terms of units relating to patients, to their carers, and to the health care professionals involved, and the methods chosen do, to some extent, explore those units. They do for example permit the comparison of the benefits and burdens engendered in the case of a single patient using the equipment in the management of illness. However again it must be said that a case study approach was not used at the outset. Had it been, the research design would look very different. It would have had to focus in on predetermined "cases," and there were too many possible variations in patients, carers and staff, to be able to investigate them all thoroughly as cases. On the other hand, the investigation of only a few would have prevented the broad approach required of an exploratory study. Therefore the methodological approach does not embrace case study, it merely reflects facets of it.

The realisation that the methodology did not follow one specific traditional model in no way detracted from the strength of the design. The process of reviewing the design reinforced the belief that the strategies employed were the appropriate ones in the circumstances, although it is acknowledged that a better design would have been formulated had unlimited resources been available. This was not however the end of the design process as a number of unexpected events led to the methodology being revised as the study progressed.

2.7 Stage 7. Methodology revised. During the early stages, difficulties arose with recruitment of participants to both the CHF and ECG studies. A number of adjustments were made to accommodate those difficulties, which resulted in significant changes to the individual evaluation strategies, though probably less so as far as the researcher's intention to investigate the disparity between assumption and reality was concerned.

Details of the methods used and the ethical considerations specific to each of the three studies are given in part 1 for the mobile phone study, part 2 for the chronic heart failure study and part 3 for the ECG monitoring study.

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PART 1.

An evaluation of the image quality achieved on a selection of mobile phones, a digital camera and real-time equipment commonly used in telemedicine applications.

CHAPTER 3: The use of images and the relevance of image quality in telemedicine. A literature review.

The advantage of using visual cues in medicine to enhance a point is not in doubt. Virtually every medical textbook carries illustrations of some kind, such as anatomy, pathologies or surgical procedures. The desire to use pictures to assist clinical practice is therefore not surprising, and some authors have commented on their value in providing accurate and permanent evidence of visible features (Frith and Harcourt, 2005) although no evidence to support the assumption of accuracy was offered by those authors.

Within a hospital situation it is common practice to rely on recorded images to assist in the diagnosis, monitoring and treatment of disease. Medical photographers are employed to record details of the physiognomy of patients and imaging departments produce many X-ray films and scans from which an expert radiologist produces a full written report for the requesting clinician. It is a testament to the power of imagery that clinicians usually insist on seeing the films or scans for themselves, despite the fact that they are not necessarily able to interpret the images fully and the expert report is readily available. Archbold and colleagues suggested that this is because the verbal descriptions may not be accurate (Archbold, Guha, Shyamsundar, McBride et al., 2005) but whatever the underlying reasons, in many scenarios the viewing of an image appears to be an important part of the diagnostic process and therefore it is only reasonable to expect that the image should be as accurate a representation of the live subject as possible. This expectation has led some authors to insist that medical photographers of excellent ability are required in order to achieve the standard of quality necessary for accurate diagnosis (Slue, Paglialunga, Neville and Stiller, 1993). Those authors drew a clear distinction between acceptable medical images and what they called, rather disparagingly, “snapshots”.

3.1 The need for images in telemedicine. Image capture and transference have become inexpensive and readily available during the past twenty years or so, mainly due to advances in digital technology. It is not surprising therefore, that healthcare workers have been keen to introduce devices such as digital cameras, mobile picture phones and videophones to support their own clinical practice. This is particularly true in the field of dermatology, maybe because dermatology is "perhaps the most visual specialty in medicine, making it ideally suited for modern telemedicine techniques…" (Massone, Wurm, Hofmann-Wellenhof and Soyer, 2008 p.101). It may on the other hand be clinical necessity that is driving the move towards remote diagnosis and monitoring.

Workforce statistics produced in September 2005 and made available online[1], indicated that there were at that time approximately 622 dermatologists working in the UK, serving a population of 60.2 million. Of the 622 dermatologists only 386 were consultants. There were 196 senior registrar and staff grades, and 40 associate specialists. The associate specialists are generally in the UK for training or experience and are not part of the permanent workforce. There is therefore a paucity of dermatology diagnosticians which it appears that GP expertise is not able to fill, as a number of authors have commented on the superior diagnostic accuracy of dermatologists above that of other medical practitioners (Harrison, Kirby, Dickinson and Schofield, 1998, Feldman, Coates, Fleischer, Mellen et al., 2001) although in one systematic review the authors concluded that the published data were inadequate to validate that claim (Chen, Bravata, Weil and Olkin, 2001).

Following primary diagnosis, patients often attend clinic where they receive follow-up care, and according to the workforce statistics mentioned above, the dermatologists were assisted in the clinics and hospitals by approximately 550 dermatology nurses. There were also approximately 550 tissue viability nurses, who also provide wound care to patients with conditions such as chronic ulceration, so the total number of nurses caring for skin conditions such as those mentioned was just over a thousand. Once the patient returned home about 45 thousand nurses and health visitors were responsible for monitoring the patients on a regular basis.[2]

The role of the community nurses and health visitors is not primary diagnosis, although in their normal care of the elderly for example they might do that on occasion. Their role is to monitor wounds and skin conditions and prioritise patient referrals for consultation if

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[1] Accessed at (http://www.healthcareworkforce.nhs.uk) &
National Statistics Online. http: // www.statistics.gov.uk
[2] RCN personal communication. 2006

necessary and that role is said to be becoming a collaborative one, between the patient and professionals from a variety of health care disciplines. (James and Bayat, 2003). Very few of those healthcare professionals have particular dermatology or tissue viability expertise. It is understandable therefore that they commonly contact their specialist nursing colleagues for advice and assistance on patient management, and that picture messaging is frequently used in cases where patients are seen at home by community nurses seeking support or advice from more experienced colleagues.[1] What is surprising however is that there is evidence to indicate that this practice is being supported at management level with little or no consideration given to avoiding the potential pitfalls of inappropriate management due to sub-optimal images. Although historically that evidence had been mainly anecdotal, according to at least one author it is appearing increasingly in the literature (Borzo, 2005). For example warnings have been issued by the Medical Defence Union about the use of mobile phones for text messaging (Norwell, 2003) and also for using them to take and send digital pictures to assist in diagnosis and management of patients (E-Health-Media-Ltd, 2004) but those warnings have referred mainly to issues of security and confidentiality. It is perhaps therefore not surprising that the healthcare staff keen to use those devices appear to be unaware of their potential weaknesses in acquiring images of clinical conditions.

Despite the potential pitfalls, the growth of teledermatology supported by the use of images appears to be certain, as it appears to fulfil a clinical need to provide remote access to experts (Eedy and Wootton, 2001). Studies evaluating the use of both store-and-forward and real-time technology in the management of chronic conditions have been undertaken with increasing frequency. The majority of these studies claim at least a potential, if not proven, benefit to both the cost and the effectiveness of certain medical specialities within health care. Whilst many of the current initiatives incorporate an element of internet communication the contribution of the internet is outside the remit of this thesis, and is therefore omitted except in a very few instances where it serves to illustrate a particular point related to image quality.

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[1] Personal communication from the head of a hospital department specialising in tissue viability.

3.2 Components of image quality relevant to telemedicine. The majority of studies relating to the use of images in telemedicine have originated from the fields of dermatology and wound care. Broadly speaking, it is the shape and colour of the lesion that an observer considers when describing a medical appearance and offering a diagnosis. For example the most commonly assessed visual features of skin lesions have been cited as border irregularity and colour variability (Marghoob, 1999).

Both shape and colour have a number of different descriptors, which for simplicity will not be employed here, but it will be appreciated that a more precise description than just those two terms is required. Colour variability for example may refer to one colour being misrepresented either as a different colour or as a different shade of the original colour. Errors of this kind can be caused by the equipment itself, in this case the digital software inherent in the device but previously by the inherent characteristics of film, or it can be caused by external factors such as improper lighting or reflection from nearby objects.

Shape as it relates to medical diagnosis is slightly more complicated, as it may refer to a misrepresentation in terms of a distortion into a different shape, or a distortion in the size of the object whilst keeping the overall shape the same, or both effects may occur simultaneously. As in the case of colour misrepresentation, errors in shape may originate within the equipment itself, such as poor quality lenses or display screen, or they may originate from poor photographic practice such as tilting the camera, thus inducing a perspective effect.

Superimposed on the requirement for accuracy of shape and colour is the requirement to be able to see those aspects sharply defined in the image. In common with the factors of shape and colour, inadequacies in the ***definition*** of an image (the ability to resolve fine detail) can also originate either from the equipment or from the operator. How good any photographic devices is at capturing and displaying an image is termed the ***resolution*** of the equipment. It is related to factors such as the quality of the lens and the number of pixels available for image capture and display (or the speed of film in analogue systems). Since it is a finite and measurable quality usually stated in the technical specifications of each device it would be redundant to address it further here. However, it should be borne in mind that regardless of the resolution of the device used, the resulting image will still be blurred (have poor ***definition***) if for example the patient or the photographer moves during the exposure, or if the photographer focuses the image incorrectly.

3.2.1 Colour as a diagnostic descriptor in medicine. Colour has been widely cited as useful in the description or diagnosis of medical conditions. Atypical moles and melanomas for example, have been described by Marghoob (op.cit.) as having various shades of brown, black, red, pink, white and blue associated with them. As a descriptive factor in the classification of wounds, colour has been considered so important that it has led to the development colour coding techniques used to assist wound evaluation (Cuzzell, 1988, Stotts, 1990, Krasner, 1995, Kantor and Margolis, 1998, Kingsley, 2003). Presumably therefore inaccurate colour replication introduces a risk of inaccurate assessment when diagnosing from images, and thus sub-optimal patient management.

The range of colours which are taken as evidence of wound condition is wide. For example according to some authors red or purple indicates granulation tissue, yellow fibrous tissue or necrotic slough, black is indicative of eschar or necrotic tissue and pink or purple indicates that re-epithelialisation has begun (James & Bayat, 2003, op.cit.). In addition to the wide variety of skin tones found in the human population, this would seem to make accurate colour replication across the entire spectrum an absolute necessity in image production, because colour can not only provide valid and reliable medical evidence but it may also have the potential to provide invalid and unreliable evidence. For example, in an equivocal image colour has the potential to effect a subliminal misperception, as is demonstrated by the image in figure 3-1. This well-known illusion may be

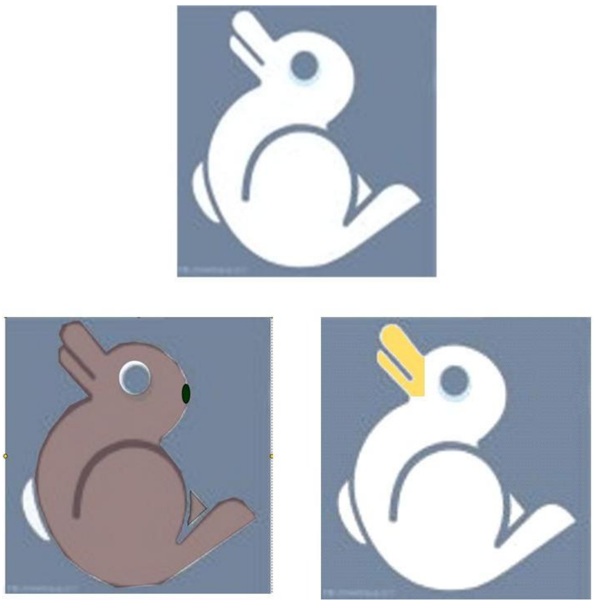


Fig. 3-1 Example of an optical illusion

identified either as a rabbit or a duck by the viewer. It will be appreciated however that an adjustment of the colour, such as might be caused either by poor photography in rendering shadows or reflections of light visible or by the technical imperfections due to the hardware or software inherent in the equipment, will favour one animal being perceived in preference to the other. Whilst this is an exaggerated example it demonstrates the potential dangers of the subjective processes of human observation. [1]

3.2.2 Shape as a diagnostic descriptor in medicine. Dermatological features are important in diagnosis, for example the borders of moles are scrutinised in order to identify irregularities and thus differentiate between benign and malignant nevi, and wound borders need to be delineated in order to determine a measure of their area. Sequential measurement of wound size in ulceration is common practice and has been advocated by some authorities in order to track changes and inform treatment strategies (Scottish.Intercollegiate.Guidelines.Network., 1998). Various methods have been described to accomplish this (Plassmann, Melhuish and Harding, 1994, Johnson and Miller, 1996, Goldman and Salcido, 2002), and according to one source, in order to be effective the method should demonstrate attributes of accuracy, reproducibility, sensitivity, flexibility and standardisation (Kanthraj, Srinivas, Shenoi, Suresh et al., 1998). When considering those requirements in respect of wound area measurements it will readily be appreciated that if those measurements are taken from a digital image instead of from the live subject, an image of poor quality has the potential to compromise patient management. If the quality of sequential images varies in different ways, then it is difficult to monitor changes accurately.

Distortion is one component of image quality which may adversely affect the presentation of the size or shape of a skin lesion or an ulcer wound. It may be particularly relevant in the serial measurement of the surface area of ulcer wounds as previously described. The two main causes of spatial distortion are;

a) poor photographic technique resulting in foreshortening or elongation of the image and;

[1][1] further examples of optical illusions can be found at http://www.coolopticalillusions.com

b) the optical and technical characteristics of the camera, such as poor quality lenses or poor quality display screens such as are often found in mobile cameraphones. As a further complication, and stringent photographic techniques notwithstanding, in the serial measurement of ulcer wounds for example it is very unlikely that the wound would occur over a completely flat surface. There would therefore be some magnification or minification of parts of the image due to “perspective” as the ulcer follows the natural curve of the body part in question. The image, unlike a patient, does not move under the pressure of a tracing implement. If in vivo measurement is compared with measurement from an image it is entirely possible that in the measurements taken from the image the interobserver agreement would be relatively high, but possibly inaccurate.

Measures to counteract the effects of distortion have been suggested, such as rulers incorporated into the image in order to make some mathematical adjustment to the length and breadth of an object. Although these may assist they rarely provide absolute accuracy for three reasons. The first is that they cannot compensate for distortion due to equipment factors, which occurs in an irregular fashion over the face of a camera or mobile phone. The second is that they rarely lie in the same plane as the wound, because the wound itself often lies on a curved surface, and the third is that a ruler often introduces a problem of perspective in itself. If the ruler is rigid it has a finite thickness, therefore the scale on the ruler is nearer to the lens than the wound, introducing magnification. If the ruler is flexible, such as the paper versions often used in wound photography, the tendency to curl over the (usually) curved surface of the body part introduces the same problem of perspective. In either case compensation for distortion is not easily achieved after an image is produced and so is an important consideration during the phase of image production.

Perspective may also exert a subliminal effect on the perception of the lesion photographed. Referring once more to figure 3-1 on page 49, if the observer focuses to the right of the animal’s head, it will appear as a rabbit. If the observer focuses to the left it will be perceived as a duck. Again this is an extreme example but illustrates the point that the human observer cannot be completely objective. This may be disadvantageous when the diagnosis of some skin lesions rests partially on the shape and irregularity of the borders. This possibly accounts for the better diagnostic performance in consultations in which the specialist has the facility to palpate or move the patient, as those distortions of space and light are more easily exposed as illusion.

3.3 The relevance of image quality to diagnosis in telemedicine. Since the emergence of digital imaging, studies evaluating the use of both store-and-forward and real-time imaging technology for purposes of informing the management of a range of medical conditions have been undertaken with increasing frequency. The majority of these studies have concluded that there was at least a potential, if not proven, benefit to both the cost and the effectiveness of certain medical specialities within health care. Most studies have also offered some illumination on the role of image quality in reaching that conclusion.
It has hitherto been assumed, by this author as well as by the majority of those who have conducted studies into the use of store-and-forward images in telemedicine, that poor image quality is a main contributor to the often disappointing results in attempting diagnostic evaluation from those images. In complete contrast to that suggestion Kevdar and colleagues, in a study of 116 patients with skin conditions, appeared to claim that image quality had not greatly affected the concordance achieved between observers (Kvedar, Edwards, Menn, Mofid et al., 1997). The authors commented however that they had ensured that standardised photographic protocols were followed in the acquisition of the photographs. Thus they were aware of at least some basic principles of photography and although there was some variation in the quality of the images, the photography conformed to some standard of professional practice designed to achieve high image quality.

Although in the minority, Kvedar and colleagues were not completely alone in suggesting that there is only a modest relationship between image quality and diagnosis. Five years later, in two consecutive studies, of 66 and 43 patients respectively with pigmented skin lesions, Piccolo et al. supported the view that the accuracy of the diagnoses in both studies was not related to the quality of the images, but concluded that it did depend on the level of diagnostic difficulty of the specific skin lesion under examination, and also to the level of experience of the diagnostician (Piccolo, Peris, Chimenti, Argenziano et al., 2002). The following year another study was conducted, in which the diagnosis of dermatological lesions via store-and-forward images were compared with face to face consultation. The authors found that in two out of the three images referred to as having poor resolution the diagnosis was still comparable to the face-to-face consultation, implying once again that image quality was not of paramount importance (Rashid, Ishtiaq, Gilani and Zafar, 2003). It should be noted that in this study a patient history and description of clinical findings were included with the images. It is therefore impossible to draw a distinction between the relative contributions of the image and the clinical report in arriving at a diagnosis in this case, however the following year Oztas and colleagues conducted a study designed to compare telediagnoses achieved with and without the assistance of clinical information (Oztas, Calikoglu, Baz, Birol et al., 2004). The accuracy of the telediagnoses, compared with face-to-face diagnoses, improved from 57% to 70% when the clinical information was available.

Those arguments notwithstanding, other authors were of the opinion that “the single most important obstacle to accurate diagnosis is poor-quality digital photography… attempts at diagnosis with substandard photographs are dangerous and frustrating” (See, Lim, Le, See et al., 2005 p.148). If a clinician is to rely on images to achieve a diagnosis then those images must be able to provide reliable information. Therefore the following sections evaluate a range of image quality components as they relate to some clinical applications.

3.3.1 The effect of operator expertise on outcomes in telemedicine. In 1990 the authors of a small study, conducted on 10 patients and using both still-imaging and a video camera to record cutaneous lesions, demonstrated that there were “many possible applications in dermatology” (Stone, Peterson and Wolf, 1990 p.913). Among those applications the authors cited the possible analysis of colour and the measurement of lesion contours, diagnostic practices which would be invaluable in the evaluation of nevi for malignancy or the monitoring of ulceration. The study was conducted in a laboratory setting and the photography was undertaken by staff from the dermatology department, who would presumably be expected to recognise the dermatological features he or she was attempting to demonstrate and so produce an optimum image. Even so the authors reported that reproducible positioning of the patient and faithful lighting conditions were difficult to achieve, both factors already mentioned as contributing to the misrepresentation of shape and colour respectively. It would appear therefore that expertise in dermatology and experience in clinical imaging do not necessarily guarantee the best image quality, and that operator expertise is an important factor.

Many authors have displayed some degree of knowledge of photography. For example Krupinski and colleagues, in their study comparing store-and-forward and face-to-face diagnoses of dermatological lesions in 308 patients, asked participants to rate the images in terms of ***sharpness and colour quality*** (Krupinski, LeSueur, Ellsworth, Levine et al., 1999). This in itself indicates that the researchers had some knowledge of photography, presumably in addition to an understanding of the clinical features they were trying to demonstrate to best advantage. It is possible therefore that the high level of concordance between store-and-forward and face-to-face informed diagnoses demonstrated in this study was due partly to the fact that a knowledgeable photographer ensured the high quality of the images.

Opinion surrounding the importance of operator expertise in digital imaging varies considerably. For example in one study the photography was undertaken by the principal researcher who admitted to having only minimal experience in either photography or dermatology (High, Houston, Calobrisi, Drage et al., 2000). The purpose of this was reportedly to replicate the reality of a busy clinical situation, inferring that it was common practice for this to happen. In that study a consumer grade digital camera was used to compare 106 dermatology diagnoses from 92 patients. The authors reported that in cases of acceptable image quality the disagreement was 2% - 16% (depending on the dermatologist) increasing to between 25% - 40% when the image quality was considered poor. It is of particular interest that those authors suggested that it would be improvements in the technical specification of the equipment that would bring about improvements in the accuracy of diagnosis, and not the photographic ability of the user. This is despite the fact that the equipment had been able to provide acceptable image quality in many of those cases and lack of photographic expertise had already been acknowledged.

In contrast to that approach, other authors have demonstrated unequivocally that they consider photographic expertise an essential requirement for success in telediagnosis. In 2002, in a study intended to evaluate the measurement of leg ulcer area using computer-aided tracing of digital camera images, the authors concluded that the method which calculated the area from digital images "is more accurate and quicker than contact tracing ***provided that appropriate care is taken when taking the pictures***" (Samad, Hayes, French and Dodds, 2002 p.137). The following year Du Moulin and colleagues stressed the need for training in taking photographs, although they did not specify the photographic aspects which needed to be addressed (Du Moulin, Bullens-Goessens, Henquet, Brunenberg et al., 2003). Interestingly they also stressed the importance of acquiring a full and accurate clinical history to accompany the images, thus it is not possible to evaluate precisely the relative contributions of image and clinical history towards arriving at a diagnosis.

Photographic expertise was considered so important by Lake that she described the development of a close working relationship between dermatologists and medical photographers, which arose from the dermatologists' requirement for excellent image quality (Lake, 2005). In a later study, in which the use of digital imaging in the triage of patients with skin lesions was evaluated, other authors considered the quality of photography so important that patients were sent to the medical imaging department of their local hospital for the photographs to be taken, in order to ensure greater reliability of the subsequent telediagnosis (McLaughlin, Tobin, Leonard, McEwan et al., 2006). That same year other authors (Knol, van den Akker, Damstra and de Haan, 2006) tried to avoid the potential pitfalls of poor image quality by requiring all the GPs participating in their study to attend a workshop on digital photography and Qureshi and colleagues compared methods of providing training in photography for patients who were to undertake the imaging themselves (Qureshi, Brandling-Bennett, Giberti, McClure et al., 2006).

There is of course the question of what constitutes "expertise" in the context of medical photography. In a study which compared digital image diagnosis with face to face diagnosis, one group of authors commented that three-dimensional lesions were more amenable to digital diagnosis than flat, generalised rashes (Scheinfeld, Kurz and Teplitz, 2003), thus it appears that the problems of variability in telediagnosis may not be limited to the photographic aspects. Even a professional medical photographer may not have the necessary experience to differentiate between the specific requirements of each individual type of wound or lesion, and although one might expect a clinician to appreciate the clinical features necessary for an accurate diagnosis, he or she may not achieve the necessary level of expertise in photographic techniques. The latter point may have contributed to the disappointing results reported by the authors of a study intended to evaluate if a device they called a “photo-email” could have saved the patient a trip to hospital (Tucker and Lewis, 2005). In that study eighteen out of the eighty-four photographs (21%), taken by consultant dermatologists, who were cited as being experienced clinical photographers, were considered to be of poor image quality. This led the authors to question the efficacy of all telediagnosis via store-and-forward images, and it is possible that a promising telemedicine initiative may be abandoned simply because of a lack of appreciation of all the factors involved in acquiring a useful image.

The question of the nature or the level of photographic expertise that is required in telemedicine appears to be even more complex when the reasons for the evaluation of the images are considered. For example Shapiro and colleagues demonstrated a 100% agreement in treatment plans when evaluating skin lesions, including melanocytic lesions, for biopsy (Shapiro, James, Kessler, Lazorik et al., 2004). This was despite the fact that not all images were of sufficient quality to allow evaluation. In contradiction to that view Mahendran and colleagues reported that a store-and-forward telemedicine system had “limited diagnostic accuracy for skin lesions” and although they acknowledged that it “may be suitable and safe for screening out clearly benign lesions” they went on to say that their study had “casts doubt on its efficiency” (Mahendran, Goodfield and Sheehan-Dare, 2005 p.209). It should be noted that it was standard practice in their study to include a colour calibration strip within the image and so the colour quality at least should have been reasonable.

3.3.2 The effect of file compression on outcomes in telemedicine. Leaving aside the issue of photographic expertise, other authors have commented on the effect of file compression in digital imaging, some concluding that even the early and relatively low resolution digital images are sufficient for some telemedicine applications (Perednia, Gaines and Butruille, 1995, Perednia, White and Schowengerdt, 1989, Roth, Reid and Concannon, 1998). Other authors have refuted that and one, whose interest was related to the telediagnosis of mammography films which require particularly high resolution of fine detail, suggested that it was digitisation and associated file compression which caused concern (Abdel-Malek, 1996). That author believed that these factors were critical as they could potentially cause loss of data which may lead to misdiagnosis. This finding was supported by other authors who found that compressed digitised images were comparatively poor at reproducing some of the clinical features relevant in dermatology, particularly the small blue/grey or red dotted appearance of some melanoma and dysplastic nevi (Provost, Kopf, Rabinovitz, Stolz et al., 1998).

However some later studies supported the view that file compression was not a problem. Benger et al. for example reported that images used for accident and emergency telemedicine purposes were fine, at least within certain limits (Benger, Lock, Cook and Kendall, 2001). They did however specifically recommend that a high resolution viewing monitor should be used. Galdino and colleagues similarly found that file compression did not affect outcomes in their field of plastic surgery, although these authors specifically warned of the inherent differences among digital cameras, which had resulted in a different appearance of colour, contrast, focus and overall quality (Galdino, Vogel and Vander Kolk, 2001). Two years later Marghoob, who is cited previously as contributing to the description of skin lesions in terms of colour and border outline, reported finding digital photographs very helpful in recognising significant changes in some skin lesions, thus the file compression had not appeared to detract from clinical usefulness (Marghoob, Swindle, Moricz, Sanchez Negron et al., 2003). Nor did Andres et al. find any difference in compressed and uncompressed files, their research having addressed the technical specifications required of digital cameras used in orthopaedic surgery (Andres, Khanna, Wenz, Faust et al., 2004). Whether the difference of opinion between these later authors and the opinions of Abdel-Malek and Provost in 1996 and 1998 respectively is due to differences in specific clinical problems is not known, but it is possible that technological improvements had occurred in the intervening period.

3.3.3 The effect of viewing parameters on image quality in telemedicine. Viewing parameters, such as the high resolution monitor mentioned above (Benger et al. op.cit.) have not been specified in every instance of the studies reported here, the authors sometimes assuming that the reader will know how the images were viewed, but in many of the studies store-and-forward images were downloaded onto a computer workstation for viewing. In a much later study using store and forward images, acquired by mobile cameraphone, for the purpose of assessing burn wounds one author commented that “the quality (size and resolution) of the display is as important as the camera resolution” (Shokrollahi, Sayed, Dickson and Potokar, 2007 p.754). The use of a computer monitor would normally afford better quality image display than would be available on the display screen of a camera or mobile cameraphone, or on a paper print, provided the parameters of colour, contrast and brightness etc., are correctly set up and monitored frequently. The paucity of reference to the display equipment in many studies may indicate an assumption on the part of the authors that this is always the case, but equally it may be an indication of the lack of appreciation by the authors that the viewing monitor is an important part of the imaging chain upon which image quality depends.

3.3.4 The effect of other unspecified technical factors on image quality in telemedicine. Not all authors have been so specific in defining the aspects of image quality to which they were referring. Many have simply employed the phrase “poor image quality” as an umbrella term which included or excluded any number of the possible component factors. For example in a study on teleradiology “poor image quality” was cited as the most common reason for not being able to read the images, followed by” lack of clinical history and not enough images” (Krupinski, McNeill, Ovitt, Alden et al., 1999 p. 166). It should be borne in mind that images derived from radiology are usually monochrome therefore they do not have the compounding complexity of colour to add to the reduction in overall quality. Furthermore they are two dimensional and therefore less problematic to focus and they are less likely to suffer from a degree of movement which human subjects are prone to do. Therefore it is difficult to imagine exactly what was at the root of the problem, but it could have been either the resolution capability of the equipment or operator errors such as poor lighting or movement that were the culprits in this case. Or of course it may have been a combination of both. However since the clinical history also informed the diagnosis to a variable extent once again it is not possible to evaluate precisely the degree to which the images were of any use at all.

In the sphere of telepathology some authors have been similarly vague in reporting their findings, one author citing “a variety of technical reasons” for the diagnoses from digital images being of lower grade than the diagnoses achieved from direct observation of the glass slides (Odze, Goldblum, Noffsinger, Alsaigh et al., 2002 p.379). A notable exception to such vague descriptions appeared to be reported the following year. In a review of common image deficiencies which had been found in one thousand seven hundred fifty-three telepathology consultations using static images, the authors stated that focus, improper white balancing of the capture device and inadequate resolution were the main contributors to poor image quality (Williams, Hong, Mullick, Butler et al., 2003). This appears on the face of it to be quite specific, however “focus” may refer to the optics of the device being inadequate, to the need for macro imaging which is not a feature available on all devices, or to operator error. Similarly “resolution” may refer to the pixel matrix available on the equipment, or may be a comment on the lack of sharpness of the final image, which in turn may have resulted from operator error such as movement. Thus the underlying causes of poor image quality were not easily dissected.

The year after that Desai et al. reported that, in a study of telepathology diagnoses related to ninety-three cancer patients, in 10.8% of cases the images were not of sufficient quality to allow diagnosis, although they gave no clarification of the causes of poor quality (Desai, Patil, Chinoy, Kothari et al., 2004). However a particularly high level of concordance (90.2%) was reported between diagnoses from digital images and diagnoses from face-to-face consultations. It must be noted that in this study the number of images taken ranged from three to twenty-seven per patient. The relatively large number of images may suggest some difficulty in obtaining the appropriate visual information, possibly for the same reasons reported by Williams et al. the previous year (Williams et al., op.cit.) or it may reflect particular diligence on the part of the photographer, which contributed to the high level of concordance.

3.3.5 The effect of colour and shape on clinical applications in telemedicine. Not surprisingly the majority of evidence pertaining to the relationship between the importance of colour and shape and the relevant clinical applications of telemedicine come from the realm of wound imaging. Given the assertion throughout the preceding text that accurate replication of both colour and shape are essential, one early study provided a surprising alternative view. In a study comparing the measurement of wound area calculated from images with those taken from contact tracing of patients, the authors found that it was the inaccuracy of colour replication which enhanced the delineation of wound margins, making them easier to see (Griffin, Tolley, Tooms, Reyes et al., 1993). This raises an interesting point about the nature of the photographic effect, which could presumably disguise important characteristics of a lesion, but which had in this case enhanced features not easily visible to the naked eye. It is possible therefore that intentional distortion of colour may have applications in other areas of telemedicine.

Other authors have acknowledged the problems of colour variation and some have suggested methods of colour calibration to counteract it. Berris and Sanguine looked towards the accurate calibration, replication and analysis of colour in digital images as potentially providing a non-invasive method of evaluating wound repair (Berris and Sangwine, 1997). In their review of published research relating to subject the authors concluded that this was a difficult task, beyond the capability of commercial software packages available at the time, although they acknowledged that the technology was possibly adequate for the diagnosis and monitoring of skin lesions. This last comment lends support to the notion that not all medical conditions are equally difficult to diagnose via images, suggesting that the imaging of skin lesions does not require such a high level of equipment performance. Other authors appear to disagree and describe other methods of colour calibration, explaining that reproducibility is essential for inter-observer agreement of conditions such as skin lesions (Lorentzen, Holstein and Gottrup, 1999, Vander Haeghen, Naeyaert, Lemahieu and Philips, 2000, Maglogiannis and Kosmopoulos, 2003, Maglogiannis, 2004). As already mentioned in the preceding text however, inter-observer agreement does not necessarily guarantee accuracy.

However colour calibration appears not to be without problems. For example in one method the authors remark that “the algorithm was developed using digital skin images of Russian patients. Because the Russian population is almost exclusively Caucasian the variability in skin colour is limited. Thus the method might not work as well in populations with larger variations in skin colour” (Matveev and Kobrinsky, 2006 p.63). In a similar study comparing the accuracy of calibrated images with non-calibrated images, the authors found that “Although calibrated images exhibit markedly improved precision and accuracy compared with non-calibrated images, all variability of the imaging process cannot be eliminated” (Vander Haeghen and Naeyaert, 2006 p.42). These authors went on to conclude “With a little care and effort, a calibrated color chart and computer software, it is possible to greatly improve the quality of clinical imaging in dermatology and possibly other fields of medicine” (Vander Haeghen and Naeyaert, Ibid). Whilst this is true and is a technique commonly used by professional photographers, in the experience of this researcher it does not appear to be a practice that most specialist nurses are even aware of, let alone use in their telemedicine practices.

In addition to colour, shape is an important factor in the evaluation of some clinical conditions, particularly wounds. For example in the study previously cited (Griffin, Tolley, Tooms, Reyes, & Clifft, 1993, op.cit.) the authors noted that although the measurements of wound area calculated from the images may be influenced by the distortion involved, they had found that both methods yielded equivalently reliable measurements. That outcome was later supported in a similar study (Rajbhandari, Harris, Sutton, Lockett et al., 1999). The authors of another similar study the following year concluded that the photographic tracings were potentially useful in wound monitoring, but noted that assessment of area calculated from images produced overall smaller readings and less inter-observer variability than the calculations arising from contact tracing taken directly from the patients (Lagan, Dusoir, McDonough and Baxter, 2000). As previously noted however inter-observer agreement does not necessarily confirm that it is more accurate. Planimetry involves the tracing of a wound over the body surface, which is rarely flat, although on a two-dimensional image it will appear so. It may be that photographic effects or poor photographic technique make it much more likely that observers arrive at the same incorrect measurement.

That same year an interesting finding was reported by the authors of one study in which bedside consultation was compared with photographic assessment of pressure sore ulceration (Houghton, Kincaid, Campbell, Woodbury et al., 2000). These authors found that although the photographic assessment had been shown to be sensitive to change in wound appearance of healing ulcers, it had not demonstrated the same sensitivity in non-healing ulcers. This finding supports the view proposed above that perhaps generalisations about the efficacy of telediagnosis are inappropriate. It certainly has serious implications for the evaluation of all studies into remote wound monitoring by digital images. If the studies were conducted on patients whose ulcer wounds were healing the results may lead readers into a false assumption that the practice is a safe one under all circumstances, which may not be the case. Therefore it is not only that different clinical specialties which may differ in their ability to deploy telemedicine strategies successfully. It may also be the different clinical situations within each speciality, or even the status of each individual wound, which determine whether telemedicine strategies are appropriate or not.

Another example supporting that view was presented in a much later study, in which digital images of sixteen patients with forty-five ulcers were used to assess the accuracy of the digital imaging method. In that study the authors noted that 7% of the wounds were too large for effective monitoring via photographs (Binder, Hofmann-Wellenhof, Salmhofer, Okcu et al., 2007). The authors do not specify the reasons for the size of the wound being a limiting factor. For example it may have been that the wound presented on a particularly curved body surface and therefore could not be imaged in entirety from one direction. Alternatively it may have been that a macro imaging facility was needed to demonstrate the fine detail of the wound, but that the wound was so large as to make it impossible to focus correctly due to the large camera –to-patient distance needed to include the whole area. Whatever the reason, the outcome implies that two ulcer wounds, even if on the same patient and photographed in the same place and at the time, may not be equally appropriate subjects for telemonitoring. Binder also reported that just over 10% of the images were blurred, underexposed, or the framing of the image was not optimum, therefore the number of patients who were unable to benefit from the telemedicine method due to the nature of their wound was presumably supplemented by patients who were not able to benefit due to poor image quality.

Debray et al. had also experienced some difficulty in replicating all the essential features of a wound in a digital image. In this case the difficulty was with the 3D aspect in the assessment of ulcer wounds via telemedicine, finding that "the lack of palpation represented a major limitation to remote wound assessment despite the use of probes to delineate the depth of any opening in the wound bed" (Debray, Couturier, Greuillet, Hohn et al., 2001 p.353). The authors added that in wound monitoring they had found that clinical data were probably as important as the images in reaching a diagnosis and forming a management plan, and it may be that the assessment of wound depth requires an additional resource, such as on-site evaluation, in addition to high quality images if the wound status is to be evaluated accurately.

The sequential tracing of wound borders to assess healing by measuring the wound area appears to be beset by difficulty. In 2003, in a review of wound measurement techniques, Flanagan reported that the greatest error occurred when identifying the wound margin (Flanagan, 2003). It would appear that the enhancement effect of colour distortion reported previously (Griffin et al. op. cit.) had not assisted in the studies that Flanagan reviewed. It is interesting to speculate whether or not an improvement in technology had actually resulted in a reduction in the accuracy of wound measurement in this case.

3.3.6 The relevance of image quality components to clinical applications in real-time telemedicine. The contribution of real-time telediagnosis in dermatology, whilst not as prolific as store-and-forward studies, should not be discounted as it lends further support to some of the arguments offered above. A number of authors have studied the effects of a variety of two-way video consultations between a specialist at a remote location and patients who are usually accompanied by a professional health care worker and may be either at home or in a local medical facility (Krupinski, Webster, Dolliver, Weinstein et al., 1999, Kobza and Scheurich, 2000, Loane, Bloomer, Corbett, Eedy et al., 2000). In the latter study comprising of ninety-six patients with skin lesions, Loane and colleagues compared real time consultations with store-and-forward evaluation. They reported that in only 51% of cases was there diagnostic agreement between the two methods, and even less agreement about the management plans suggested for those patients. Furthermore the authors commented that the video consultations were more clinically efficient because store-and-forward telediagnosis "limits the dermatologist's ability to obtain clinically useful information in order to diagnose and manage a patient satisfactorily" (Loane et al., op.cit. p1241). A similar comment came from Carli and colleagues, who evaluated the reliability of diagnoses by dermoscopy on photographic slides alone (Carli, De Giorgi, Argenziano, Palli et al., 2002) and concluded that it was not an entirely reliable method, due to the inability to perform an associated in vivo examination of the clinical characteristics of the lesions. However, once again the quality of the image may not have been the only limiting factor, as dermoscopy is limited in the information it can provide even when conducted in vivo and some lesions are more difficult than others to diagnose (Skvara, Teban, Fiebiger, Binder et al., 2005).

Despite the difficulties mentioned by the various authors, the overall impression given in the studies reviewed was that the diagnosis or monitoring of a number of medical conditions via either real time or store-and-forward images is potentially viable, although the quality of the images affects the diagnostic accuracy as well as the level to which the clinician can have confidence in the decisions reached. Whilst funding is not infinite and many telemedicine practitioners would welcome the ability to buy the latest top-of-the-range photographic equipment, it should be appreciated that advanced cameras of well-known manufacturers sometimes demonstrate worse colour accuracy than low-cost cameras and that neither cost nor manufacturer can be assumed to be indicators of quality (Matveev, 2002). This is a rather alarming finding as clinical practitioners have a duty to ensure that the both their photographic skills and their choice of equipment are of an adequate standard, and they might reasonably expect to be able to rely on both factors of manufacturer's reputation and cost to inform their choices. This is no less the case in the store-and-forward telemedicine applications using mobile cameraphone images and those issues are explored below.

3.4 The use of mobile phone technology in telemedicine. In view of the reported success of telediagnosis and monitoring, and the fact that in 2002 according to a leading market research company almost 80% of the population owned a mobile phone and the trend rising (MORI., 2002) it was perhaps inevitable that the wide range of technological possibilities associated with mobile phones would be evaluated for use in telemedicine.

A wide range of intervention strategies via mobile phone communication have been proposed. Advice, education, alerts and even the collection of assessment data via text messaging have been suggested (Downer, Meara, Da Costa and Sethuraman, 2006). The recording and transfer of a wide range of physiological data have also been explored as a telemedicine application suitable for mobile phones. (Vaisanen, Makijarvi and Silfvast, 2003). There have even been reported cases of the video capability of cameraphones being used to good effect in medical emergency (Gray, 2005 [1]; Parikh and Wong, 2007), however it is the still picture capability of mobile phones which is of interest in this work and that is the focus of the issues addressed below.

Many studies spanning more than a decade have claimed cost and healthcare benefits of using mobile cameraphones to transfer still images in a variety of clinical situations. They have been used to transfer images of meals for dietary assessment (Wang, Kogashiwa, Ohta and Kira, 2002) and radiological images in order to access specialist advice (Yamamoto, 1995). However it is the imaging of human physiognomy related to dermatology and wound monitoring that provides the largest complement of clinical applications and the shortcomings of those studies appear to echo those that were evident in the studies that had employed digital cameras as the image capture device. For example in a study intended to evaluate the use of cameraphones supplied to some of the emergency services in Scotland in order to triage injuries prior to their arrival at hospital, (ElectronicGovernment, 2003) the initiative was abandoned because, according to one news report, the divisional officer for community safety in that emergency service had questioned the quality of the images and questioned whether the technology was good enough to provide a reliable service (McDougall, 2004). No specific detail relating to either the various components of image quality or the technological limitations was offered, and nor was there any mention of photographic expertise.

[1] This reference is no longer available at the URL cited but is reproduced in appendix 1

Similarly in other studies relating to teleconsultation via a mobile camera-phone, in this case the triage of patients with extremity injuries, the authors attributed the inferior diagnostic performance of the telemedicine method to inadequate definition of the image. Whether this was due to the equipment, to file compression or to poor photography was not specified, but in common with many other authors they concluded that advances in technology would afford cameraphones the potential for future applications in telemedicine (Hsieh, Tsai, Yin, Chen et al., 2004, Hsieh, Jeng, Chen, Yin et al., 2005).

The inclusion of additional clinical data appears to assume the same importance when using mobile phones in telemedicine as it did when digital cameras were used. In one study which compared the outcomes in terms of the management plans formulated for 60 patients with extremity injuries, online communication between residents and consultant plastic surgeons resulted good levels of agreement between the remote surgeons. The images involved certain aspects reliant on colour replication, such as the evaluation of gangrene and other wound descriptors, however it is difficult to separate the contribution of images from other aspects of the remote examination which were communicated online. Furthermore, in common with many of the studies that used digital cameras, agreement cannot be taken to prove accuracy, nevertheless the authors concluded that “The preliminary results showed that the camera phone is valuable and bears potential for remote management of the extremity wound” (Tsai, Pong, Liang, Lin et al., 2004 p.584).

In attempting to define the contribution and/or limitations of the mobile cameraphone digital image, the authors of a later study investigated the mobile phone photography of 95 patients with a variety of skin conditions, this time without additional clinical data (Massone, Lozzi, Wurm, Hofmann-Wellenhof et al., 2005). In this study three tele-consultations yielded an average correct score of 70% when compared to the face-to-face diagnosis. Whilst this appears to suggest that additional clinical information is essential, the authors did comment on poor image quality, which they attributed to limitations of the optics of cellular phones, particularly in respect of macroimaging, and also to limitations of the photographer, who was a medical student who did not have experience in either dermatology or photography. The authors did not enlarge on the reasons for the choice of photographer but the comment appears to indicate that a dermatologist may have produced more informative photographs.

A much more explicit evaluation of the limitations of mobile cameraphone images emerged from a study also conducted in 2005, in which physicians separately evaluated 61 leg ulcers for nine variables of clinical feature via mobile phone images received by email, and compared their findings to those of a third physician who performed a face-to-face consultation. The clinical features specified included elements which incorporated some aspects of both colour and distortion as described previously, such as erythema, granulation tissue at the normal border, etc. The image quality was regarded as "very good" in 20% of the photographs and "good" in a further 59%, leading to the conclusion that "Although this study was performed with the first generation of these devices we were able to demonstrate the feasibility of such a telemedical wound care consultation" (Braun, Vecchietti, Thomas, Prins et al., 2005 p.254). That comment infers that they too were looking to advances in technology rather than improvements in photographic skills to improve the image quality.

Other authors supported that view but some were much more specific, saying "the real issue is not resolution. The crux lies in the optical abilities of the camera and the quality of the lens" and also "it was difficult to keep the phone still" (Larsen, Clemensen and Ejskjaer, 2006 p.361). These authors went much further in their description of the limitations of the use of mobile cameraphones, explaining that they had found it necessary to use a digital camera to collect supplementary images as the mobile phone images exaggerated the red colour of the skin. They also explained the need to use synchronous communication to describe features such as swelling (indicating that depth or 3D replication is a problem in images) and smell (indicating that some clinical features are not able to be replicated via an image).

None of those limitations appeared to be a problem for Shokrollahi and colleagues when they found a high correlation between the face-to-face assessment of surface area and depth in burn wounds and the assessments conducted from mobile cameraphone images of the same patients (Shokrollahi, et al., 2007 op.cit.). The authors commented on the rapid technological growth in mobile cameraphones and questioned why the potential applications remained untapped in healthcare. However advances in technology have in fact expanded the range of applications, as seen for example in the automated assessment of ulcer wounds. In one example a mobile cameraphone was interfaced via Bluetooth with a laptop computer and used to photograph ulcers, automatically detecting the borders for the calculation of the surface area. The area of the ulcer wound was calculated by counting the number of pixels circumscribed by the wound border and then multiplying that value by the pixel area measurement (Duckworth, Patel, Joshi and Lankton, 2007). Whilst this method appears to yield more reliable results than planigraphy performed by a human, it must be remembered that the original image is still framed by a human operator. It is therefore subject to operator error, such as distortion caused by incorrect camera angulation and patient positioning, or blurring caused by the difficulty in holding the phone still.

It appears from the literature that even fewer authors have considered the effects of inadequate operator expertise in mobile phone telemedicine than with conventional digital camera images. Shokrollahi et al., for example, claimed that one of the differences between conventional telemedicine and mobile phone telemedicine was that the conventional method required training, inferring that the use of a mobile phone did not (Shokrollahi et al., op.cit.). However this may be an issue that adopts greater prominence in mobile phone imaging due to the evaluation of initiatives in which patients record images of their wounds or skin lesions themselves.

It was acknowledged in 2002 that the use of mobile phones in healthcare would require some attention to the hitherto unresolved issues of user acceptance and user friendliness (Maglaveras, Chouvarda, Koutkias, Meletiadis et al., 2002) but the feasibility of patients taking images by digital camera for use in follow-up monitoring was demonstrated the following year (Eminovic, Witkamp, Ravelli, Bos et al., 2003). Two years after that a group of elderly patients in Japan were asked to take photographs of themselves for healthcare purposes (Kotani, Morii, Asai and Sakane, 2005). It is interesting that three out of nineteen patients refused to do it by instant camera but agreed to do it by mobile cameraphone. The reader is left to speculate on potential reasons for that, but to send a picture from a mobile phone is a relatively simple one-stop affair whereas the use of a digital camera requires an interface with another device.

The need for user friendliness and patient acceptability was further borne out in 2008, when 58 patients were asked to use a mobile cameraphone to photograph themselves in order to evaluate that as a method of remote triage. The results were compared to the outcomes of a face-to-face consultation (Ebner, Wurm, Binder, Kittler et al., 2008). In that study 50 out of the 58 did not want to do it, forty of those being because they could not use the camera of the mobile phone unassisted and the physician took those photographs. The remaining eight received a short training period, although this was not in the art of photography but in the technical aspects of using the equipment. Again clinical data contributed to the formulation of a diagnosis so it is difficult to define the contribution made to diagnosis by the images alone, but the authors reported that the results were encouraging.

The majority of studies evaluating telemedicine applications have resulted in the authors claiming that there is great potential for remote diagnosis based on information from mobile cameraphones. This potential has not translated into widespread safe and effective practice at the present time, and nor does there appear to be much, if any, solid evidence on which such widespread practice could reliably be based. The reasons offered by authors for the often disappointing results are at best many and varied and at worst they are unspecific or uninformed. If telemedicine initiatives are to flourish there is a need to explore those reasons, and it was from identifying that need that the idea of this study was born.

3.5 The need for this study. A study of the literature has yielded more questions than answers. Not only “are mobile cameraphones as good as a digital camera for store-and-forward imaging in telemedicine?” but more fundamentally “were digital cameras good enough anyway?” Particularly in relation to mobile cameraphones the questions are far too numerous to list, but include; “does image quality depend on cost?”, “have technological advances made a difference to image quality?”, “does viewing on a computer monitor make a difference?”, “do real-time imaging devices deliver images of equivalent quality?”, "how important is image quality anyway?", "does it matter who takes the photograph?", "are some lesions more easily diagnosed than others on photographs, and if so, which and why?", "does diagnostic ***agreement*** equate to diagnostic ***accuracy***?", "what level of accuracy is ***good enough***?"

There is little point in attempting to answer the big questions based on clinical or operator variability until the basic questions of colour and shape accuracy relating to the various devices have been explored. The following studies attempt to answer just a few of those questions by evaluating a range of equipment commonly used in the fields of dermatology and tissue viability, in their ability to replicate colour and shape accurately. Colour and distortion are addressed in a manner intended to simulate "best practice" conditions that might be available in a clinical situation within the community setting. That is without the use of specialist hardware or software and without recourse to a professional photographer and associated laboratory, but under ideal conditions of amateur photography, utilising the best techniques so that operator errors are kept to a minimum.

CHAPTER 4: An evaluation of the accuracy of colour capture and display on a range of telemedicine equipment.

4.1 Methods.

4.1.1 Aims.

- To evaluate a range of equipment, commonly used in telemedicine for purposes of remote diagnosis or monitoring of visual features, in their ability to replicate colour and shape accurately, and in particular,

- To identify any discrepancies between views expressed previously, either in the literature or expressed verbally by interested parties, and the findings elicited by this study.

4.1.2 Design. This study relies on the outcomes of a series of observational tests performed by a cohort of students, mainly qualified nurses, who were studying on a variety of post graduate health science courses.

4.1.3 Participants. The participants were all volunteers from the student body of the university in which the study was conducted. The time-frame in which this study was conducted was severely limited as all observations had to be conducted during optimum daylight conditions and at exactly the same time, to avoid variations due to differences in ambient lighting. Therefore the participants comprised a convenience sample of those who were available and able to complete all the observation tasks during a two-hour period on a clear morning (n=12). Three were males and nine were females, age range 17 – 47 years.

4.1.4 Measures. All participants undertook all observational tasks. The observation of each device yielded 25 results of individual colours. Each result was categorised as being correct, being of correct colour but with errors in the shade (1-6 errors possible), being of a completely different colour or being absent. Thus 12 participants undertaking 15 observational tasks each comprising 25 separate observations yielded 4500 elements of data, which are used to draw comparisons between the devices.

4.1.4 Ethical considerations. Advice was sought from the vice chair of the university ethics committee for health studies who made the judgement that it was not necessary to seek ethics approval. There are no funding or employment bodies involved in this study. The participants volunteered their own time therefore study hours were not compromised and the study had the approval of the tutor responsible for the courses being undertaken. The rationale was that it was beneficial for undergraduate nursing students to be aware of practices they were likely to experience in the course of their work and post graduate students would benefit from experience of the research process. The participants were fully informed about the nature and purpose of the research by means of a personal presentation by the researcher, given during one lecture by the vice chair of the ethics committee and supervised by him. No volunteer was excluded although not all were able to undertake the observational tasks during the specified period, however all participants were provided with lunch and a comfortable rest area for the duration of the tasks. All participants were assured of anonymity and that no individual data would be published. All were offered the opportunity to be informed of the results of the study. In terms of the obligation to society, this study will inform the discussion surrounding the use of some devices currently commonly used in the diagnosis or treatment of patients. It will add to the body of evidence which supports or rejects some of the commonly held beliefs which at present have little basis in fact. In doing so, it may impact on patient care.

4.1.6 Procedure.

4.1.6.1 Methods of data collection. A number of copies of identical shade cards obtained from a paint manufacturer were used to make twenty-four identical matrices made up of the coloured squares. Each set consisted of 7 shades of each of brown, blue, yellow, red and green, (colours which may be clinically relevant as previously explained in section 3.2.1 on page 49. This provided a total of 35 different hues. A diagrammatic representation of one set of coloured squares is shown in figure 4-1. Paint shade cards were used because they provided multiple copies of a very large and freely available range of colours and shades. For each colour the series of shades selected ranged from light to dark in roughly equal increments. The extremes of the colour ranges were selected so as still to be easily distinguishable from each other with the naked eye. Therefore the paler shades were not so pale as to appear white to the naked eye, nor were the darker shades so dark as to appear grey or black. Each coloured square was assigned a two-digit identification number. The first digit represented the colour (1 = brown, 2 = blue, 3 = yellow, 4 = red and 5 = green). The second digit represented the shade (1 = palest and 7 = darkest). Thus 11 represented pale brown, 57 was dark green, and so on.

All identification such as name and batch number was removed from the paint cards, leaving blank pieces of coloured card approximately 2 centimetres square. Random numbers were written on the back of each coloured square in one complete set, and that number was copied onto the corresponding square in the other twenty-three sets. A note was made of the random number and the two-digit colour identifier to which it corresponded. One complete set of coloured squares was placed in an envelope and a colleague asked to select and discard ten at random. The remaining twenty-five were arranged at random in a square matrix and glued onto a piece of cardboard as shown in figure 4-2. Three more identical matrices were constructed, leaving twenty complete sets of coloured squares. Each set of loose squares was packed in a protective envelope and stored until the tests took place.

The original matrix of 25 squares was photographed on each of ***four**** mobile phones and a digital camera. (*See description of phones 4 & 5 on the following page.) The POTS, ISDN2 and ISDN6 systems, when used during the colour assessment test, transferred the image in real-time and that procedure is described more fully on pages 76-77.

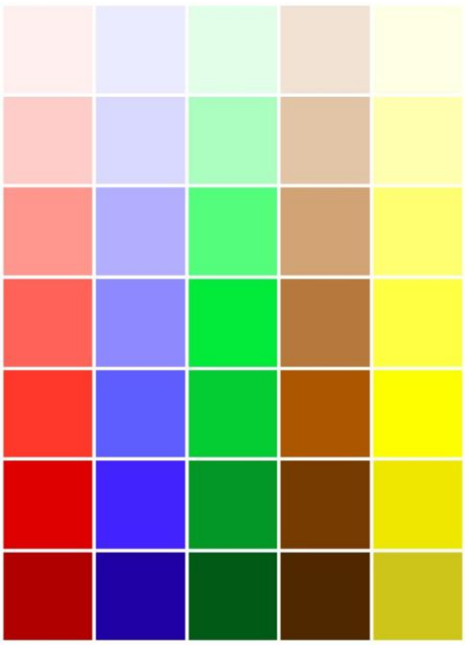


Fig. 4-1 Diagrammatic representation of array of coloured squares.

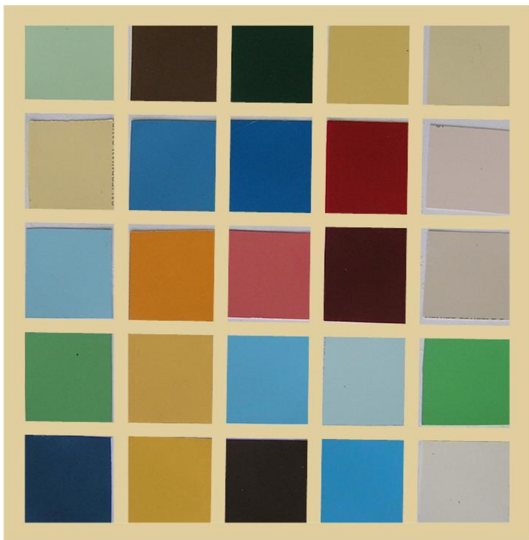


Fig. 4-2 Matrix of 25 squares comprising the test object

A range of photographic devices commonly used in telemedicine were selected and used to image the test matrix. Most were selected by convenience, being already available to the researcher however two of the mobile phones were bought specifically for the purpose of being able to test a "state-of-the-art" cameraphone. The technical details were as follows:-

- Mobile phone 1 had been a "bottom-of-the-range" model, available free with network contracts, having a 3.3 x 2.4 cm picture display, 176 x 220 display pixel array. 640 x 480 camera pixel array and 65k colours. This phone was no longer commercially available as it was considered obsolete and had been discarded. It was retrieved from a dustbin.

- Mobile phone 2 was a "middle-to-low-range" model, which was still commercially available, either gratis or for a small fee with network contracts, having a 3 x 2.2 cm picture display, (the display pixel array was not given), a 640 x 480 camera pixel array and 65k colours.

- Mobile phone 3 was a "middle-to-upper range model", costing £40 – £50 with a network contract, and having a 3 x 2.3 cm picture display, a 640 x 480 camera pixel array but only 256 colours. It was new to the market.

- Mobile phone 4 was a "state-of-the-art" device, costing in excess of £200 as a stand-alone phone or in excess of £100 if purchased with a network contract. It had a 3.7 x 3.4 cm picture display, 240 x 320 display pixel array, 1632 x 1224 camera pixel array and 256k colours. It was at the time the most recent mobile cameraphone to have been released commercially and was marketed on the strength of its camera capability.

- Mobile phone 5 was an identical model to phone 4 and was purchased from the same source at the same time. This phone received the image from phone 4, its "sister" phone, by MSN messaging and this was included to provide an indication of whether any errors occurred in colour recognition which might be due to data losses during electronic transfer.

- The Digital Camera was in the upper to middle-of-the-range category from a well-known manufacturer of photographic equipment. It was a new purchase and a relatively recent model, and selected as it was deemed representative of the type of camera reasonably available to nurses or other healthcare workers in the field. It was intended for domestic, not professional, purposes, being suitable for "beginner to serious amateur" and boasting a four megapixel camera array and a 3.8 x 2.8 cm picture display. The display pixel array was not specified in the literature accompanying the camera.

- The real-time imaging equipment comprised a POTS videophone, an ISDN2 videophone and an ISDN6 conferencing facility. All real-time devices were already available in the university setting and had previously been used in telemedicine research trials.

In each case the matrix was photographed under optimum daylight conditions, all photography being performed within a one-hour period during the mid-morning of a bright day. The highest possible resolution available to each piece of equipment was selected. A tripod was used with the digital camera to minimise camera shake and to ensure that the camera remained at right angles to the matrix photographed.

The mobile phones were not equipped with connections appropriate for a tripod. A frame was constructed which enabled each phone to be held firmly in the correct plane perpendicular to the matrix, as can be seen in fig 4-3. The matrix was rotated through ninety degrees before photographing it on each piece of equipment, so that participants would view it from a different angle on each piece of equipment and so reduce the likelihood of their recognising that it was the same matrix on each image from the colour

Fig. 4-3 Mobile phone setup for photography of coloured matrix.

pattern displayed. The images captured on each mobile phone and also on the digital camera were copied onto a laptop computer. In the case of the video apparatus "photography" in the conventional sense did not occur but the image was captured and displayed in "real-time" during the test procedure as described below.

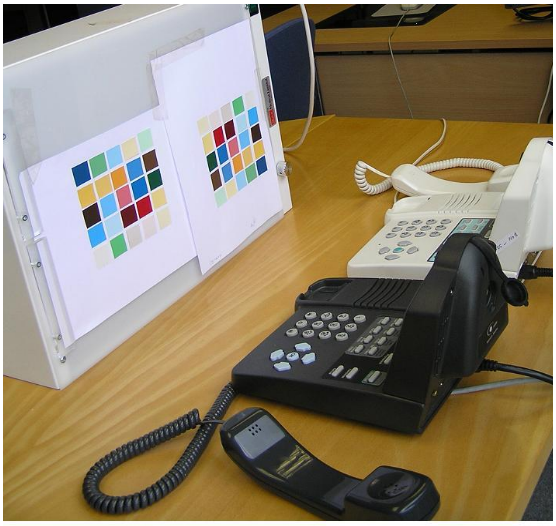


Fig. 4-4 Setup of POTS & ISDN2 videophones

The POTS videophones (white phone in figure 4-4) were connected to the conventional telephone socket and the connection made by dialling the appropriate telephone number in the normal manner. The matrix was positioned in full daylight and the videophone making the call (and therefore transferring the image of the matrix) was positioned so that the integrated camera was aligned with the centre of the matrix and at right angles to it. The POTS videophone receiving the call was in a remote location within the same building.

The ISDN2 videophones (black phones in figure 4-4) were set up in a similar manner to that described for the POTS videophones except that both were connected via the ISDN2 telephone connection.

The ISDN6 conference facility was set up as shown in figure 4-5 and used in the manner recommended by the manufacturer for transmitting images of documents. For this purpose, colleagues at a London tertiary centre assisted. The teleconference coordinator at the tertiary centre positioned the matrix under the integrated light in the document holder in the room dedicated to teleconferencing, as used for clinical consultations. A conference call was convened between the tertiary centre and the university and the camera at the tertiary centre adjusted by the teleconferencing coordinator, so that a large image was projected on the screen at the university. The ambient lighting in the teleconferencing room at the university was restricted to diffuse daylight and the screen positioned so that there was no glare. Participants were positioned so as to have maximum daylight available for viewing their complement of coloured squares.

Sixteen workstations were set up. Nine of these were equipped with devices showing an image of the matrix of 25 coloured squares, those being five cameraphones, one digital camera and three real-time devices. Six of the seven remaining workstations had laptop computers showing an image captured by each of the cameraphones and the digital camera. At the remaining workstation the image of the matrix was replaced by the original matrix. This was in order to identify any errors that might be due to eyesight rather than to inaccurate image reproduction. A complete set of thirty-five coloured squares and a supply of the data collection forms containing a blank template of the same size and shape as the original matrix were made available to each workstation. The data collection forms can be seen in figure 4-6.

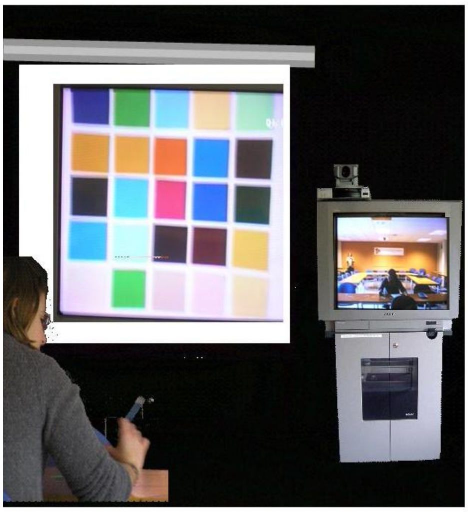
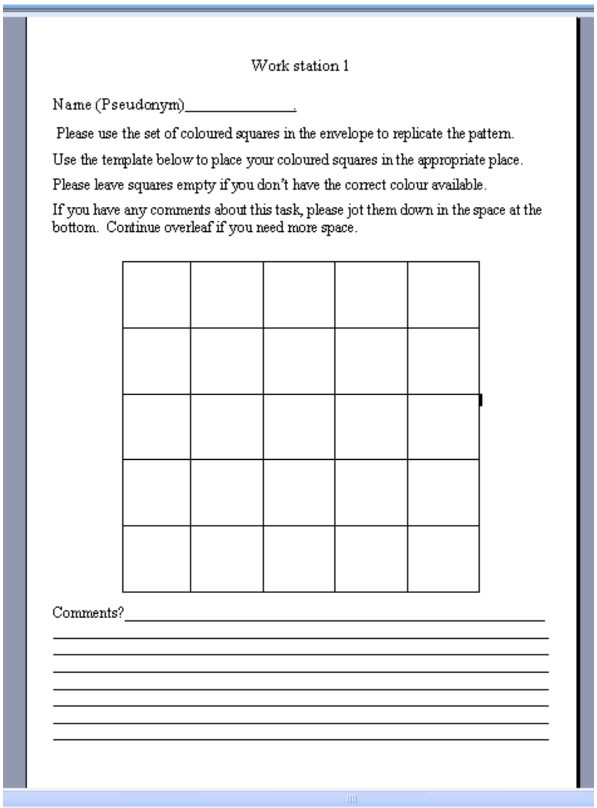


Fig. 4-5 ISDN6 Videoconferencing setup



Work station 1

Name (Pseudonym)______________.

Please use the set of coloured squares in the envelope to replicate the pattern.

Use the template below to place your coloured squares in the appropriate place.

Please leave squares empty if you don't have the correct colour available.

If you have any comments about this task, please jot them down in the space at the bottom. Continue overleaf if you need more space.

Comments?____

Fig. 4-6 Mobile phone colour comparison data collection form.

Participants were invited to select a pseudonym anonymously from a collection of twenty and to use it on all data collection forms. Each participant was then directed to a workstation where they wrote their pseudonym on the data collection form supplied. They then attempted to reproduce the image displayed on the equipment by placing selected coloured squares from the complete set of 35 available in front of them onto the corresponding square on the template. They were asked to leave empty any square for which they did not have a corresponding coloured square, and to leave to one side any redundant squares. In fact all colours occurring in the matrix were available to every participant but the opportunity to convey the information that the colour perceived did not match any of the colours available, rather than to guess at the closest approximation, made it possible to recognise poor image reproduction more easily. Participants were invited to write any comment they felt relevant in the appropriate area at the bottom of the form.

When participants indicated that they had completed each task a member of staff asked them to leave the work station, after which the number on the back of each coloured square was copied by the staff member onto the corresponding position on the data collection form. All thirty-five squares were then shuffled and replaced face-up on the desk and a new data collection form placed ready for the next participant. All participants performed the test on all pieces of equipment and also on the "face-to-face" original matrix.

4.1.6.2 Methods of data analysis. In order to carry out comprehensive statistical analyses it is necessary to have access to the raw data. Most statistical tests are based on assessing the difference between summary statistics (means, medians etc.) for groups (devices, colours etc.) with respect to the spread of the data within the different groups. These tests cannot be undertaken just using summary data (means, medians etc.) alone therefore for most of the analyses presented below the raw data, originally recorded in an Excel file, were re-arranged and transferred to the software programme "PASWStatistics 18" for analysis.

In all analyses the Kruskal-Wallis test was used. This is the non-parametric equivalent of one way ANOVA for 3 or more groups so it does not assume that the data are normally distributed, which is appropriate due to the small number of data observations within the groups (devices, colours etc.) for each analysis.

The statistical analysis of inter observer agreement was carried out using Fleiss' kappa test. The raw data were entered into an Excel file for analysis. The results were interpreted according to Altman (Altman, 1991 p 404) as shown in table 4-6 on page 117 of this document. Altman's interpretation is adapted from the work of earlier authors, (Landis and Koch, 1977). For ease of orientation, the following summary outlines the foci of the analyses.

Section 4.2.1 addresses the viewing on the face of the original nine devices when all observations of matches of coloured squares in the matrix were recorded as either correct or incorrect. The non-parametric Anova (Kruskal-Wallis) test was used to test whether there was a statistically significant difference in the percentage accuracy of colour recognition;

1) according to device, when considering all five colours collectively.
2) according to colour when considering all nine devices collectively.
3) according to device when colours were considered collectively and errors in shade were permitted to be considered as a correct result.

Section 4.2.2 addresses the changes in recognition accuracy when the images from each of the six still-imaging devices were transferred to a laptop computer for viewing. The non-parametric Anova (Kruskal-Wallis) test was used to test whether there was a statistically significant difference in the percentage improvement in the recognition accuracy;

1) according to device when considering all colours collectively.
2) according to colour when considering the devices collectively.

Section 4.2.3 explores the findings from the above analyses in greater detail. It was not considered sensible to subject the many different sub-sets of data to the same statistical analysis, due to the likelihood of incurring Type I errors (i.e. finding spurious statistically significant results). The previous analyses demonstrate the presence or absence of statistically significant differences in the percentage correct between devices and colours, including any statistically significant differences which may still exist when errors in shade are permitted to be counted as correct and when a laptop computer is used for viewing purposes. The graphs in this section simply explore this in more detail.

Section 4.2.4 addresses the phenomenon of colours being perceived as a completely different colour. The non-parametric Anova (Kruskal-Wallis) test was used to test whether there was a statistically significant difference in the percentage of colours being mistaken for a completely different colour;

1) according to colour, both when considering the 6 still-imaging devices collectively and also when considering all 15 viewing opportunities collectively.
2) according to device, both when considering all colours collectively. This aspect is explored both when taking only the 6 still-imaging devices into account and also when comparing results from all 15 viewing opportunities.
3) according to device when considering the mean change in colours misidentified when images from the 6 still-imaging devices were viewed on a laptop computer.

Section 4.2.5 explores the findings from the above analyses in greater detail, using graphical representation to illustrate relevant points. Again it was not considered sensible to subject the many different sub-sets of data to the same statistical analysis, due to the likelihood of incurring Type I errors (i.e. finding spurious statistically significant results). The previous analyses demonstrate the presence or absence of statistically significant differences in terms of the misperception of colour between devices, both when considering only the still-imaging display and also when the images are displayed on a laptop computer. The graphs in this section simply explore this in more detail.

Section 4.2.6 compares participants. The non-parametric Anova (Kruskal-Wallis) test was used to test whether there was a statistically significant difference in the percentage accuracy recorded by each of the twelve participants.

Section 4.2.7 addresses the inter-observer variability for the data presented above. Fleiss' kappa measurement of concordance was used to test whether there was statistically significant agreement between all participants;

1) when considering each coloured square as a separate entity.
2) for each device, according to colour, for the seven categories of shade
3) for each device, according to colour, for integrated categories of shade

4.2 Results - Colour recognition accuracy

4.2.1 Images were viewed on the normal display of the original device.

4.2.1.1 According to device, all colours considered collectively. The results are displayed graphically in figure 4-7. No device attained an accuracy of 50% or greater. When all colours were considered collectively there was a statistically significant difference between the devices in terms of the percentage of the coloured squares which were identified correctly by the participants. (K-W Chi-square = 38.365 with 8df and $p<0.001$.)

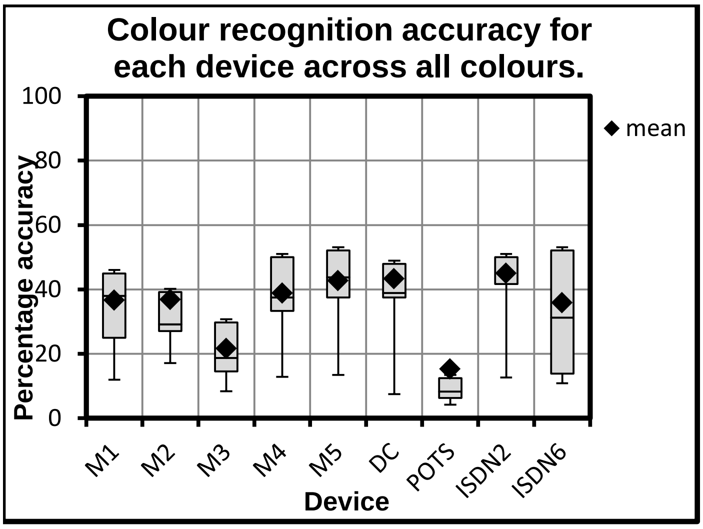


Fig. 4-7 Box and whisker plot of colour accuracy for each device across all colours.

When judged by these parameters the POTS videophone was the worst performer, achieving an accuracy of only 18%. The cheapest mobile phone (M1) performed almost as well as the most expensive state-of-the-art (38% & 40% respectively) although when the image on the expensive model (M4) was transferred to an identical model (M5) via MSN messaging the performance was found to have increased (40% rising to 44% post MSN messaging). Its performance after MSN transfer was comparable to that of the digital camera, which in turn was better than Mobile 2 (44% and 38% respectively). Of all the mobile phones, the mid-priced model performed most poorly. The ISDN6 conferencing facility performed poorly compared with the ISDN2 videophone (38% and 47% respectively).

4.2.1.2 According to colour, considering all nine devices collectively. The data are summarised in figure 4-8. When all the scores from every device were amalgamated there was found to be a statistically significant difference in the extent to which individual colours are recognised with absolute accuracy (K-W Chi-square = 18.465 with 4df and p=0.001).

This indicates that there is a statistically significant difference in terms of overall accuracy between the five colours. Judged by these parameters brown has the poorest result with only 31% of the brown shades being identified correctly. Blue has the greatest accuracy overall with 55% being identified with complete accuracy.

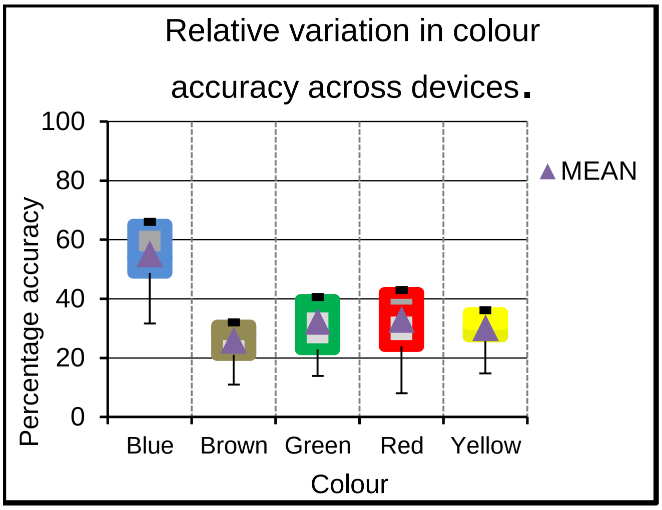


Fig. 4-8 Box and whisker plot of colour accuracy across all devices.

It is clear from figure 4- 8 that the recognition accuracy of each colour varies across the devices. When the recognition accuracy of each colour is demonstrated as it applies to each device separately, a more complex pattern emerges. This is demonstrated in figure 4-9, where it can be seen that although in general the blue hues were more accurately recognised and the brown hues least accurately recognised, there are a number of exceptions. For example in mobile 1 the red hues out-perform the blues and in mobile 3 three the blue and brown hues achieve the same (poor) level of accuracy.

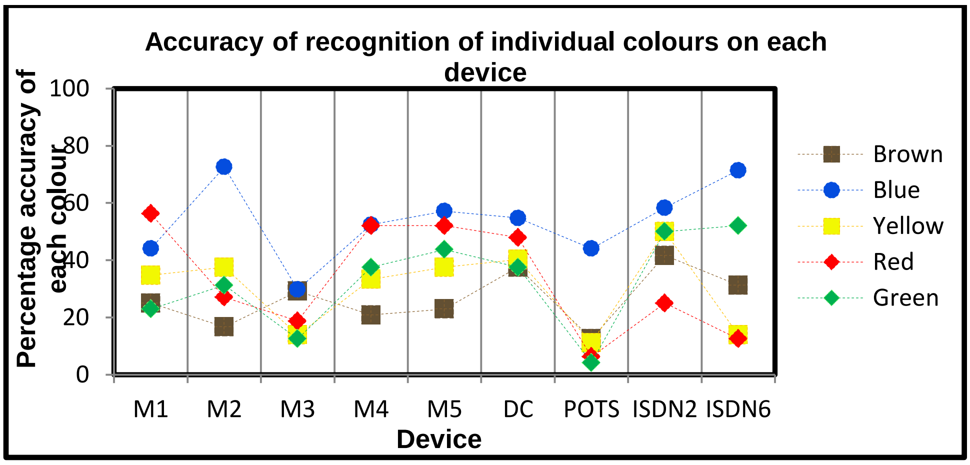


Fig. 4 – 9. Graph of percentage accuracy of each colour perceived on each device.

4.2.1.3 According to device, considering all colours collectively and permitting errors in shade to be included as correct results. The accuracy did not improve to the same extent for all devices. Results of the chi-square test showed that there was a statistically significant difference between devices when errors in 1 shade, 2 shades and 4 shades were included. The difference for 3 shades was not shown to be statistically significant in this sample. The data are summarised in table 4-1.

	+1 shade	+2 shades	+3 shade	+4 shades
K-W chi-square	17.483	17.311	14.557	16.518
Df	8	8	8	8
p-value	0.025	0.027	0.068	0.036

Table 4-1. Differences in improvements when errors in shade are included as a correct result.

Figure 4-10 shows the performance of each item of equipment, comparing its accuracy when variations of shade are included as correct scores in the results. As can be seen in the graph, the inclusion of a one shade error almost doubles the score for each item of equipment, bringing the overall accuracy to approximately 70% in the majority of devices. The exceptions are the mid-priced mobile phone (M3) the POTS videophone and to a lesser extent the ISDN6 video-conferencing system. With the inclusion of two or three variations of shade of colour the scores for most devices approach, or even exceed, 80%, the exceptions again being the mid-priced mobile phone (M3) and the POTS videophone which are much lower.

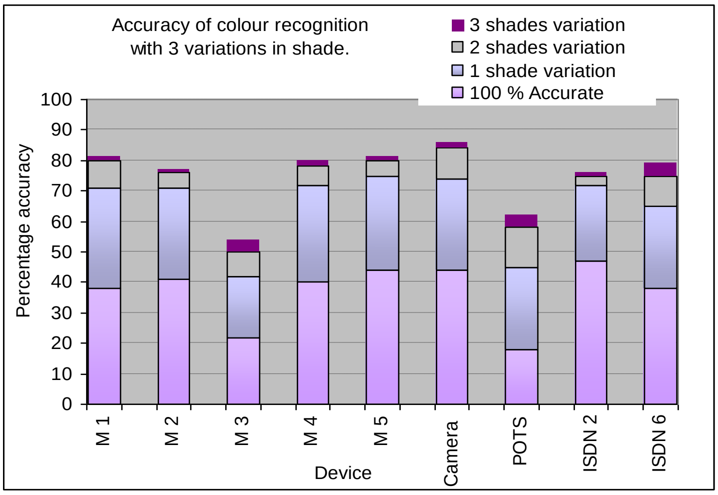


Fig 4-10 Accuracy of colours identified when errors in shade are discounted.

4.2.2 The changes in accuracy of colour recognition when the images were viewed on a laptop computer. No still images were captured with the real-time devices therefore they do not appear in this section.

4.2.2.1 Changes in colour recognition accuracy according to device, across all colours. When considering the colour recognition accuracy of individual devices (for complete accuracy only) it can be seen from figure 4-11 that the transference of the image to a laptop computer improved the results in every case, at least when the results from all colours were amalgamated. The mean change in the percentage recorded as correct is presented in table 4-2. The differences between devices in the level of improvement were not found to be statistically significant however. (K-W Chi-square =5.188, df =5, p=0.393.)

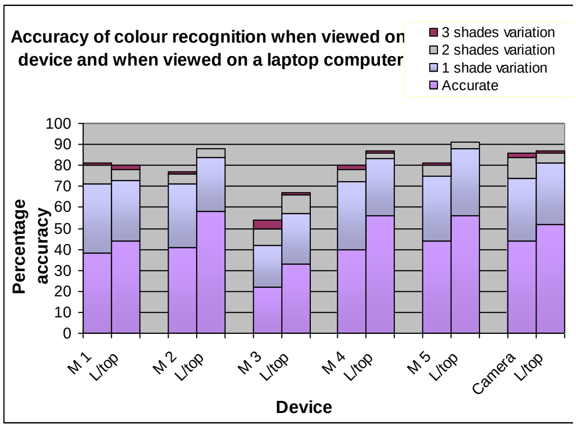


Fig 4-11 Comparison of colour recognition accuracy, across all colours, between viewing on device and viewing on a laptop computer

device	Mean change percentage correct
M1	.4
M2	13.4
M3	12.0
M4	7.0
M5	12.0
Camera	2.0

Table 4-2. Mean change in percentage of accurate colour recognition accuracy for each device when the image is viewed on a laptop computer.

4.2.2.2 Changes in colour recognition accuracy according to colour, when considering all devices collectively. It can be seen from the illustration in figure 4-12 on the following page that when the image was transferred to a laptop computer there was an improvement in the recognition of each colour when the results were amalgamated across all six devices. The mean change in percentage correct varied from 3.96% in the blue colours to 19.1% for the red colours and the data are summarised in table 4-3, however the Anova analysis demonstrated no statistically significant difference in level of improvement between colours. (K-W Chi-square = 3.885, df = 4, p = 0.422).

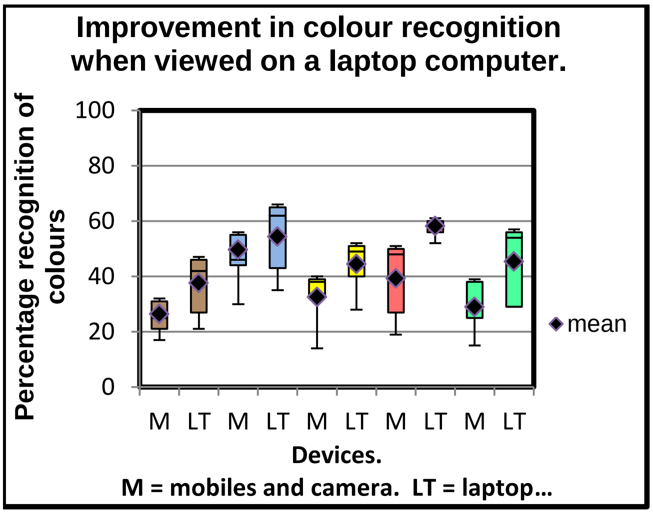


Fig 4-12. Changes in colour recognition accuracy, according to colour, when original images are transferred from the six devices to a laptop computer.

colour	Mean percentage improvement
Brown	12.5
Blue	3.96
Yellow	11.8
Red	19.1
Green	15.3

Table 4-3. Mean improvement in accuracy (%) of colour recognition for each colour when images are viewed on a laptop computer compared with viewing on the original device.

However, once again the generalisation is not fully representative of the complex changes in performance. The changes in recognition accuracy of each colour, as perceived on each individual device following transfer to the laptop computer, are illustrated in figure 4-13 on the following page. It can be seen in that figure that the accuracy of recognition of some colours in certain specific devices actually fell. For example, in both mobile 2 and the digital camera the accuracy of recognition of the blue hues fell, as did recognition of the brown hues in mobile 3.

When a one shade variation was included as an acceptable result, the improvement in accuracy of computer display over device display ranged from 4% to 15%. The image from the digital camera showed only a modest improvement and its overall accuracy was rivalled by the images captured by mobile 2 and mobile 4. With the inclusion of the 1 shade error, the accuracy of the digital camera image viewed on a laptop was marginally exceeded by the image which has been transferred by MSN messaging prior to being loaded onto the laptop.

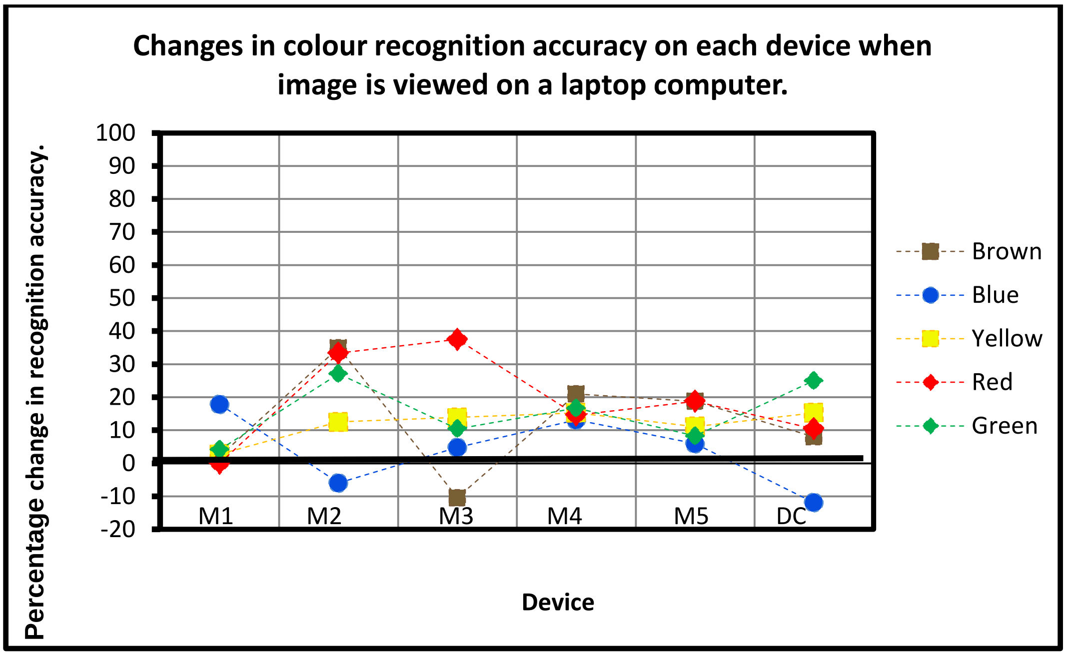


Fig 4-13. Changes in recognition accuracy of each colour for each device when the image is transferred to a laptop computer.

4.2.3 Exploration of the recognition of colour incorporating all variations in display.

Although brown tones were the least accurately identified overall, it can be seen in figure 4-14 that the individual devices demonstrate very different capabilities with respect to this colour. The ISDN2 videophone out-performed the other two real-time devices and it also out-performed all the still-image devices when the image was viewed on the face of the device. It even out-performed or very nearly equalled some of the still imaging devices after their images had been transferred to the laptop computer.

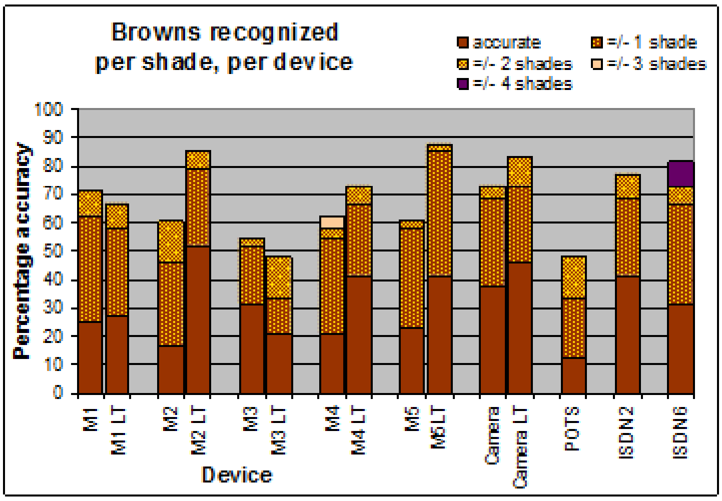


Fig 4-14 Accuracy of recognition of brown tones on all devices

Of the still-image devices the digital camera was the best performer when viewed on the screen of the imaging device, both when complete accuracy is considered (range 17% - 38%, the digital camera yielding an accuracy of 38%) and also when a one shade variation is included (range 46% - 83% with the digital camera yielding 83%). However when the images were viewed on a laptop computer the improvement seen in Mobiles 2, 4 and 5 result in their closely approaching or out-performing the digital camera in terms of absolute accuracy (range 21%-52% with digital camera yielding 46%). When a variation of +/- one shade was included a similar pattern emerged, the range in this case being 33%-85% with the digital camera yielding 73%.

It is tempting to suggest that the reasons for the difference in results when the images are viewed on the face of the device may be due to the relative sizes of the viewing screens on the device, however the viewing screen of Mobile 4 (and therefore also Mobile 5) was slightly larger overall than that of the digital camera (see section 4.1.6.1 page 74 for details). Furthermore, since both devices were able to be moved by the observer for comfortable viewing, it is likely that the reason lies in the technical specifications of the display.

The laptops used to display the images were not identical models and this cannot be discounted as a reason for the relative differences in the improvements in recognition accuracy recorded. Further considering the mode of display, Mobile 2 shows an absolute accuracy of just below 17% from the face of the device, rising to just over 52% when viewed on the laptop, an improvement of just over 35%. Mobile 1 however showed an accuracy of 25% on the viewing screen of the device, rising to only 27% on the laptop, an improvement of only 2%. This reinforces a previous assertion that image capture and image display cannot be considered as one entity when assessing the quality of a photographic device. It is an interesting anomaly that Mobile 3 yielded poorer recognition accuracy via the laptop than on the device, at least in the brown part of the spectrum. One possible reason for this is that the other aspects of image quality (resolution, distortion, definition) were also poorer in this device and so degraded the overall appearance of the image. Those faults, being more evident on the laptop display, may have affected the perception of the colour. Another explanation is that the exaggerated reddening of colour previously observed by some authors, as described in chapter 3 on page 67, may have occurred to a greater extent in this device than in the others. That colour distortion, being more easily seen on the laptop display, may have led to observers mistaking more of the brown squares for red ones in the matrix viewed. More detail in errors of colour perception is given in section 4.2.4.

As suggested by the overall results for the blue tones, it can be seen in figure 4-15 that each device demonstrated greater accuracy in this part of the spectrum (range 30%-73%) particularly when including one shade of variation (range 61%-90%). The cameraphones performed as well as, or in some instances slightly better, than the digital camera, which scored 55% recognition with absolute accuracy and 77% with a one shade variation included. The anticipated exception was Mobile 3 which achieved a recognition score of only 30% for absolute accuracy and just over 60% when a one shade variation was included. When viewed on the laptop computer the absolute accuracy recognition fell slightly in both Mobile 2 and the digital camera, but with the inclusion of +/- one shade variation as a correct score all the still-image devices performed approximately equally (range 85%-91%), again with the predictable exception of Mobile 3 which nevertheless achieved a recognition score of 75%. The real-time equipment also performed relatively well. The ISDN 6 system yielded a better score than the ISDN2 system, achieving 71% and 58% respectively for absolute accuracy and 88% and 81% with the inclusion of +/- one shade error. Both did better than the POTS videophone which rendered 45% absolute accuracy and 65% with a

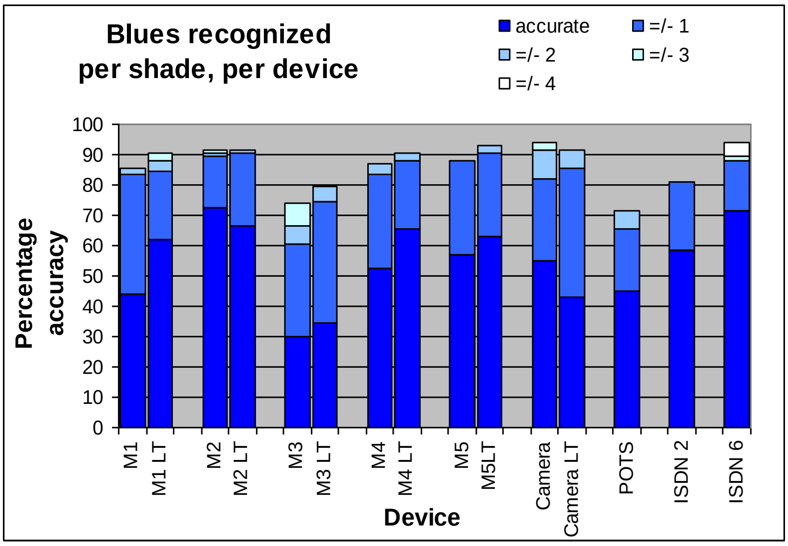


Fig 4-15 Accuracy of recognition of blue tones on all devices

+/- one shade variation, but this was still better than Mobile phone 3, except in the instance of including an error of one shade variation when displayed on a laptop computer.

Yellow tones did not demonstrate an encouraging level of accuracy of colour recognition in the still-imaging devices when absolute accuracy was considered (figure 4-16). Excluding Mobile 3, which was again by far the worst performer with a score of only 14%, the range of accurate scores was 33%-39%. The digital camera was at the top of that range achieving a colour recognition score of 39%. The devices were therefore quite similar in performance. When taking the one shade variation into account the accuracy of recognition was much higher and the differences between devices also increased slightly, (range = 71%-85%) but this time the digital camera was at the lower end of the range with a score of 71%, therefore had not performed as well as most of the mobile phones.

In considering the real-time equipment the pattern reflects that demonstrated by the brown tones, with the ISDN 2 videophone performing much better than the other two devices, yielding a 50% score for the correct recognition with absolute accuracy, rising to 75% with the inclusion of one shade variation, compared with only 14% rising to 49% and 8% rising to 29% by the ISDN 6 and POTS equipment respectively.

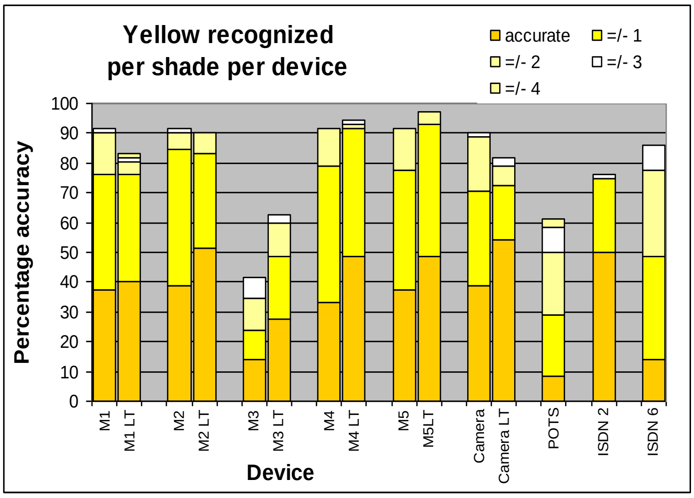


Fig 4-16 Accuracy of recognition of yellow tones on all devices.

All still-imaging scores for recognition of absolute accuracy were slightly higher when the images were viewed on the laptop computer, the improvement ranging from 2%-16%, with Mobile 1 again showing the least improvement. However when a one shade variation was included in the assessment, Mobiles 3, 4 and 5 showed an improvement of 13%-25% , with Mobile 3 showing the greatest improvement. Mobiles 1 and 2 and the digital camera showed very little difference to the scores the observers had recorded when looking at the face of the device directly.

In the red part of the spectrum it can be seen in figure 4-17 that the recognition of absolute accuracy ranged from only 6% in the POTS videophone to 52% in mobiles 1 and 5. Again Mobile 3 was the worst performer of the still-image equipment at 19% but Mobile 2 did not fare much better with a score of 27%. The digital camera was poorer than mobiles 1, 4 and 5 by an average of 3% and their respective scores demonstrated approximately the same pattern when the images were transferred to a computer, although the image transferred by MSN messaging appeared to perform better than all other equipment. It achieved a similarly high score when including the error of a one shade variation, being 85% for both the red and brown tones. The poor performances given by M2 and M3 showed the greatest improvement after transfer to the computer, rising from 27%-60% and from 19%-56% respectively. The inclusion of an error of one shade variation raised their scores further still, yielding 79% & 75% respectively, which was little different to the digital camera which showed an accuracy of 79% under the same conditions.

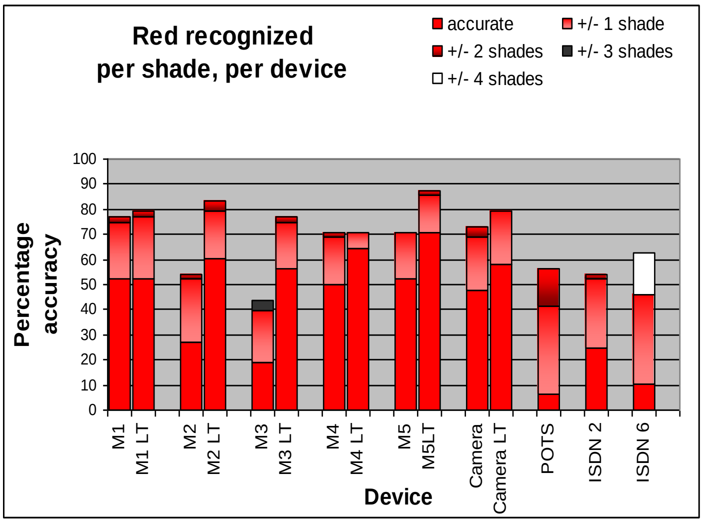


Fig 4-17 Accuracy of recognition of red tones on all devices.

The real-time equipment demonstrated poor recognition accuracy in the red part of the spectrum, with neither the POTS nor the ISDN6 systems rising above 10% for absolute accuracy. The ISDN2 videophone again did better, but not particularly well, with an absolute accuracy of 25%. The three systems fared much better with the inclusion of a 1 shade variation, and under these conditions their scores ranged from 41%–52%, again not particularly encouraging given the importance of red tones in contributing to the perception of skin, pigmented lesions and infection.

The green tones showed the greatest variation in accuracy recognition between devices (Figure 4-18) ranging from only 4% for the POTS videophone to 44% for Mobile 5 after transfer via MSN messaging, with the digital camera resolving 38% of green tones with absolute accuracy. Surprisingly the ISDN2 and the ISDN6 equipment, yielding scores of 50% and 52% respectively, did better than any of the still imaging devices when viewed on the screen of the device. Only when transferred to the laptop computer did Mobiles 2, 4 and 5 perform as well or slightly better, attaining scores of 56%, 54% and 52% respectively. The greatest improvements, as might be expected were seen when a one shade error was included and the image viewed on a computer. Again excluding Mobile 3 which, attaining 40%, was a particularly poor performer, the range of recognition accuracy for the still-image equipment was 62%-92%, the digital camera giving the greater score, closely followed by Mobiles 2 and 4 with scores of 85% and 87% respectively.

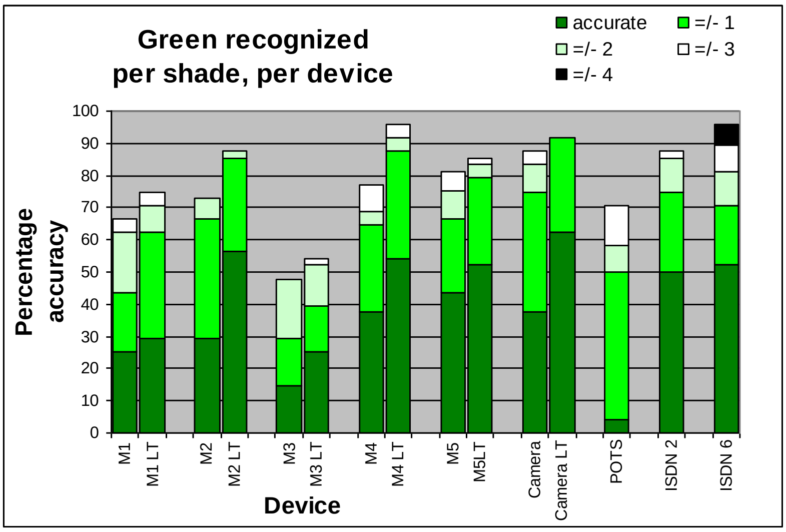


Fig 4-18 Accuracy of recognition of green tones on all devices

Arguably one of the most complex relationships to comprehend in terms of accurate colour display is the effect of changing viewing parameters on the rank order of precision. It is implied from comment in the preceding literature review that some colours may be considered more important than others in certain specific clinical situations. The variable parameters of assessing viewing accuracy, such as the device, the colour, and to what extent shade is important, have been shown to exert an effect on the extent to which colour is considered to be perceived accurately. Thus those parameters have the potential to alter the rank order in which colours are considered to be presented accurately. Since the relative accuracies of colour recognition, as brought about by differences in viewing conditions, may have some clinical relevance, they are illustrated below for completeness.

Referring to figure 4-19, when the images were viewed on a laptop computer compared with being viewed on the original device, a different hierarchical order of colour recognition accuracy was seen to occur across all devices except mobile 4. For example on the display screen of the digital camera the blue tones were recognised more accurately than any other colour and the greens least accurately. When transferred to laptop computer this result was reversed, the greens being recognised most accurately and the blues least accurately. This variation is cannot be dismissed with a simple comparison however, as a change in the display of any one of the red/blue/green tones will affect the perception of all other colours. The accuracy score of the blue colours was lower when viewed on the laptop computer rather than on the original device, falling from 55% to 43%, a trend which was also seen for M2, but not for the other devices. On M3 the rank order of the brown tones fell from most accurately recognised to those least accurately recognised when viewed on the laptop computer, whereas the red tones rose from third place to most accurately recognised.

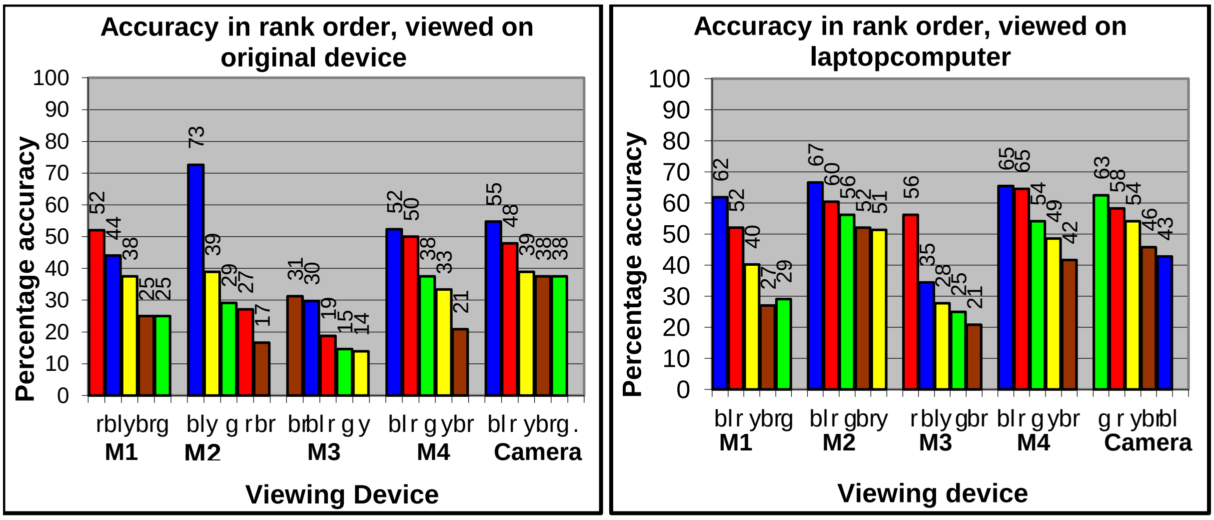


Fig 4-19 Differences in the rank order of colour identification when viewed on the original device, on a laptop computer,

This indicates a complex pattern of change. For example if colour distortion exists between the blue/green tones, that distortion may be more evident when the image is viewed on the better display of the laptop computer, leading to lower but more representative colour recognition scores. Alternatively, it is possible that the computer display introduces colour distortion of its own, which may act to amplify the original colour distortion or, by happy coincidence, may act to correct it. Therefore although the colours are not perceived accurately this is not the fault of the imaging device but the display device. The computer display can be manipulated by the operator, for example either to reflect his or her preferences in brightness or contrast, or in selecting a lower colour specification (e.g. 16 bit instead of 32 bit) to accommodate limited processing power of the computer.

Comparing the brown tones captured by the digital camera with those captured by M2, when viewed on the laptop the browns were next to least accurate in both cases, although M2 achieved the higher accuracy score (52.1% compared to the digital camera which scored 45.8%). These factors may contribute to the observation that when viewed on the laptop computer the digital camera could arguably be said to be inferior to M2, although individual scores for the green and yellow tones on the camera image were slightly higher.

If a plus or minus one shade difference may be deemed acceptable and is included as an accurate score, then when viewed on the original device only M2 retains the same rank order of colour accuracy, and a comparison of scores including a +/- 1 shade error between those images viewed on the original device compared with the same images viewed on a laptop computer, shows that the hierarchical order of colour recognition accuracy changes again. (Refer to figures 4-20 and 4-21 on the following page).

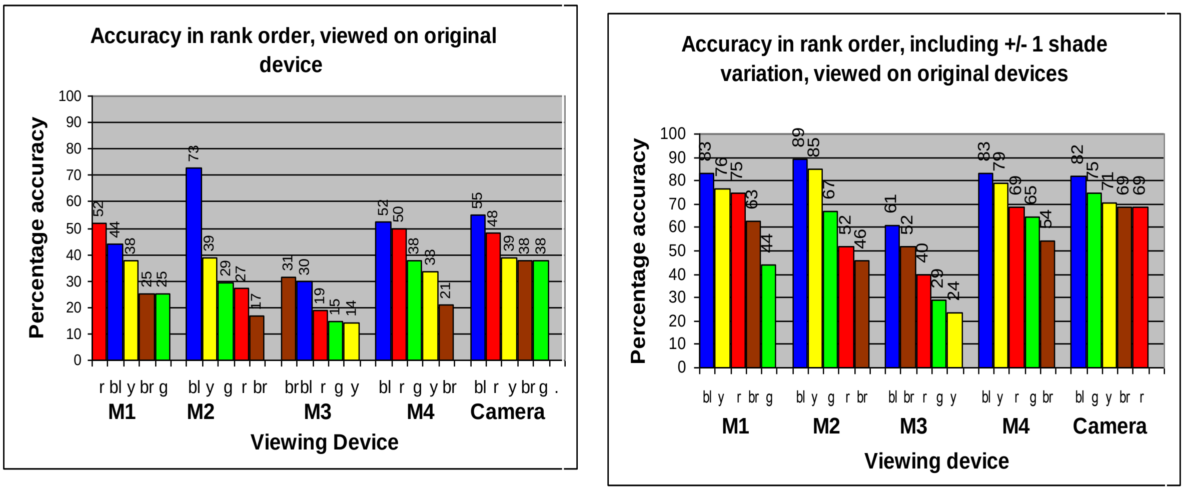


Fig. 4-20 Differences in the rank order of colour identification when a 1 shade error is included.

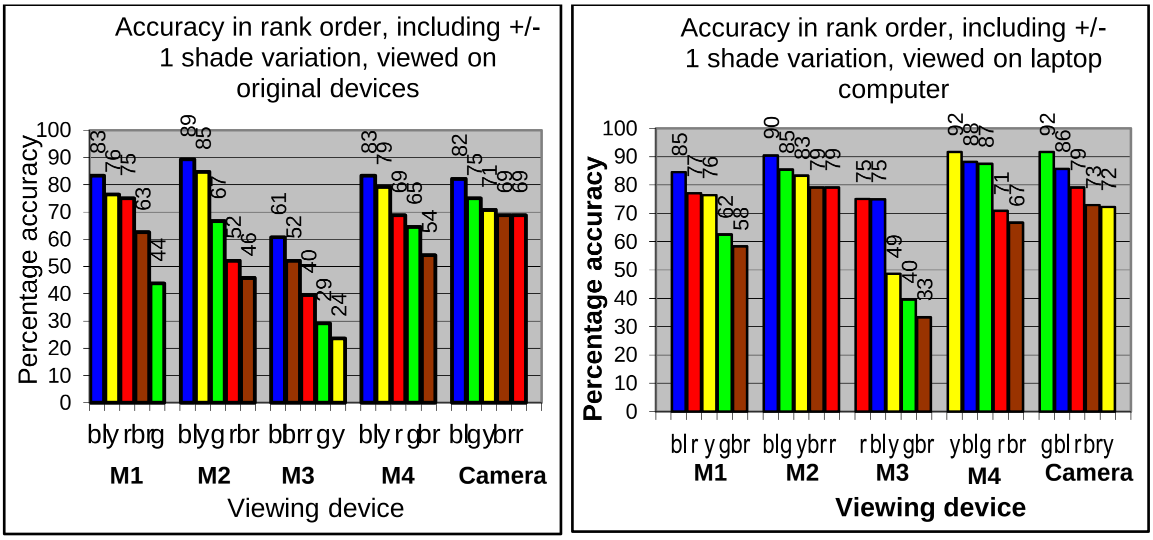


Fig.4-21. Comparison of rank order of colour identification when images including an error of +/- 1 shade are viewed on the original device and on a laptop computer.

Figure 4-22 shows that the transfer of the image from mobile 4 by MSN messaging did not effect a change in the rank order of the accuracy scores when the transferred image was viewed on the face of an identical cameraphone, although there was a slight increase in the accuracy scores of all colours, the increases ranging from 2.1% in the red and brown tones, to 4.8% for the blue tones. Nor was there a change in the rank order of accurate colour recognition on mobile 4 when the original image was transferred to the laptop computer. Blue tones achieved the highest score, followed by red, green, yellow and brown tones, although every score was higher, with increases ranging from 13.1% for the blue tones to 20.8% for the brown tones.

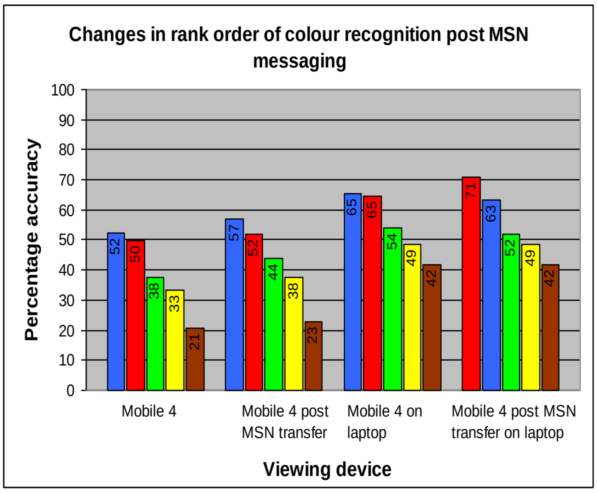


Fig. 4-22 Changes in the rank order of colour identification post MSN messaging, when viewed on the original device, on a laptop computer.

The image received via MSN messaging and subsequently transferred to the laptop computer, demonstrated another variation in rank order, with the recognition of the red tones (70.8%) being slightly higher than that of the blue tones (63.1%). This effect was due not only to the increase in accuracy scores of the red colours (64.6% rising to 70.8%) but also to a slight fall in the accuracy scores of the blue colours (65.5% falling to 63.1%). The rank order of the other colours remained unchanged.

As shown in figure 4-23 on the following page, when a +/- one shade error was included in the analysis the rank order altered in a variety of ways, but none replicated either of the patterns which had occurred when only absolute accuracy was counted. The MSN messaging process had not altered the rank order when viewed on the face of an identical device, but the scores increased for all most colours, the exception being the yellow tones which fell slightly from 79.2% to 77.8%. The uploading of the pre and post MSN transference images onto a laptop computer resulted in the greatest changes in the rank order, with yellow showing the greatest accuracy, affording scores of 91.2% and 93% for the original and post MSN images respectively. In the post MSN image the red and brown tones scored 85.4% and 84.4% respectively. Whilst the scoring of absolutely accurate identification had been relatively low for the brown tones overall, it was possible that confusion had occurred between the red and brown colours. With scores of over 90% this seemed less likely to have been the case and more likely that the errors were related to the misidentification of exact shades rather than colours, however it is interesting that the pattern of accuracy changes, rather than simply the accuracy scores.

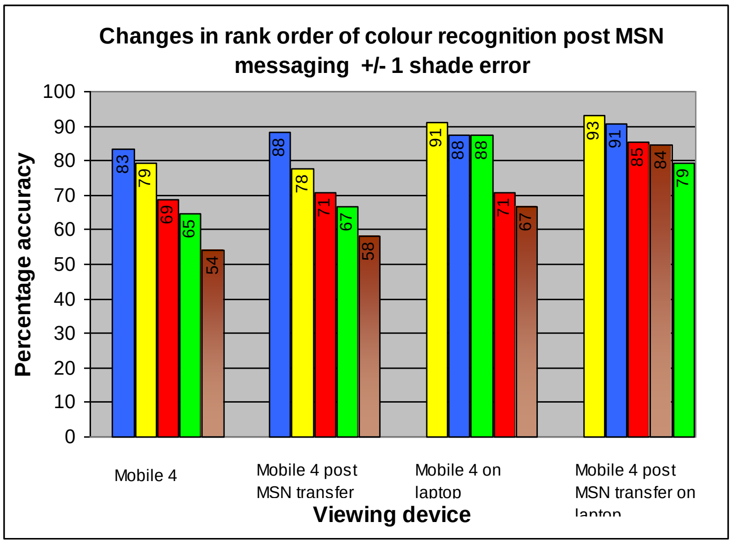


Fig. 4-23 Changes in the rank order of colour recognition post MSN messaging, when including a +/- 1 shade of error.

4.2.4 The incidence of colours misidentified as a completely different colour, regardless of shade. There were 529 incidences of colours perceived as an entirely different colour over all viewing possibilities (5 mobile phones and a digital camera which were viewed on the original device **and** on a laptop computer, 2 videophones and 1 ISDN6 teleconferencing facility). This comprised 12% (rounded to the nearest whole number) of the total number of viewing opportunities of coloured squares.

4.2.4.1 Misidentification of colour, according to colour, when considering all devices collectively. When only the original still-imaging devices were taken into account (that is, excluding errors recorded from the laptop computers) there was seen to be a statistically significant difference between the colours thus misidentified. (K-W Chi-square = 17.317 with 4 df and p = 0.002.) Figure 4-24 on the following page shows the variation in the misinterpretation of each colour. It can be seen that a staggering 27% of red tones and 15% of brown tones (rounded to the nearest whole number) were identified as an entirely different colour when all devices were considered collectively. Almost 66% of those errors occurred in the very palest and very darkest tones present (348 incidences). However 181 of those errors occurred in the middle range, in which colours could be expected to be relatively easily distinguished from one another. In addition to the 529 incidences of incorrect colour identification, there were 430 (9.6%) incidences of coloured squares being recorded as absent. Unfortunately it is not recorded whether those incidences were perceived as errors in colour or simply as errors in the exact shade. It is possible therefore that the true value of misperception of colour is higher than that recorded here.

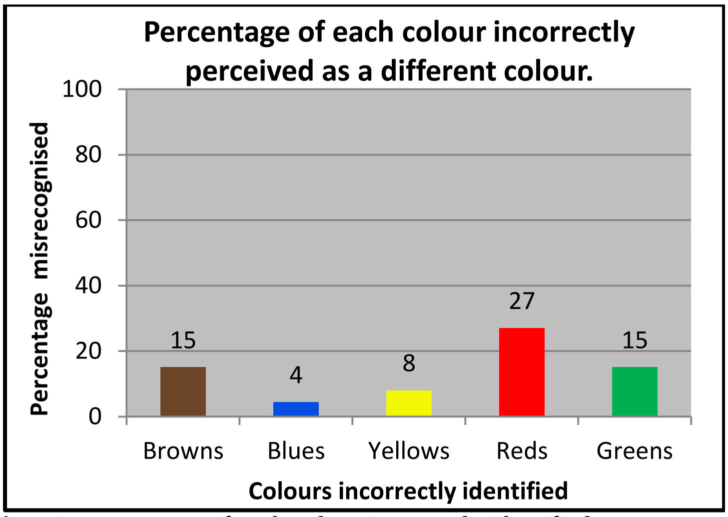


Fig 4-24 Percentage of each colour incorrectly identified as a different colour.

A summary of the errors which were recorded is presented in table 4-4 below, in which the instances of error exceeding 10% are highlighted in pink for ease of viewing.

Colours present	Colours perceived					
	brown	blue	yellow	red	green	absent
brown	65.3	0.9	1.6	10.2	2.5	19.4
blue	1.2	85.3	0.0	0.1	2.8	10.6
Yellow	2.0	0.0	80.2	5.2	1.2	11.3
red	25.2	0.0	0.7	62.5	1.4	10.2
green	10.4	2.5	0.0	2.1	76.2	8.8

Table 4-4. Percentage of each colour mistaken for a different colour.

The difference was also shown to be statistically significant, in terms of the percentage of colours mistaken for a completely different colour, when all fifteen viewing opportunities (i.e. including real-time imaging devices and viewing on laptop computers) were considered together. (K-W Chi-square = 28.936 with 4 df and $p<0.001$.)

4.2.4.2 Misidentification of colour, according to device, when all colours are considered collectively. When the data were further analysed to determine if there was a significant difference between the inaccurate recognition of colour according to device, no statistically significant difference was found between the still-imaging devices. (K-W Chi-square = 9.075 with 5 df and p = 0.106.) When all fifteen viewing opportunities were considered together however a statistically significant difference in terms of the percentage of colours mistaken was demonstrated. (K-W Chi-square = 27.269 with 14 df and p=0.018.)

4.2.4.3 Mean change in percentage of colours recorded as incorrect when images from the six still-imaging devices were viewed on a laptop computer. In the majority of cases the transfer of images to a laptop computer reduced the incidence of error of colour identification, with the exception of mobile 1, for which the mean percentage error increased when the image was viewed on a laptop computer. (See table 4-5.) The difference between devices in terms of the change in percentage of error was shown to be statistically significant. (K-W chi-square=15.035, df=5, p=0.010).

Device	Mean change in percentage incorrect
M1	5.2
M2	-14.2
M3	-14.2
M4	-4.0
M5	-7.6
Camera	-0.8

Table 4-5. Mean change in error of colour identification for each device when images are transferred to a laptop computer.

4.2.5 Further exploration of the misperception of colour as a completely different colour. The pattern of incorrect perception of colours as an entirely different colour is described more fully in this section.

4.2.5.1 Perception of brown tones. In this study 15% of the brown shades actually present were mistaken for other colours (n=108). Of those errors, 46 occurred at the extreme ends of the spectrum, with 13 errors relating to the palest shade and 33 relating to the darkest shade. Sixty-two occurred in the mid-tonal range. When comparing the perception of the brown tones on each device, and discounting errors in shade, it can be seen from figure 4-25 that the range of squares correctly perceived as brown ranged from 48% - 88%. There was a relatively high incidence of missing responses within the range of brown tones, indicating that the respondents did not recognise the exact match, however as mentioned above it cannot be identified whether it was a misperception in colour, or merely in the exact shade.

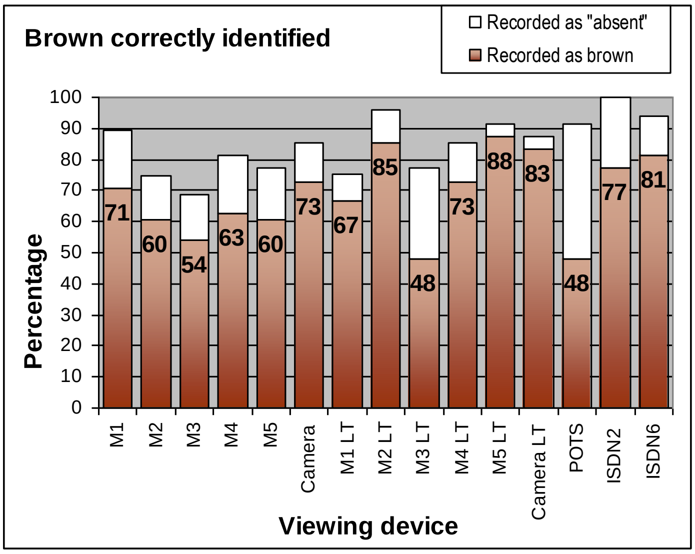


Fig 4-25 Percentage of correct identification of brown tones on each device

Brown perceived as blue occurred on nine occasions out of a possible 720, seven of these occurring at the extreme ends of the tonal range. No instance of this was recorded in any of the real-time equipment, the digital camera, or Mobiles 2 and 3, although one instance was

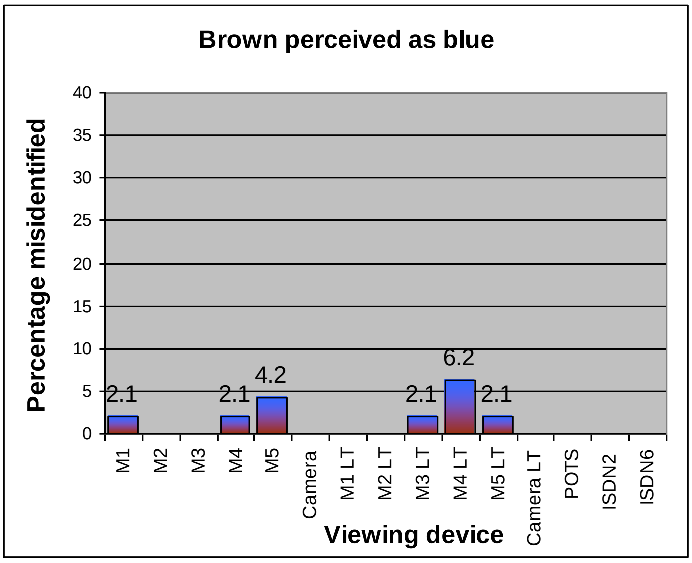


Fig 4-26 Incidences of brown perceived as blue

recorded in the image from mobile 3 which was displayed on a computer. The highest observed occurrence was for mobile 4 after transfer to laptop (figure 4-26). In this case there were three instances of brown tones being perceived as blue, two out of the three being the very darkest shade of brown presented.

Brown perceived as yellow was rare occurrence, occurring only eight times in total, out of a possible 720 opportunities. It did however occur on one occasion on the digital camera and this was not at either extreme of the tonal range. Referring to figure 4-27 it can be seen that the main occurrence was on the POTS equipment, on which three instances were observed, all three being the darkest shade of brown which was misidentified as dark yellow.

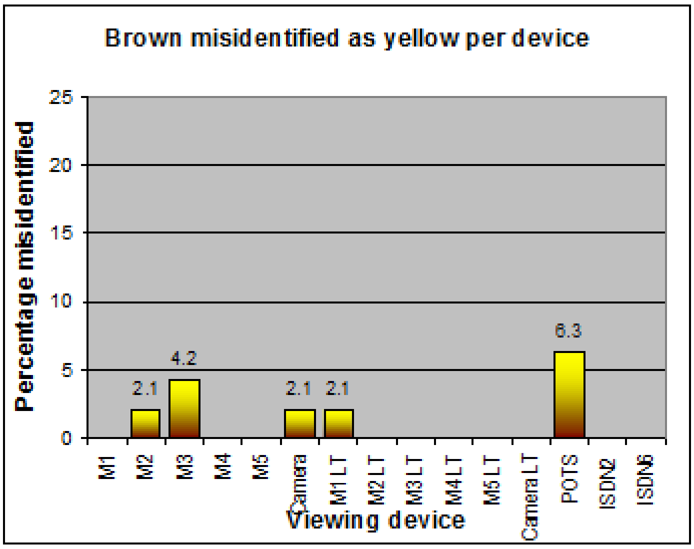


Fig 4-27 Incidences of brown perceived as yellow.

Brown perceived as red. Brown was misidentified as red on sixty-seven occasions (9.3% of the brown tones actually present). From the graph, (figure 4-28) it can be seen that M2 was the worst offender, but the digital camera did not perform particularly well when used to view the image, with 12.5% of the browns being misidentified as red. The image captured by the digital camera did not improve a great deal when viewed on a laptop computer as 8.3% of the brown tones were still perceived as red. The most

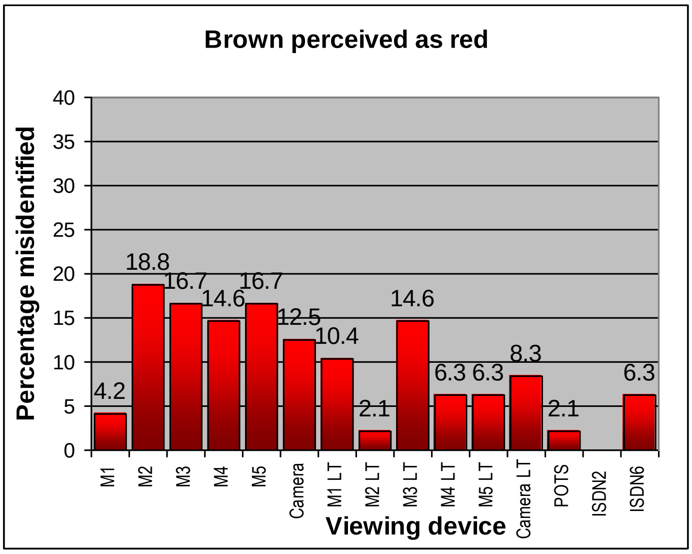


Fig 4-28 Incidences of brown perceived as red

dramatic improvement in brown tone recognition occurred on M2, on which almost 19% were thus misidentified when viewed on the face of the device, falling to just over 2% when viewed on the laptop computer.

Brown perceived as green. Within the occurrences of brown being misidentified as green (figure 4-29) the observations of particular interest were M1 and the digital camera, specifically because both demonstrated an increase in this phenomenon when the image was viewed on the laptop computer. The numbers were very small, being just two occurrences on M1, both of which concerned the very darkest shade of brown. This total rose to six when viewed on the laptop, three of which concerned the darkest shade, one the palest shade and two in the mid-tonal range. On the face of the digital camera however there was no brown/green misperception on the face of the camera, but two when that image was viewed on the laptop computer. Again it was noted that there were no instances of a brown/green misidentification exhibited by the real-time equipment.

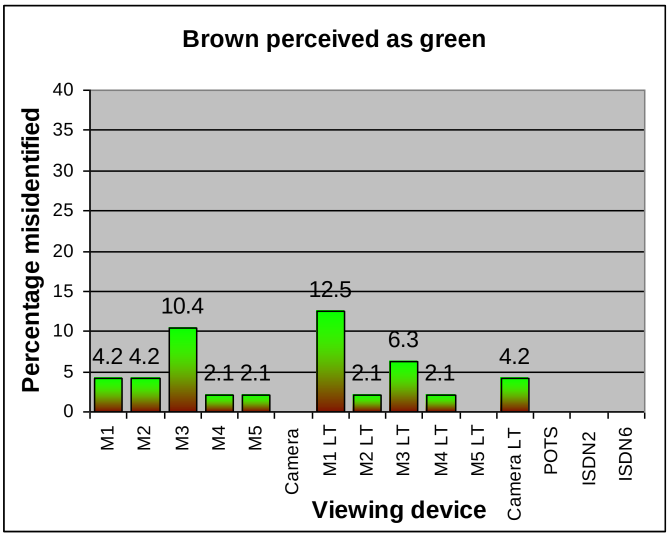


Fig 4-29 Incidences of brown perceived as green

4.2.5.2 Perception of blue tones.

As already indicated and as can be seen in figure 4-30, the blue shades were in general the most accurately recognised. Of those not accurately recognised most were recorded as being absent so again it is difficult to know whether that was due to misidentification of shade or colour. Following the trend of other results,

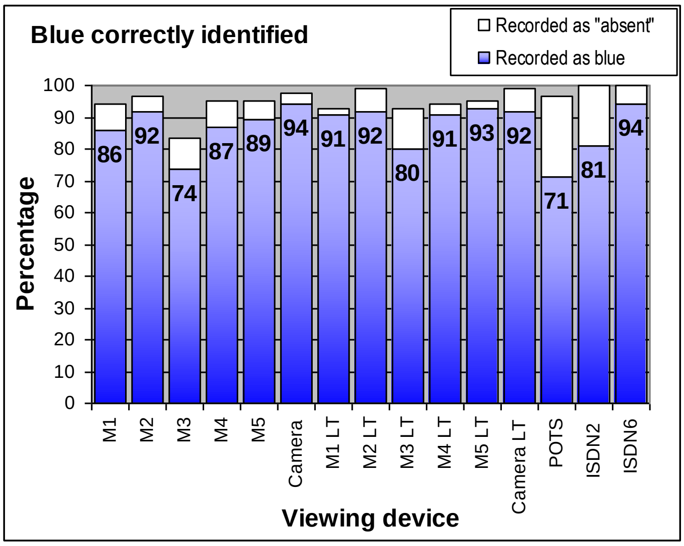


Fig 4-30 Percentage of correct identification of blue tones on each device

M3 performed most poorly of the still imaging devices although still achieving 74% and the POTS device achieved only 71% accuracy. There were no instances of blue being perceived as either yellow or red, and relatively few as brown or green. Those are addressed together in the following section.

Blue perceived as brown or green. Referring to figure 4-31, where the misperception of colour occurred there were seventeen instances of it being mistaken for brown, ten of those occurring at the palest end of the spectrum, and thirty-four instances of it being mistaken for green, of which twenty-two were at the extremes of the tonal range. The notable exception in mistaking the blue for green was found on M3, in which eight incidences of misidentification occurred in the mid-tonal range, in addition to four occurring at the extremes of tonal range. There was an improvement on that result when the image was transferred to a computer for viewing, indicating once again the anticipated inferiority of the display on the face of M3.

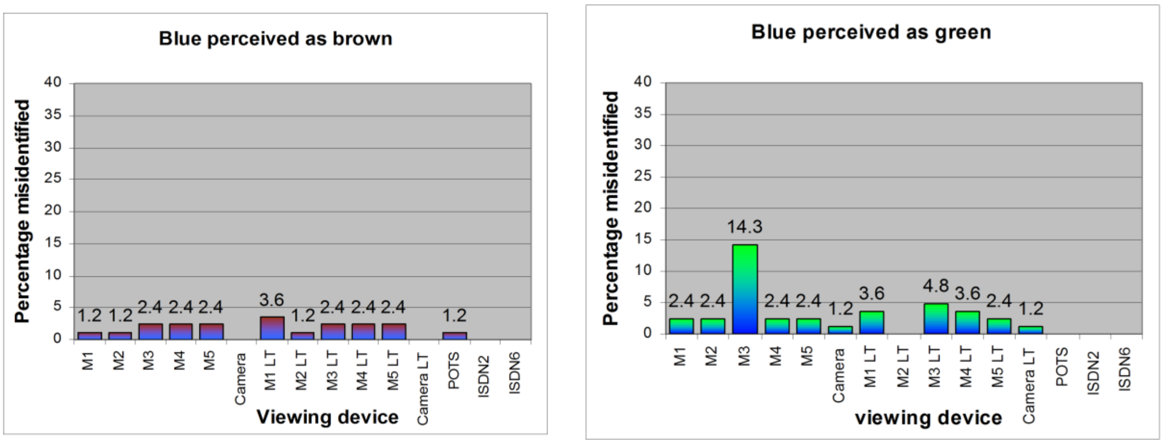


Fig 4-31 Incidences of blue perceived as brown or green.

4.2.5.3 Perception of yellow tones. Referring to figure 4-32 it can be seen that when errors of shade are ignored the yellow tones demonstrated a high level of accuracy of colour recognition which was roughly equivalent to that of the blue tones, although the precise scores for individual devices differed. Again the instances of colours recorded as absent were not able to be differentiated between errors of colour or shade, but as might be expected from such a high colour recognition score there were relatively few errors recorded. No instances of yellow being mistaken for blue were recorded and unsurprisingly the lowest overall score was achieved by M3, both on the face of the device and when viewed on a laptop computer. The POTS device was the next lowest, achieving a score of 61%. The accuracy score for the digital camera fell by 8% when the image was transferred to the laptop computer.

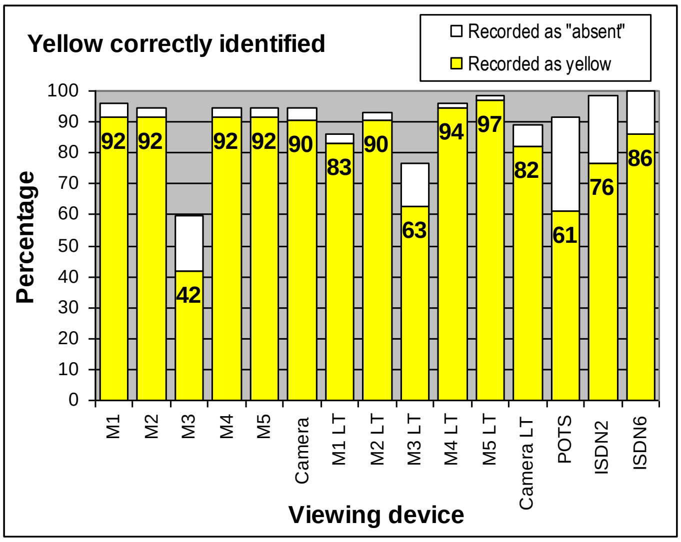


Fig 4-32 Percentage of correct identification of yellow tones on each device.

Yellow perceived as brown. There were 29 instances of yellow being identified as brown, occurring mainly in the two darkest yellow tones. M3 was the worst offender (figure 4-33), although the image from the digital camera, when viewed on the laptop computer performed equally badly.

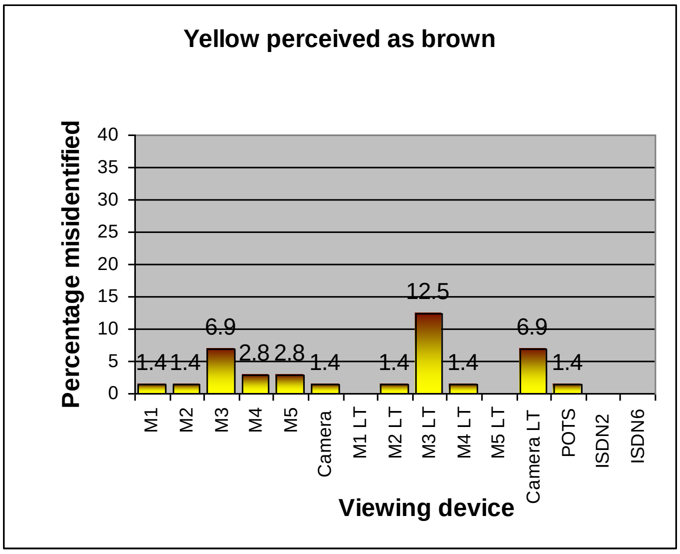


Fig 4-33 Incidences of yellow perceived as brown.

Whilst the poorer score achieved by the image from M3 when viewed on a laptop may indicate that the shortcomings in image capture are not fully realised until that image is displayed on a superior device, the fact that this has happened also to the digital camera image suggests that it is in fact the display device (i.e. the laptop) which may be at fault.

Yellow perceived as red. Referring to figure 4-34 it can be seen that all except the digital camera image viewed on the laptop and the ISDN6 image had at least one occurrence of yellow perceived as red. Nineteen instances occurred on the face of M3, and of these only seven involved the extremes of the tonal range.

That score dropped to eight when viewed on the laptop computer, of which three were the darkest tone of yellow and none was the palest. The fact that most errors were occurring in the mid-tonal range indicates a real shift in the colour reproduction, rather than eyesight difficulties in distinguishing between two very pale or very dark shades of two different colours

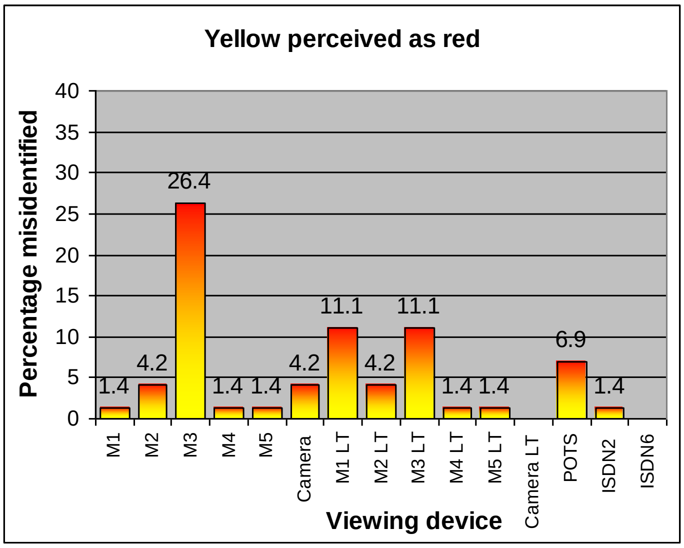


Fig. 4-34. Incidences of yellow perceived as red.

Yellow perceived as green. Again mobile 3 stands out as demonstrating the greatest number of errors recorded (figure 4-35) and since a number of both the blue and the yellow colours were perceived as green on the face of this device, and less on the laptop computer, it is likely that the display is at fault to a greater extent than the image capture. The image from the digital camera, when viewed on the laptop computer, had a greater number of errors recorded, although the numbers were very

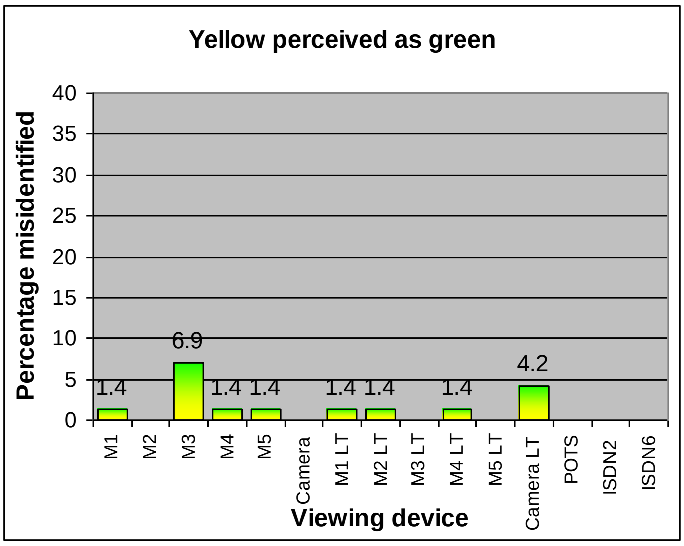


Fig. 4-35. Incidences of yellow perceived as green.

small (three instances, two of which involved the darkest tone). If the computer monitor display had a tendency towards over-enhancement of green tones then it is clearly easier for yellow to be compromised than, say, red. However since this did not happen with M3, it is possible that the errors were due at least in part to some observers using an inappropriate viewing angle, as this changes the perception of colours seen.

4.2.5.4 Perception of red tones. It can be seen in figure 4-36 that once again M3 was the worst performer in terms of visualising the red tones, yielding an accuracy score of only 44%. The real time equipment did not perform much better, with scores ranging from 54% on the ISDN2 videophone to 63% for the ISDN6 equipment. One reason for the poor performance may be found in the comparison of those red tones accurately perceived as red and those misidentified as brown, and this is discussed further in the next paragraph. No instances of red tones being misidentified as blue occurred.

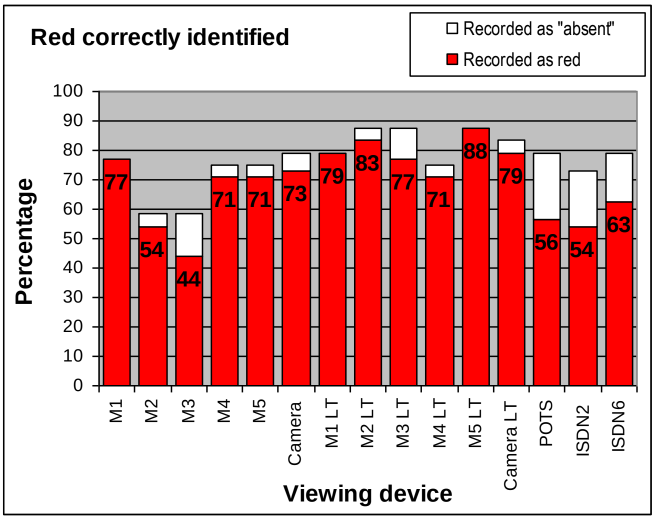


Fig 4-36 Percentage of correct identification of red tones on each device.

Red tones perceived as brown. Referring to figure 4-37 it can be seen that a relatively large percentage of red tones were misidentified as brown, ranging from 10.4% in the images from M3 and M5 which were viewed on the laptop computer, to 38% in the image of M2 viewed on the face of the device. Since the darker that the colour red becomes the closer it is to brown, this perhaps lends support to the suggestion that the viewing angle may be responsible for errors in perception, as it can readily be verified that red tones vary considerably when the viewing screen of a laptop computer is adjusted in angle relative to the observer. This may also explain the anomalous finding when the image from M4 was viewed on the laptop computer. To provide further evidence for this argument, the sum of the red tones perceived as either red or brown were combined and are presented in figure 4-38. It can be seen that very high scores were recorded, the range being 77% - 98% with a standard deviation of 7%.

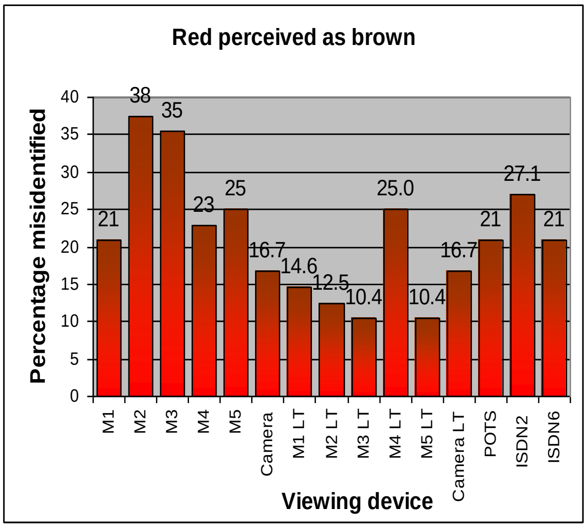


Fig 4-37 Incidences of red perceived as brown

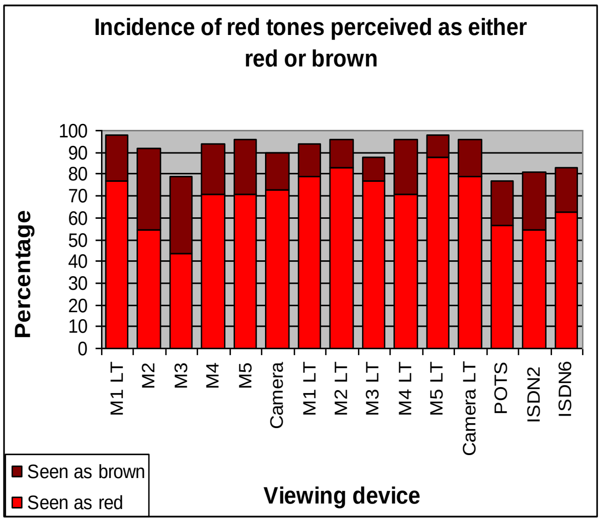


Fig 4-38 Incidences of red perceived as either red or brown

Red tones perceived as yellow. Although only three instances of this occurrence were reported (figure 4-39) one of those being on the face of M3 which could arguably be said to explicable as M3 had been found to be consistently poor in colour reproduction, it was considered odd that the two other instances involved a red tone which was in the middle of the range and not at either extreme.

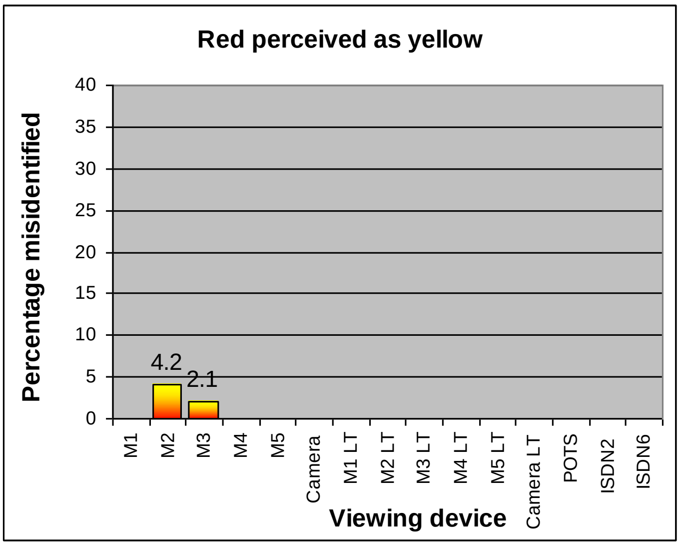


Fig 4-39 Incidences of red perceived as yellow

Whilst experimenting with the viewing angle it was noted that as the angle became more extreme the red tones appeared to veer towards the yellow part of the spectrum, but appearing orange rather than yellow. Whilst this might reasonably be mistaken in the very darkest tone of yellow, it was not easily mistaken in the mid-tonal range. It seems unlikely that two observers would be mistaken, either in the coloured square they chose or in the respective position they had placed it on the blank matrix, because they were reproducing a pattern and therefore the error would have caused mistakes to occur in adjacent squares. However it is possible that some other unidentified factor had influenced the colour perceived, for example a reflection of an article of clothing worn by the participant might conceivably have been cast on the face of the viewing device.

Red tones perceived as green. There were eleven errors of this type made by seven participants. It will be seen from figure 4-40 that there was no conformity in pattern. For example the instances which were recorded from the display screen of the digital camera did not occur when that image was transferred to a laptop computer. However the same error did not occur on the display screen of M5 but was recorded when that image was transferred to a laptop computer. Of the errors, three were made with the shades at the very palest extreme, three at the darkest extreme and five in the middle tonal range. This finding was particularly difficult to comprehend in terms of changes in colour saturation due to viewing angle, as despite many attempts the author was not able to reproduce this finding. At extremes of viewing angle red variously appeared as brown, terracotta, pale pink, yellow and even pale lilac at one extreme angle, but on no occasion did the author perceive red as green.

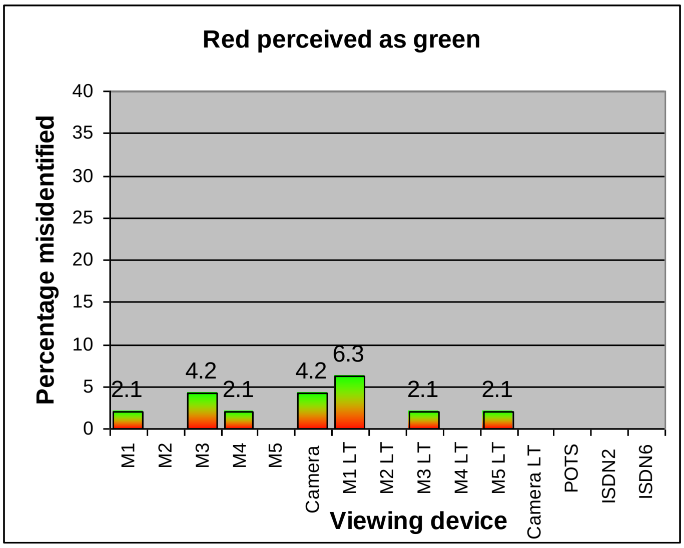


Fig 4-40 Incidences of red perceived as green

Red – green colour blindness is not uncommon, however since participants who did not score 100% accuracy on the face-to-face task of re-creating the coloured matrix were omitted from this study it is unlikely to be due to that factor. Furthermore there were eleven errors of this type made by seven participants. Of these, three were made with the shades at the very palest extreme, three at the darkest extreme and five in the middle tonal range. Again the possibly has to be considered that the misperception may be connected to some factor related to either the environment or to certain participants. As previously explained natural daylight was used during the study and the room where the viewing occurred was a dedicated telemedicine conference room and had been decorated accordingly, with plain walls of muted beige, therefore this effect was not likely to have been caused by ambient lighting. However it is possible that some participants sat in a position where reflections of, for example, either of an item of clothing or of the shrubbery outside the window, interfered with the viewing process.

4.2.5.5. Perception of green tones (figure 4-41). The recognition of green tones was on the whole slightly poorer than blue or yellow, but better than the brown and overall slightly better than the red. The accuracy ranged from 48% to 96%. M3 was predictably the worst performer and the accuracy was improved only slightly when that image was viewed on the laptop computer. The image from the digital camera performed better than the most expensive mobile (M4) when viewed on the face of the device, but that order was reversed when viewed on the computer, the digital camera image achieving an accuracy score of 92% against 96% for the image from M4. No instances were recorded in which green tones were mistaken for yellow, but the other errors are presented on the following pages.

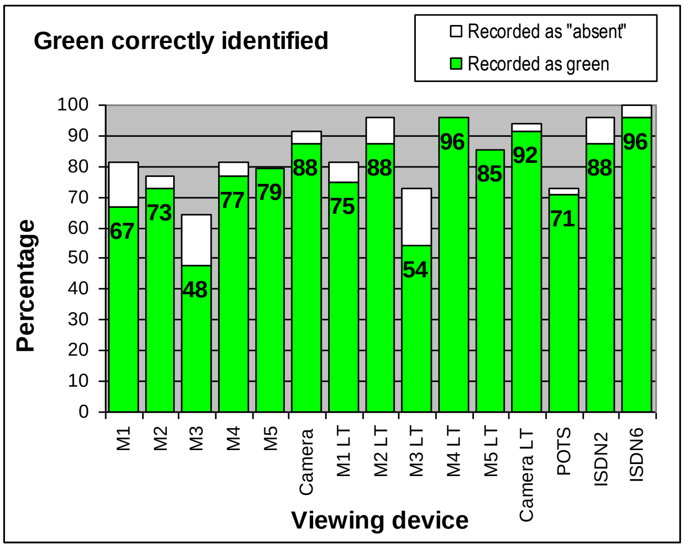


Fig 4-41 Percentage of correct identification of green tones on each device.

Green tones perceived as brown. As seen in figure 4-42, the incidence of green tones being identified as brown was a relatively common finding, the exceptions being the images from both M4 and the digital camera when viewed on the laptop computer and ISDN6. 23% of the green tones were identified as brown on the face of M3, which reduced to just under 15% when that image was viewed on the computer.

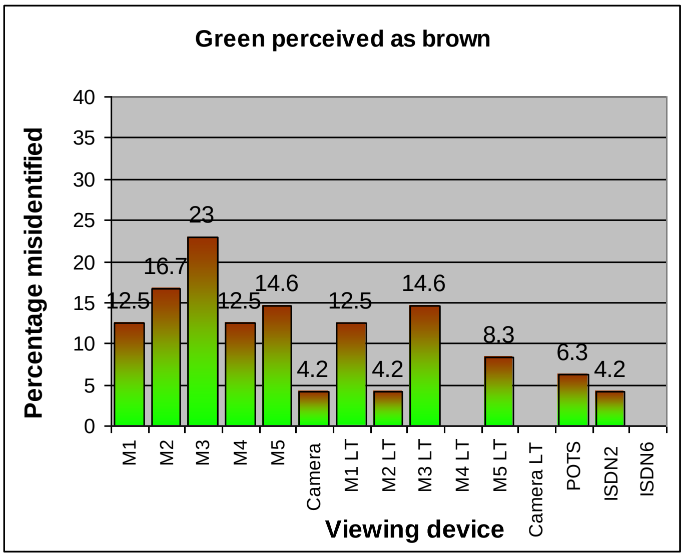


Fig 4-42. Incidences of green perceived as brown

Green tones perceived as blue. Twenty errors of this type occurred, and are shown as percentage of error in figure 4-43. Seventeen of those errors involved the very darkest shade of green being mistaken for the darkest blue. There was no recorded incidence of green being mistaken for blue or indeed blue being mistaken for green on any of the real time equipment, although it is acknowledged that there were more incidences of colours being reported as absent in the images displayed on the real time equipment.

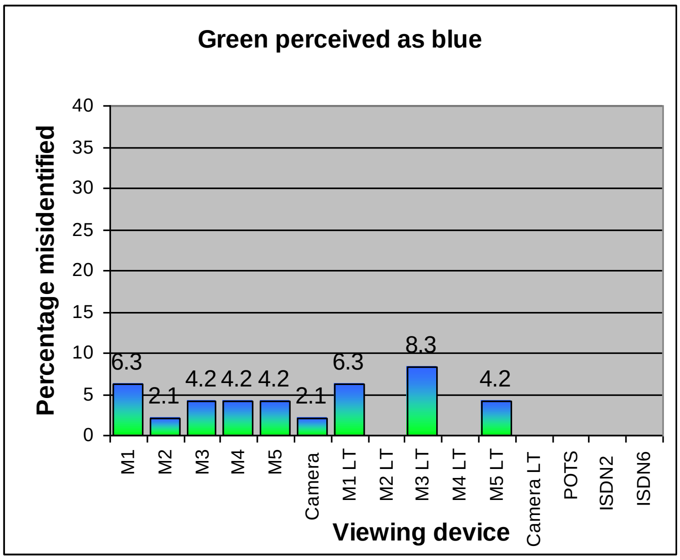


Fig 4-43 Incidences of green perceived as blue

Green tones perceived as red. It can be seen in figure 4-44 that there were very few incidences of this error occurring. None occurred in M1, two in M2, 3 in M3 and only one occurrence in each of M4, M5 and the digital camera. Three of those occurrences involved the extremes of shade. However when the images were transferred to the computer two scores worsened, those being M4 and the digital camera, both of which increased by 1. Again there was no recorded incidence of this occurring in the real time equipment. Once again, during further experimentation the researcher was able to replicate this phenomenon by changing the viewing angle, although to such an extreme extent that it is difficult to believe that any participant would choose to view an image from this angle.

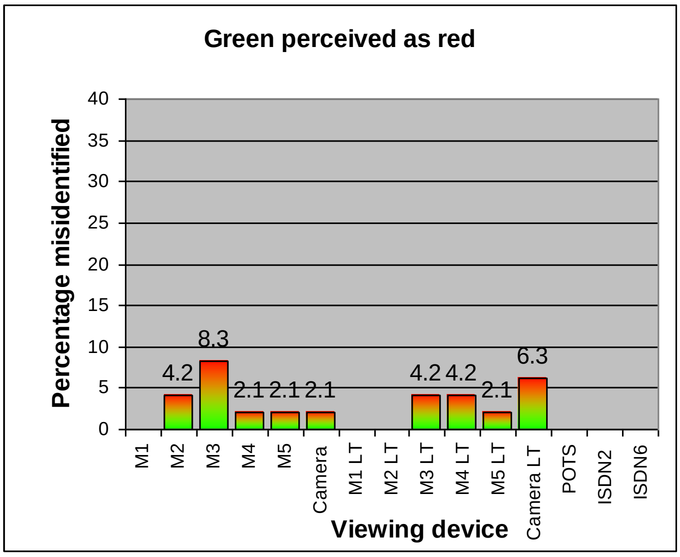


Fig 4-44 Incidences of green perceived as red

4.2.5.6 Errors in recognition of colour, regardless of shade, as seen on each device before and after transfer to a laptop computer. Figure 4-45 illustrates the extent to which each colour was mistaken for another colour on the four cameraphones. The devices display some similarity in the greatest errors, for example the frequency of the confusion between red and brown tones is evident, as is to a lesser extent the confusion between green and brown tones and between yellow and red. However it is clear that the devices do not behave in an identical fashion when the image is viewed on the display screen of the device. When the images from the cameraphones were transferred to a laptop computer the confusion between red and brown tones was seen to persist, although the patterns of error had changed a little (figure 4-46). To give just one example it can be seen in the illustration that when viewed on the face of the original device M2 shows a greater degree of error where red is perceived as brown than does M1, but when the images were viewed on the laptop computer the levels of error are almost equal.

Following transfer of the image from M4 via MSN messaging, although there were slight differences in the exact scores the pattern of error is virtually identical (figure 4-47), the most frequently occurring error again being the confusion between red and brown tones. There was a slight reduction in colour identification error when the image sent via MSN messaging was viewed on the laptop computer.

The digital camera showed a similar trend in red/brown confusion (figure 4-48) which again appeared to persist even when the image was displayed on the laptop computer. Other errors were few and although the pattern of error appears to be very different when viewed on the laptop, it is acknowledged that the numbers were very small and a larger sample size may have yielded different scores.

Finally the real-time equipment (figure 4-49) had fewer recorded errors than the still image equipment, with the single largest error again being red mistaken for brown. The ISDN2 and ISDN6 equipment performed particularly well, although there were a relatively large number of colours reported as being absent.

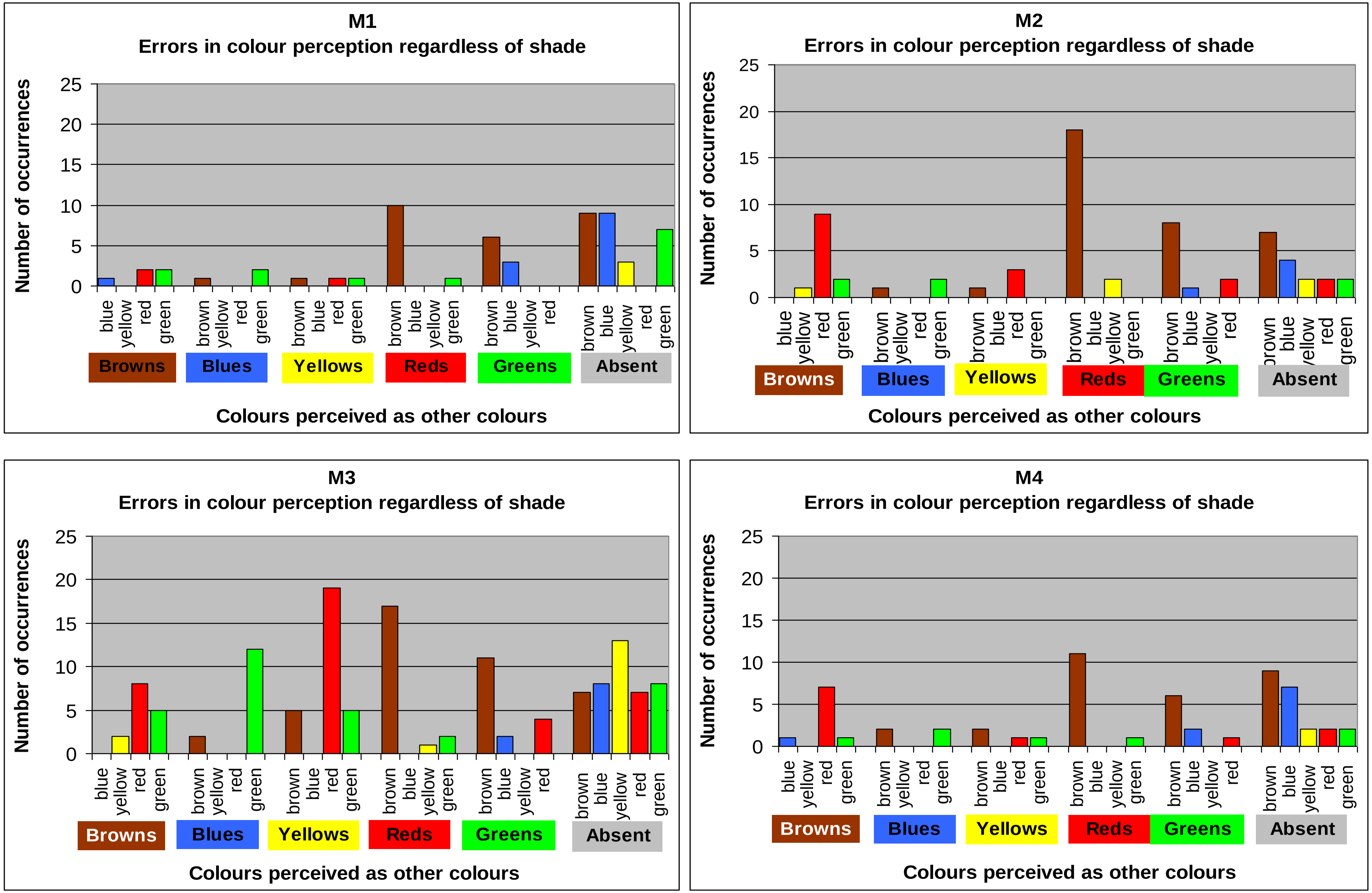


Fig 4-45 Patterns of error in colour identification, regardless of shade.

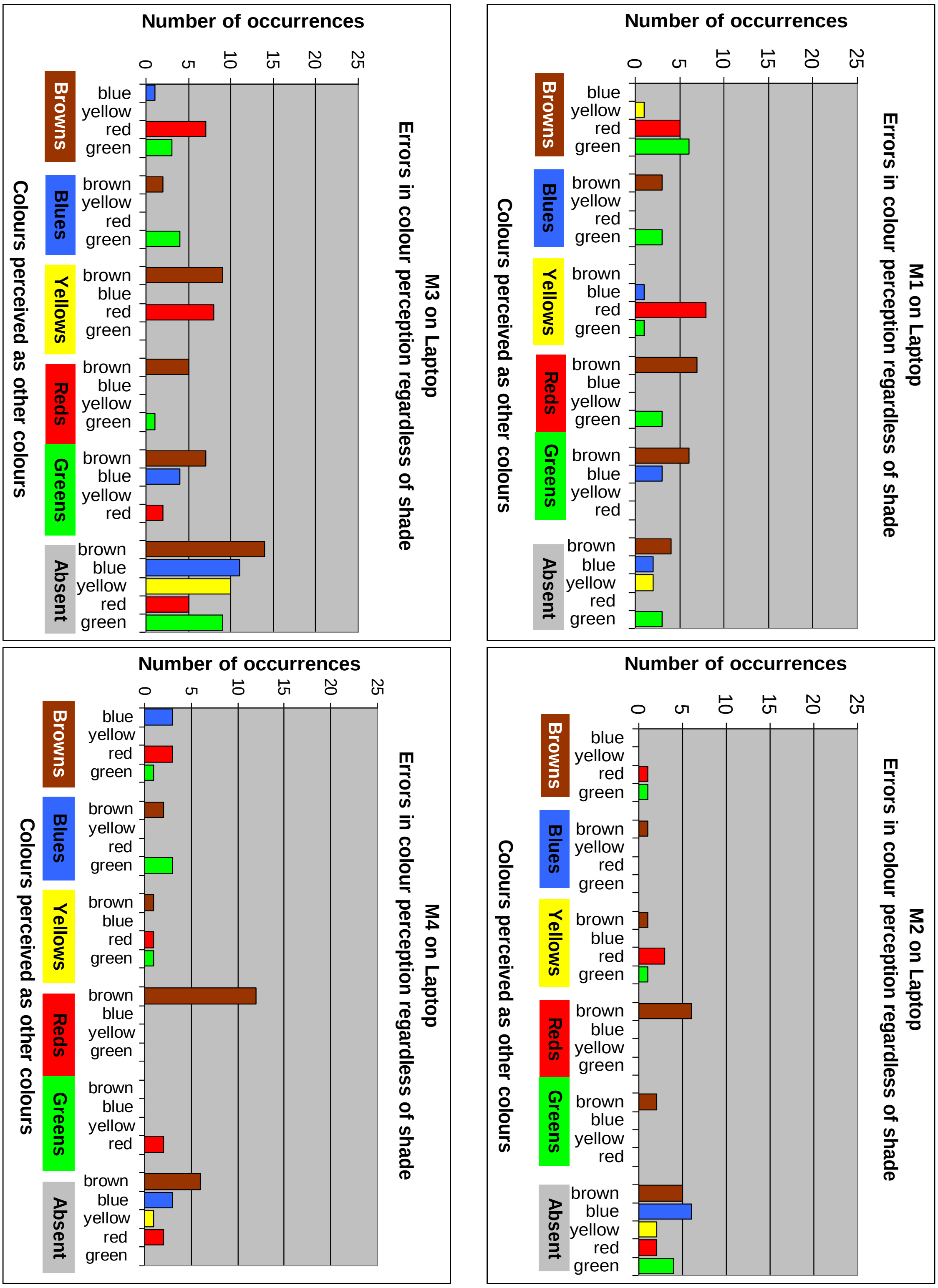


Fig 4-46 Changes in errors in colour perception, regardless of shade, when image is viewed on laptop computer

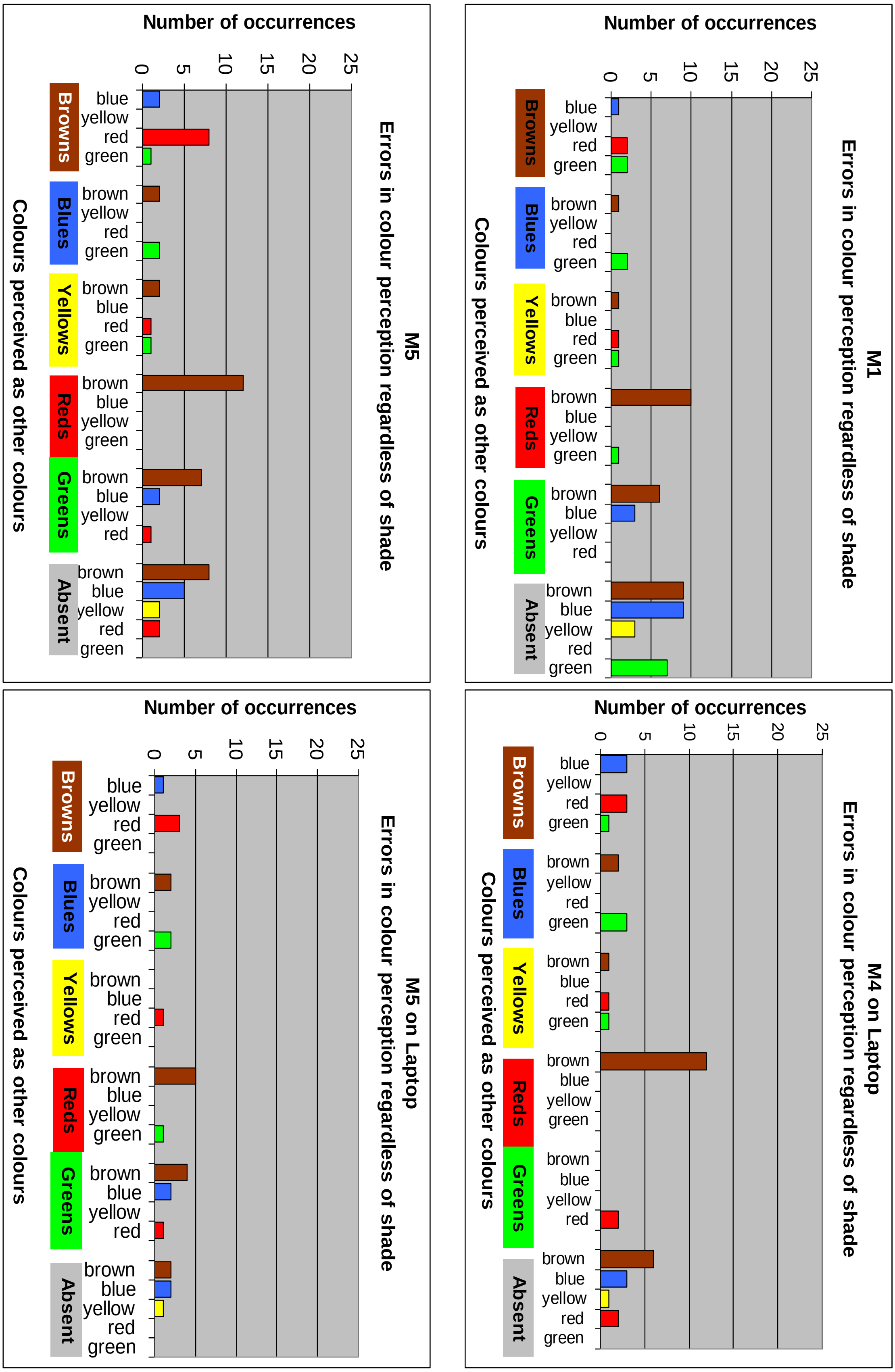
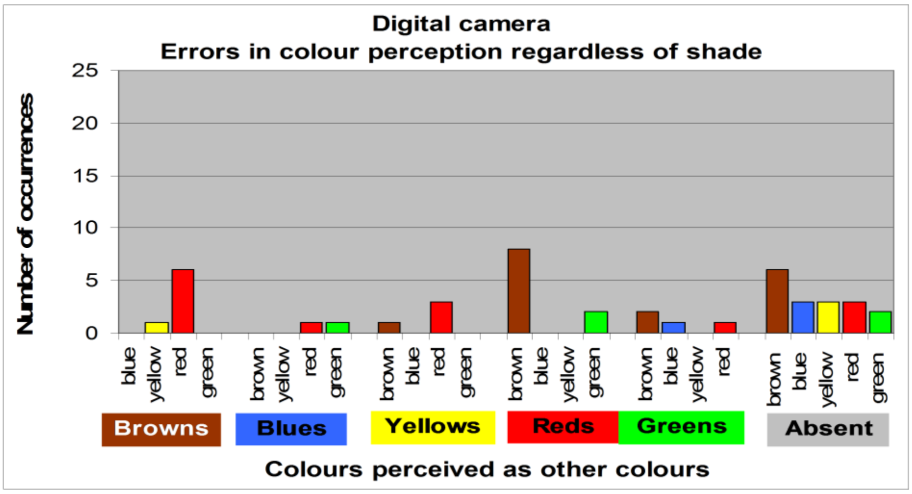


Fig 4-47 Changes in errors in colour perception when image is transferred via MSN messaging



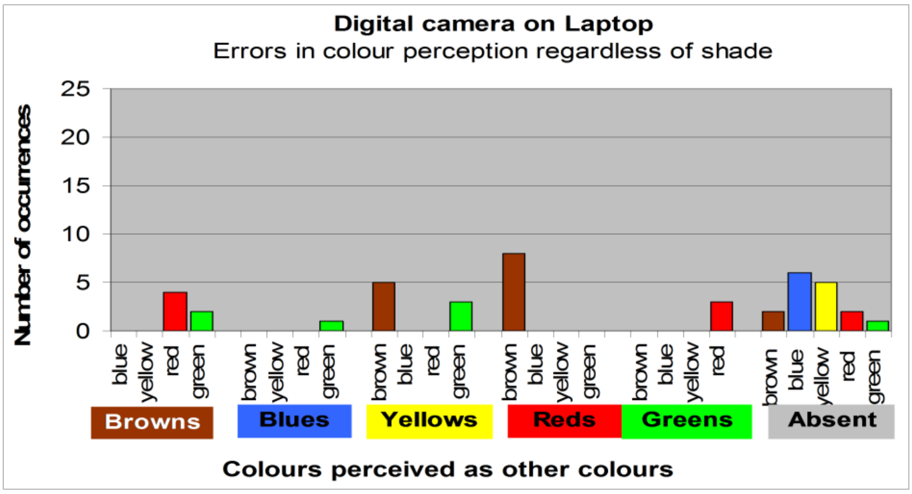


Fig 4-48 Changes to errors in colour identification when the image from the digital camera is transferred to and viewed on a laptop computer.

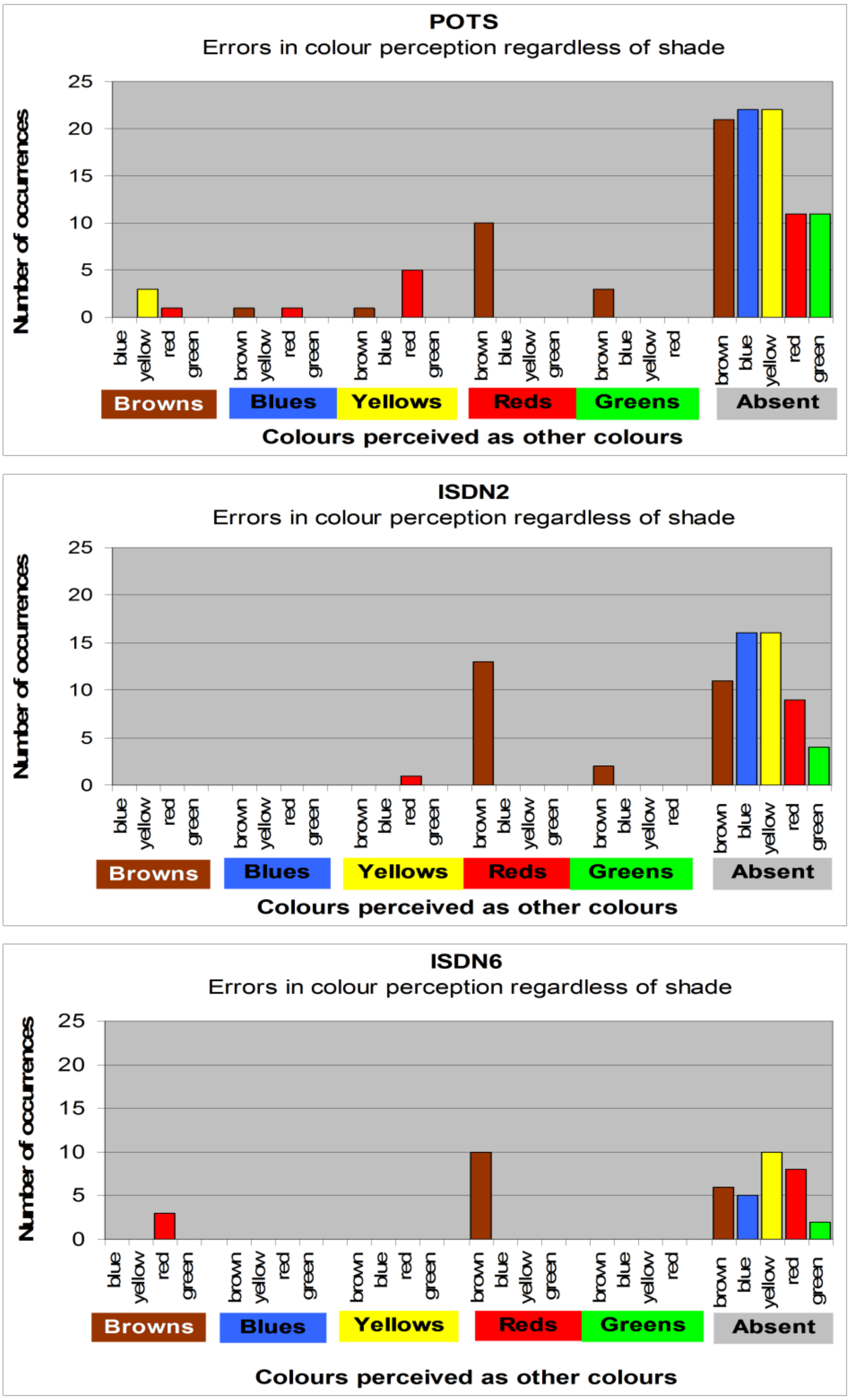


Fig 4-49 Patterns of error in colour identification on POTS, ISDN2 and ISDN6

4.2.6 Comparison of the accuracy of the twelve participants. The K-W test produced a Chi-square test statistic of 9.85 with 11df and p=0.544. Therefore no statistically significant difference was demonstrated between the participants in terms of the percentage of squares accurately identified.

4.2.7 Inter-observer agreement and variability. For the purposes of this section it is important to understand that in this case good agreement can refer to high accuracy in colour recognition, in which case the devices can be said to be accurate in their colour reproduction and display. Alternatively, good agreement can be achieved when the accuracy of colour recognition is poor. In that situation it is convenient to consider errors in the perception of a particular tonal shade to be either “positive” or “negative.” In this context a “positive” error is one in which one shade or colour was positively represented by the imaging device as a different shade or colour present in the matrix, but the same “wrong” colour was perceived by many participants. This situation would occur if, for example, there was a systematic flaw in the colour representation of the imaging device, such as incorrect colour balance or perhaps manufacturers deliberately enhancing red tones to make the image appear “brighter.” A “negative” error on the other hand would describe a situation in which participants recorded incorrect shades or colours, but did not record the same “wrong” colour, thus affording poor agreement between participants. Such a situation might arise if, for example, the appearance was affected by changing circumstances external to the imaging and display software. Reflections and changes in viewing angle have already been suggested as examples of this.

Fleiss’ kappa was selected as the statistic of choice to measure of inter-observer agreement in his section as it relates to situations such as this one in which there were multiple observers. Cohen’s statistic on the other hand is specific to two observers. The interpretation of the kappa scores given conform to those prescribed by Altman (op cit.) which for ease of reading are reproduced in table 4-6.

Value of ***K***	Interpretation
<0.2	Poor agreement
0.21 – 0.40	Fair agreement
0.41 - 0.60	Moderate agreement
0.61 - 0.80	Good agreement
0.81 - 1.00	Very good agreement

Table 4-6. Interpretation of k values after Altman (1991).

4.2.7.1 Kappa calculations considering each square as a separate entity. The results given in table 4-7 are presented in order of best to least agreement when each coloured square was taken to be a separate entity. It can be seen that the three real-time devices appear from this table to be the better performers, however this is not necessarily a true representation as these three devices have the greatest number of colours recorded as absent. As previously explained there was no way to ascertain how the absent data were perceived, for example as being only marginally different to any of those available to the participant, or if they were perceived as being entirely different.

Overall it can be seen that there was poor agreement recorded on every still imaging device except one. The exception was mobile 2 which demonstrated slight agreement when errors in shade were ignored. Interestingly, this device had one of the highest incidences of confusion between the brown and red tones, indicating that this was indeed a failing in the equipment.

Poor participant agreement is perhaps not surprising in the situation where each separate square observed is considered as a separate entity, but it was surprising that when ignoring errors in shade, which might reasonably be expected to improve agreement, it actually made it worse in six devices (highlighted in yellow in table 4-7). Of the six devices three related to images viewed on a laptop computer, which lends support to previous comments regarding the changes in perception which can occur with this equipment. However, this finding also occurred on the digital camera and on mobile 4, which was the top-of-the-range mobile phone.

Device	Separate shades	Integrated shades
ISDN 6	0.23182	0.24879
POTS	0.23157	0.26380
ISDN 2	0.17106	0.15260
Mobile 2	0.15718	0.20050
M 4	0.13701	0.12297
Mobile 1	0.09706	0.11895
Camera Laptop	0.08518	0.14017
M5	0.08288	0.10977
M3 Laptop	0.08201	0.11960
M4 Laptop	0.07309	0.06402
M1 Laptop	0.07218	0.06520
Mobile3	0.05755	0.07678
Camera	0.04620	0.03623
M2 Laptop	0.04404	0.01995
M5 Laptop	0.03953	0.05863

= Fair agreement = poor agreement

Table 4-7 Kappa statistic for each device, taking each square as a separate entity

4.2.7.2. Kappa calculation per device by colour, for the seven categories of shade. It can be seen from table 4-8 that for most devices and colours fair to moderate levels of agreement were achieved. The lowest levels of agreement were in respect of shades of brown, in three cases this being poor. Two of the three cases comprised the image from M1, displayed both on the face of the device and also on the laptop computer. The third was the image from M3 which was displayed on the laptop computer, although surprisingly when viewed on the face of the device agreement was fair to moderate. For the green and blue shades however M3 demonstrated only slight or poor agreement. The highest levels of agreement were in respect of shades of red, and there was a high incidence of the red tones being misidentified as brown. The devices tested varied considerably in the extent to which observers using them achieved agreement in respect of perceptions of shade. The best was ISDN 2, followed by the image from M2 displayed on the laptop, the image from M5 displayed on the laptop, and the image from the digital camera displayed on the laptop. In every case the use of a laptop improved the level of agreement achieved for the device in question, despite the often poorer accuracy recorded when using the computer to display the image. The extent of improvement varied markedly between devices, with the greatest improvement seen in the digital camera image and the smallest improvement in M3.

Device	Browns	Blues	Yellows	Reds	Greens	Average
M 1	-0.03363	0.31510	0.20224	0.40450	0.24736	0.22711
M 2	0.27667	0.42392	0.33451	0.44218	0.28481	0.35242
M3	0.27353	0.19794	0.21470	0.32776	0.19661	0.24211
M 4	0.22607	0.30120	0.53531	0.34740	0.28607	0.33921
M 5	0.24366	0.31290	0.38469	0.36586	0.30009	0.32144
Digital Camera	0.25812	0.30675	0.30609	0.29833	0.30339	0.29454
M1 Laptop	0.18645	0.39617	0.28302	0.40836	0.29844	0.31449
M 2 Laptop	0.33520	0.38225	0.39808	0.44169	0.41083	0.39361
M 3 Laptop	0.18433	0.25145	0.23454	0.35382	0.27717	0.26026
M 4 Laptop	0.23494	0.38767	0.42298	0.44682	0.45378	0.38924
M 5 Laptop	0.31900	0.36684	0.44351	0.51158	0.32709	0.39360
Camera Laptop	0.34130	0.32572	0.33138	0.43803	0.48625	0.38454
POTS	0.37396	0.30926	0.24529	0.49108	0.48171	0.38026
ISDN 2	0.30687	0.39176	0.32716	0.52969	0.460y74	0.40324
ISDN 6	0.26324	0.423y81	0.38172	0.410y60	0.38326	0.37252
AVERAGE	0.25265	0.33952	0.33635	0.41451	0.34651	0.33791

= Poor agreement = Fair agreement = Moderate agreement

Table 4-8 Kappa statistic for each device by colour, for the seven categories of shade.

4.2.7.3 Kappa calculation for each device by colour, for integrated categories of shade. Referring to table 4-9 below it can be seen that when errors in shade were ignored the levels of inter-observer agreement were substantially increased. The highest levels of agreement were in respect of red and the lowest were for brown. The images from M2 and M5, when displayed on the laptop computer, demonstrated consistently substantial agreement across the entire colour range, suggesting that the errors in colour recognition were also common to observers, thus indicating that the red/brown confusion was common to all participants and therefore likely to be a consistent flaw in colour representation. Similarly, the images from M4 and subsequently transferred via MSN messaging to M5, when displayed on the laptop achieved Kappa scores which indicated very high levels of agreement. ISDN 2, which had achieved the best (albeit moderate) agreement in respect of individual shades, did not score particularly highly when shade categories were integrated.

Device	Browns	Blues	Yellows	Reds	Greens	Average
M 1	-0.04155	0.58951	0.31716	0.62368	0.16318	0.33040
M 2	0.34130	0.67552	0.69140	0.57356	0.54432	0.56522
M3	0.40340	0.34005	0.24615	0.42106	0.23665	0.32946
M 4	0.37364	0.60621	0.66391	0.57860	0.52975	0.55042
M 5	0.40257	0.67238	0.56702	0.60533	0.54848	0.55916
Digital Camera	0.47720	0.13095	0.52145	0.53188	0.56914	0.44612
M 1 Laptop	0.36372	0.60946	0.59155	0.70241	0.43671	0.54077
M 2 Laptop	0.62688	0.65091	0.67553	0.64240	0.72415	0.66397
M 3 Laptop	0.22760	0.47904	0.39475	0.58092	0.32720	0.40190
M 4 Laptop	0.45859	0.67482	0.81903	0.54218	0.75948	0.65082
M 5 Laptop	0.72015	0.72449	0.84164	0.74400	0.64649	0.73535
Camera Laptop	0.57395	0.64962	0.51276	0.73776	0.59921	0.61466
POTS	0.43365	0.45875	0.35943	0.52425	0.58824	0.47286
ISDN 2	0.50002	0.57889	0.54088	0.57175	0.64425	0.56716
ISDN 6	0.50645	0.63051	0.50121	0.47327	0.65269	0.55283
Average	0.42451	0.56474	0.54959	0.59020	0.53133	0.53207

= Poor agreement = Fair agreement = Moderate agreement

= Good agreement = Very good agreement

Table 4-9 Kappa statistics for each device by colour, for integrated categories of shade.

4.2.8 Summary of the findings. A summary of the statistical analyses is given in table 4-10 below.

Test of mean percentage accuracy		Findings
As displayed on device, (excluding laptop computer):-		
Comparison of devices, colours considered collectively.	>	Statistically significant difference demonstrated.
Comparison of colours, devices considered collectively.	>	Statistically significant difference demonstrated.
Comparison of devices, colours considered collectively & errors in shade included in results.	>	Statistically significant difference demonstrated for errors in 1,2 and 4 shades. (No statistically significant difference for 3 shades.)
Improvements in mean percentage accuracy when displayed on the laptop computer:-		
Comparison of still-imaging devices, colours considered collectively.	>	No statistically significant difference demonstrated in the level of improvement between devices.
Comparison of colours, devices considered collectively.	>	No statistically significant difference demonstrated in the level of improvement between colours.
Incidence of colours misperceived as a completely different colour.		
Comparison of colours, **still-imaging** devices considered collectively.	>	Statistically significant difference demonstrated between colours misidentified.
Comparison of colours, **all** viewing opportunities considered collectively	>	Statistically significant difference demonstrated between colours misidentified.
Comparison of only still-imaging devices, colours considered collectively	>	No statistically significant difference was demonstrated between devices.
Comparison of all viewing opportunities, colours considered collectively	>	Statistically significant difference was demonstrated between devices.
Comparison of change of mean percentage error when images viewed on laptop computer.	>	Statistically significant difference was demonstrated between still-imaging devices.
Observer accuracy and agreement		
Comparison of the accuracy of the 12 participants	>	No statistically significant difference demonstrated between participants in percentage accuracy.
Comparison of participant agreement according to device, considering all 15 viewing opportunities	>	Poor agreement was recorded for all except the ISDN 6 and POTS devices.
Comparison of participant agreement according to colour, considering all 15 viewing opportunities	>	The highest levels of agreement related to red tones. The lowest levels of agreement related to brown tones For the still-imaging devices transfer to laptop improved the levels of agreement in every instance.

Table 4-10 Summary of findings of analyses.

In addition to the analyses on the previous page a number of observations were made which, whilst unable to benefit from statistical analysis due to the small numbers involved, may be relevant in terms of their clinical significance. Those additional observations are as follows:-

- Typically only about 30-50% of colours were perceived accurately on the imaging devices, even under the best conditions of amateur photography.
- Whilst there were some statistically significant differences demonstrated in the accurate recognition of colour, both according to colour and according to the devices, the patterns of variability were complex.
- On the whole brown tones were the most poorly replicated and the blue tones best replicated, although this did not hold true for every device or every condition of viewing.
- The digital camera often performed better than the mobile phones, but in some cases some mobile phones performed better when considering individual colours, particularly the red tones.
- The accuracy of colour replication did not appear to be related to the cost or to the stage of technological development of the devices.
- There was considerable variability between observers, with very good agreement being achieved only in a very few instances.

4.3 Limitations of the study.

There are a number of limitations to this study which make it difficult to draw hard and fast conclusions about the precise performance of individual devices.

The participants were neither randomly selected nor were they a cohort of specialists such as dermatologists with years of experience of looking at images. A cohort of nurses were chosen because they were used to looking at patients with a variety of visual clinical presentations and would potentially employ any of the devices in any one of a number of ways at some time during their career. There was no attempt at counterbalancing for two reasons. Firstly, in a normal working environment nurses make such assessment of patients throughout their working day. Thus even if a statistically significant difference were found in their viewing accuracy according to order of viewing (and with such small numbers that would be both unlikely and unreliable), it would not be possible to insist on those conditions being met in the clinical situation. Secondly, the participants varied in the time taken to complete observations. Had counterbalancing been employed it would have reduced the overall number of observations, thus reducing even further the data available.

The number of participants, or ***sample size***, was one of the major limitations to statistical analysis. A larger number of participants would have provided more data, however participant numbers were restricted by the limitations set for the time period of data collection. Whilst that time period could have been extended it was thought important that the viewing conditions should be kept as constant as possible. Even in the most settled conditions of weather the ambient daylight changes throughout the course of the day, due to the sunlight traversing different thicknesses of atmosphere. That in turn affects the perception of colour. Therefore it was decided to review the initial data from a single cohort conducting observations within a strictly limited time period, with a view to adapting the method towards a clinically relevant scenario for a future study. From a practical perspective the sample size in this case is only relevant if no, or very few, errors were found. In reality just one such error, regardless of whether it is the device, the colour or the mode of viewing which caused that error, is indicative of a problem which may cost a life. 12 participants have adequately demonstrated that their perception of colour from images captured and displayed on a range of devices is neither very accurate nor consistent.

The ***measures used*** to collect the data provided a good indication of what is likely to happen in the clinical situation. It may have carried more weight from the scientific perspective had the wavelength of reflected light been measured. This however would not have included the idiosyncrasies of viewing by humans, and furthermore it carries the risk of assumption that if the image were indeed a close representation of the original, then the process of using this equipment for diagnosis was a safe one. It was therefore a more realistic approach to test the current situation first and to follow that with further research into the individual components of any error found.

No still images were captured from real-time devices, which in retrospect would have provided a useful comparison against still image capture by cameraphones or digital camera. Finally, although there was space on the form to include any comments participants felt relevant, they were not specifically invited to comment on the colours which they felt had recorded as absent. In retrospect this would have been very useful as without that comment it is impossible to know whether the missing data indicated a small error in perception of shade or whether the relevant portion of the matrices had been perceived as an entirely different colour.

Access to resources, for example expert support and a greater range of equipment (or the funding to purchase it) would have permitted a more robust study in terms of defining stricter parameters of operation. One example was in the choice of the computers used to compare different modes of display. It seems likely that better image quality is achievable on a computer monitor than on the face of the mobile phone or camera. The results did not invariably confirm this however and it is possible that the better image quality available to the computer monitor was not fully demonstrated in this case due to variations in the brand of computer available and the fact that the laptop version allowed for variation in viewing angle. In addition, the lack of expert assistance in achieving standardised parameters of contrast, brightness and colour setup also meant that the viewing parameters were more variable than would have been the ideal under strictly controlled laboratory conditions. Since the best conditions of amateur photography were aimed for it would have been better had this been achievable. However once again the reflection of normal clinical practice provided useful data and avoided a potential misconception that viewing images on a computer invariably improved the quality.

Generalisability is a particularly difficult concept to evaluate in this case, as it applies to the individual components of the image tested and also to the overall concept of diagnosis from captured images. “Do no harm” is the fundamental principle of medical care, and therefore one must emphasise that individual findings related to colour, device or viewing conditions are not generalisable under any circumstance. On the other hand the fact that accuracy in colour recognition cannot be relied on, even when using the best technology currently available, is a fact generalisable to every circumstance and is particularly important to its use for medical diagnosis.

4.4 Discussion. The questions posed at the end of chapter three (pp. 69-70), which arose from the review of the literature, cannot be fully answered by this study. Nevertheless it has provided evidence to support some of the assumptions made by previous authors and negate others.

The opinion that a digital camera should always be used in preference to a mobile phone was emphasised when it was included as a recommendation in the American Telemedicine Association's Practice Guidelines for Teledermatology (Krupinski, Burdick, Pak, Bocachica et al., 2008) . The results of this study support that guideline in some circumstances but not in others. Whilst it is true that the digital camera was the better performer if all the colours are considered to be of equal importance, it has already been noted that in this study the colour which was identified correctly in the greatest number of cases (blue) was that which might be considered to be the least clinically relevant, as there was only one reference in the preceding literature review to blue in relation to diagnosis. Conversely the colour which was identified with least accuracy (brown) was arguably the one which has the greatest clinical relevance as there was much more comment in the literature relating to brown shades, particularly in the diagnosis of skin lesions which is complicated by the wide variety of skin tones occurring in the human population.

Drawing from those clinical indications, if skin tones and the changing pigmentation exhibited by naevi are the most important visual features for a clinician, then there is a case for concluding that the relatively inexpensive mobile phone (M2) should be used in preference to the digital camera provided that the images were viewed on a computer, as the accuracy of the brown tones recognised from the mobile cameraphone image reached 79.2%, and on the digital camera image it was 6% lower (72.9%). Furthermore two of the mobiles outperformed the digital camera in the red tones as well, both on the face of the original device and also on the laptop computer. One of those mobile phones was the most expensive “state-of-the-art” device (M4), the other one being the obsolete (and gratis) device (M1). These results support the view of Matveev and colleagues, in that as far as the integrity of colour replication is concerned cost is not an indicator of quality (Matveev 2002, op.cit.). Matveev, a consultant dermatologist, further commented that he had not only found that the red and brown colours were most poorly reproduced photographically, but also that they were often confused by observers in practice, making diagnosis of skin lesions, erythema and infection particularly difficult (personal conversation conducted in Graz, Austria., unrecorded). The findings in this study further support Matveev's findings.

The discussion is further complicated if errors in shade are deemed to be clinically important, which in evaluating changes in pigmentation they may well be. However it is not known whether diagnostic assessment relies on absolute colour representation or whether it relies on a comparative assessment when contrasted either against the surrounding tissue, or against the tissue as it appeared on a previous occasion. If the latter case is true then an error of one or two shades may not be relevant to the clinical diagnosis provided that the error is constant. Alternatively there may be an argument for deliberately adjusting the shade of certain colours in order to enhance them, such as to provide better visualisation of the borders of a wound so that it can more accurately be measured, as appears to have been found by accident by authors of a study previously reviewed (Griffin et al., op.cit.).

Similarly confounding arguments apply to the insistence that images should be viewed on a computer, as that is not without complications either. Despite the results indicating that transferring the images to a laptop computer did improve the recognition accuracy in the majority of cases, and in view of the point made earlier that the mode of display is as important as the capture of the image (Shokrollahi et. al., op.cit.), this cannot be considered a blanket recommendation. There was some evidence to suggest that even laptop computers of identical make and model may differ in their display characteristics, and furthermore there was some indication that the mobility of the viewing screen on a laptop computer may be responsible for some distortion of the perceived colour. It would be tempting therefore to draw the conclusion that desktop computers with fixed monitor screens should be used in preference to laptops. However this study offers no evidence to support that view, as desktop computers were not tested and they may perform equally badly, or even worse.

Given the arguments proposed above, there may be a case for considering the notion that each clinical condition requires specific items of photographic and display equipment to demonstrate its individual features to best advantage. There are however dangers in this approach. The fact that one photographic apparatus yields much better image quality than another does not necessarily mean that the device is good enough. It must be remembered that the accuracy of colour recognition demonstrated on the range of devices addressed here was relatively poor, particularly if errors of shade are considered significant (and that has yet to be explored). Added to that, the images used in this study were captured using the best photographic techniques available to the knowledgeable amateur, including optimum conditions of daylight, a method of holding the device still during photography and selecting the appropriate settings for exposure. This is not likely to be the case in all clinical situations, where limited space, poor lighting and inexpert technique will add to the inherent shortcomings of the equipment. Conversely of course, simply because one photographic device has poorer colour replication or lower resolution than another, it does not necessarily mean that it is inadequate for all purposes. For example it was mentioned in chapter three that some authors had found real-time consultations valuable for providing information that still images alone could not. Reversing that argument, in the personal email correspondence from Dr. Smith, cited on page 7, Doctor Smith had made it clear that whilst the video conferencing was a useful tool, additional still images were often required for the visualisation of the wound area. The inference here is that real-time imaging fulfils a different function to the still-images, therefore it is possible that the concept of “quality” as it refers to both modalities is not measured by the same parameters. Accuracy of colour in a video device may be entirely irrelevant in a scenario where appearance can be described verbally by a nurse or health visitor attending the patient at home. Thus before equipment is evaluated on technical parameters alone some analytical thought must be given to defining the needs it is intended to fulfil.

Similarly some analytical thought must be applied to the limitations of telemedicine strategies which are acceptable, in relation to the options which may or may not exist.

Expediency may dictate the limits of working practices in telemedicine. For example although the digital camera may prove to be the better vehicle for recording images, digital camera images need to be uploaded to be transferred. Sometimes it may be preferable to get a second opinion whilst the nurse in on hand to do something about a problem, rather than wait for the nurse to return to the office and then schedule a second visit to the patient. Depending on the clinical situation, even a modest cameraphone may be good enough to access that second opinion in a timely and cost-effective fashion, provided it can adequately replicate the specific clinical features necessary for diagnosis in that particular situation. Similarly, although the ISDN2 device provided a much more accurate representation of the image, if a patient has to be seen at home where there is only a single telephone line, and a two-way consultation is necessary, then the choice is between using the POTS model or nothing.

The growing markets for mobile cameraphones and laptop or notebook computers indicate that there is a need for transportable data. Even if these machines were proved to be inferior to a desktop model for viewing the clinical presentation of medical conditions, the shortage of dermatologists in the UK previously cited may make it necessary for policy makers within the National Health Service to make a choice between a rapid diagnosis via mobile phone (with or without a laptop or notebook computer) and no rapid diagnosis at all. In other words the option of providing the highest possible quality of service in every circumstance is simply not available. The best a practitioner can do is to evaluate the choices available to him or her, and decide which of them may be of any benefit at all. The question is how to make those practices which involve instant photography as safe and reliable as possible.

The ideal answer would be to conduct rigorous research in order to map the optimum technical requirements for both image capture and image display in telemedicine, dictate those requirements to the manufacturers of equipment and finally give the resulting ideal equipment to any practitioner ever likely to take a photograph of a patient. This may be possible in the long term, but telemedicine is happening here and now using equipment commercially available. To test and assign every device on the market in terms of its appropriateness for telemedicine applications in every clinical situation is clearly not practical. Not only are the clinical requirements not yet identified in terms of best colour replication, but the rapid progress of technology makes it impossible to test every new device. Furthermore the ancillary issues related to human factors, such as how to achieve optimum conditions of photography and viewing with each new device could not be ignored and that would present an impossible training burden. However given the old adage that "It's a poor workman who blames his tools", it is the task of decision-makers in the health service to ensure that both the "tools" and the "workmen" are able to do the job effectively. In the absence of evidence to the contrary, it must be assumed that the measure of good "tools" in this case must be the faithful replication of the subject photographed, rather than the artificial enhancement of certain features. That is, the image does not have to be pretty, it has to be accurate.

Problems of accurate colour recognition appear to fall into two main categories, one being the variation in colour due to the choice of device used and the other being due to variation in human practices of taking and viewing photographs. The photographic ability of the operator has not been addressed in this study apart from the removal of operator variables, as far as possible, from the tests conducted. It will be mentioned in the following discussion only in the context of the variability in clinical expertise that is likely to be encountered in the wide range of clinical scenarios where telemedicine may be found.

4.4.1 One pragmatic interim solution. The problem of variable colour replication between devices is not entirely accidental. When photographic film was the only medium able to capture images there were a number of different film types available, each intended for a specific purpose. Thus Kodak film was tailored towards capturing red and blue tones, excellent for photographing brightly coloured scenes such as sand, sea and sky. Fuji on the other hand was the film of choice for recording woodland landscapes, as it enhanced the brown and green tones. Some film was produced specifically for portraiture, being tailored toward replication of skin tones and this was used mainly by professional photographers as it was very expensive. The average layman, with little more than "point and shoot" ability, would not achieve noticeably better results than he would with the cheapest product and in any event the more brightly coloured photograph appeared to be the preferred choice of this group of users. It appears that a parallel situation exists today within the field of digital photography. The professional or knowledgeable amateur is still able to select a high quality camera (although perfect colour reproduction is now achieved through the use of techniques for adjusting the white balance) whilst the mobile cameraphone market is aimed at the "point and shoot" layman. Following previous marketing strategies manufacturers have incorporated software features such as edge enhancement and face recognition, into mobile cameraphones, in an attempt to compensate for poor photographic ability and thus achieve the "brighter" (but less faithful) picture. Ironically this often makes it even more difficult to obtain a photograph which accurately replicates the original subject, as turning off the "helpful" automatic features requires some advanced knowledge of the device. Not only are many cameraphone owners still of the "point and shoot" variety, but the frequency with which owners exchange their mobile phones for newer models makes it unlikely that they will ever fully grasp the peculiarities of each device.

According to the guidelines proposed by Krupinski, which have already been mentioned in this chapter, practitioners should "recognise that safe and effective telehealth practices require specific training, skills, and techniques" (Krupinski et al., op.cit. p289). It would be an easy matter to adhere to Krupinski's proposed guidelines of ensuring that photography was undertaken by people with skill and training if the photography were carried out in large hospitals, where medical photographers in consultation with dermatologists know what essential features they are attempting to demonstrate, but this is not the case. The clinical scenarios that give cause for concern here are those such as the community nurse or health visitor who "sees something funny" and seeks advice from a specialist nurse, or the clinic patient who is housebound and seeks between-visits advice from his specialist clinic nurse. In those scenarios there is a danger that the images will be of the "snapshot" variety previously described (Slue et al., op.cit.) unless measures are introduced to improve them. Therefore the pragmatic approach would be to devise measures which are appropriate to any photographic device and every user. Thus they would need to be simple to understand, easily accomplished, relatively inexpensive and, since the practice of imaging patients by cameraphone is already a fact of healthcare, able to be implemented quickly.

In terms of colour replication the obvious solution is to insist on colour calibration in every image, the problem being that image calibration requires some knowledge and expertise in itself. In the clinical situations described so far it is the operator of the device who is likely to have the least expertise both in photography and in the clinical specialty, be it dermatology or wound care. The difficulties of training every member of staff who may ever take a photograph of a patient have already been outlined, however from the operator's perspective calibration only requires that a strip of paper be included in every image, therefore it should be easily accomplished. The more difficult task of achieving the calibration lies with the clinician receiving the image. Since those clinicians are likely to be found in a specialist clinic or department within a hospital there is likely to be expert support available, as medical photography or medical physics personnel routinely carry out quality monitoring of the viewing equipment in X-ray departments. Therefore it should not pose a great problem to ensure that the viewing conditions for telemedicine applications are maintained at the highest level. The clinician's responsibility would be to ensure that they adhered to best practice in terms of the viewing conditions. Examples of this might be ensuring ambient lighting conditions by switching off extra lighting or closing the window blinds as necessary, ensuring the contrast and brightness functions of the monitor remain at the optimum level and ensuring that diagnosis is made from the appropriate viewing position, not compromised by using an acute viewing angle because two or more people are trying to view the same monitor screen for example.

However having placed the onus for image quality on the clinician receiving the image, the quality of the raw data is important. For the best colour replication the use of daylight rather than artificial light is the first basic rule, although as seen from the results of tests in this study colour calibration will still be required of every device, even a digital camera, to produce an accurate representation of the subject. Whether this should form the basis of a guideline in the UK is a question for the experts in consultation with managers to answer. However it must be stressed that this measure can be seen as no more than a "quick fix" of one immediate problem. The bigger picture, to use a pun, encompasses questions about the nature of imaging required to illustrate each clinical problem to best advantage and how best to provide that imaging. It includes consideration of ancillary factors such as the contribution that verbal or written description of the clinical history makes to the outcome of remote consultation and to what extent non-visual clues such as smell or texture are important in each case.

Nowadays the potential for immediate and cost effective solutions to difficult clinical problems make it unreasonable to deny the opportunity to use these tools in any field of clinical work where they are found to be helpful. It is up to the experts in the various fields to decide what constitutes “optimal”, what is “good enough” and what, in extremis, is “the best we can do”. It is up to the experts, in consultation with the managers, to prescribe what is appropriate and what is necessary. Given the outcomes of the equipment tests described in this study it is difficult to see that there is any justification for doing nothing.

Conclusions.

- There was found to be statistically significant variation between devices in terms of the mean percentage of accuracy of overall colour recognition, but not in line with predictions that images would improve as mobile technology was developed and that newer more expensive would produce better images than obsolete models.

- There was also found to be statistically significant variation between colours in terms of the mean percentage of accuracy of colour recognition when the devices were considered collectively.

- The mean percentage accuracy in colour recognition improved overall when the images were viewed on a laptop computer, although there was no statistically significant difference demonstrated in that improvement, either according to device or according to colour.

- The results have demonstrated that the pattern of accuracy of colour capture and display is extremely complex, so much so that generalised recommendations related to device, colour or viewing method cannot reliably be made. This is very important clinically where patient diagnosis and treatment may rely on correct identification of colour.

Chapter 5. A comparison of the distortion characteristics of the still imaging devices.

5.1 Introduction. Distortion and definition have relatively common test tools associated with their evaluation. Definition is a product of the resolution of the equipment and external factors such as poor photographic technique causing “blurring” of the image. Resolution is directly controlled by the manufacturer, being related to the number and size of pixels making up the matrix of a digital image and the quality of the lens used. These factors are determined by the manufacturer and the information is freely available to purchasers, therefore this aspect of image quality will not be addressed here.

Distortion, arising from the curvature of the viewing screen and also from misalignment of the central plane of focus by the operator, usually causes straight lines to be perceived as curves, particularly towards the periphery of the screen. This can be seen in Figure 5-1 which is a photograph of the face of one mobile cameraphone displaying a picture of a straight line grid. The “bending” of the lines is particularly noticeable at the edges of the picture.

In this example the effect of the distortion is to make the squares appear to bulge out from the corner points. This is termed “barrel” distortion, and acts to make the area enclosed by the square to appear to larger than it is in reality. Sometimes the distortion presents an alternative appearance, in which the sides of the square are drawn towards the centre of the square, creating the effect known as “pincushion” distortion. In that case the area enclosed by the square would appear smaller than it is in reality. However on mobile phones, and also on older television screens before the introduction of flat screen technology, barrel distortion was the common form, due to the convexity of the screen. The distortion therefore is also partially determined by the manufacturer, but is rarely identified in the technical specifications of the device. Nor is it always easy for the operator to recognise when the central plane of focus is misaligned during the photographic phase, and this is particularly the case with irregular shaped devices such as some mobile phones. Nor is it always easy to identify distortion when viewing the resultant image.

Furthermore, when the observer is aware that the object viewed is in fact a vertical or horizontal structure, such as in a picture of a doorway, familiarity with the object causes the brain to compensate for the distortion and the curvature is not noticed. However in irregular objects, such as the margins of an ulcer wound, the brain is not able to compensate and the observer perceives what is displayed as reality. In such cases the viewer would be unaware that the image was distorted and that therefore any measurements made from such an image would be inaccurate. The study described here will therefore compare the area of a square displayed in the centre of the viewing screen with the area of identical squares which are displayed at the periphery of the viewing screens of a range of mobile cameraphones and a digital camera.

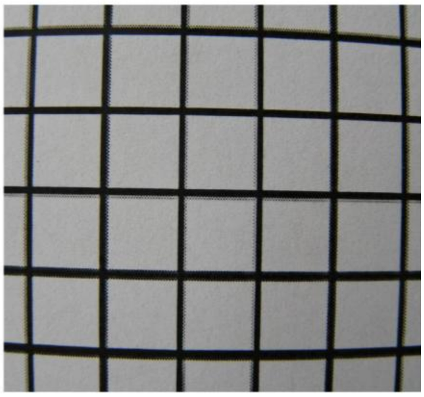


Fig 5-1 The effect of screen distortion on straight lines

5.1.1 Aims.

- To compare a range of equipment, commonly used in telemedicine for purposes of remote diagnosis or monitoring of visual features, in the extent of distortion of an image as it is displayed on the face of the device, and

- To ascertain to what extent the assumption made by some previous authors, that cost and technical obsolescence are predictive factors in image quality, are correct in the case of distortion.

5.1.2 This pragmatic experimental design compares the measured areas of an image of a matrix of 1 cm square shapes across the faces of four mobile phones and a digital camera.

5.1.3 Participants. There were no participants in this study. All images and measurements were acquired by the researcher.

5.1.4 Measures. The defined areas circumscribed by computer software technology were compared in terms of the percentage difference between the area in the centre of the field of view and eight areas occurring around the edges of the field of view. Those differences in percentage area were compared between devices.

5.1.5 Ethical considerations. In terms of the obligation to society, this study will inform the discussion surrounding the use of some devices currently commonly used in the diagnosis or treatment of patients. It will add to the body of evidence which supports or rejects some of the commonly held beliefs which at present have little basis in fact. In doing so, it may impact on patient care. There are no funding or employment bodies involved in this study and no participants.

5.2 Method for the comparison of distortion. A grid comprising a number of squares measuring 1cm along each side was printed onto a sheet of A4 paper. It was photographed using each of the four mobile phones and a digital camera, ensuring that the image of the squares filled the whole of the field of view, including the periphery. The photographic apparatus was the same equipment as used for the colour comparison study in chapter four, with the exception of the real-time equipment, which was not included in these tests. The details are repeated here for ease of reading. Three of the mobile phones were selected by convenience, being available to the researcher, and one bought specifically for the purpose of being able to test a "top-of-the-range" cameraphone. The technical details were as follows:-

- Phone 1 was a "bottom-of-the-range" model, available free with network contracts, having a 3.3 x 2.4 cm picture display, 176 x 220 display pixel array. 640 x 480 camera pixel array and 65k colours. This phone had been thrown away and was retrieved from a dustbin.

- Phone 2 was a "middle-to-low-range" model, which was available either free or for a small fee with network contracts, having a 3 x 2.2 cm picture display, (the display pixel array was not given), a 640 x 480 camera pixel array and 65k colours.

- Phone 3 was a "middle-to-upper range model, costing £40 – £50 with a network contract, and having a 3 x 2.3 cm picture display, a 640 x 480 camera pixel array but only 256 colours.

- Phone 4 was a "top-of-the range" model, costing in excess of £100 with a network contract, and marketed on the strength of its camera capability. It had a 3.7 x 3.4 cm picture display, 240 x 320 display pixel array, 1632 x 1224 camera pixel array and 256k colours.

- The Digital Camera was in the upper to middle-of-the-range category from a well-known manufacturer of photographic equipment. It was intended for domestic, not professional, purposes, being suitable for "beginner to serious amateur" and boasting a four megapixel camera array and a 3.8 x 2.8 cm picture display. The display pixel array was not provided in the manufacturer's literature.

In each case the matrix was photographed under optimum daylight conditions, all photography being performed within a one hour period during the mid-morning of a bright day. The highest possible resolution available to each piece of equipment was selected and in the case of the digital camera a tripod was employed to minimise camera shake and to ensure that the camera remained at right angles to the matrix photographed. The mobile phones were not equipped with connections appropriate for a tripod therefore a frame was used which held the phone firmly in the correct plane perpendicular to the matrix, as was shown previously in figure 4-3 on page 75.

Each cameraphone was set to display the captured image, and a photograph taken of the display screen using a digital camera, ensuring that this time the image appeared in the centre of the field of view and incorporated a wide border, to exclude any distortion which might occur at the periphery of the camera. (See figure 5-2 below for one example of the resultant photograph showing viewing screen in centre and large border around.) Both the frame for immobilising the cameraphone and the tripod for immobilising the camera were employed and care taken to align both devices perpendicular to each other. Each captured image was transferred to a desktop computer with a flat monitor screen, and adjusted until it filled the monitor screen. In this way the grid appeared in the centre of the monitor screen with a large border surround, thus also limiting any distortion which may have occurred at the periphery of the monitor screen.

A designer software package (Autocad) was used to calculate the area of a series of squares, numbered one to eight around the periphery, and the one in the centre. A schematic diagram of the relevant squares is shown in figure 5-3 on the following page. The technique involved moving a pen-type cursor to outline the edges of any particular shape and when the shape was enclosed the area was calculated automatically. The researcher had over twenty years' experience of this technique, in delineating tumours in the process of CT scanning, nevertheless each square was measured three times and the mean area calculated.

Fig. 5-2 Photograph of one cameraphone showing image of grid

The area of the central square was designated as being 100% for the purposes of the calculation and the area of each of the other eight designated squares was calculated in terms of the percentage relative to that of the central square. Thus any square calculated to be over 100% was perceived as being larger than the central square, and any calculated to be less than 100% was perceived to be smaller.

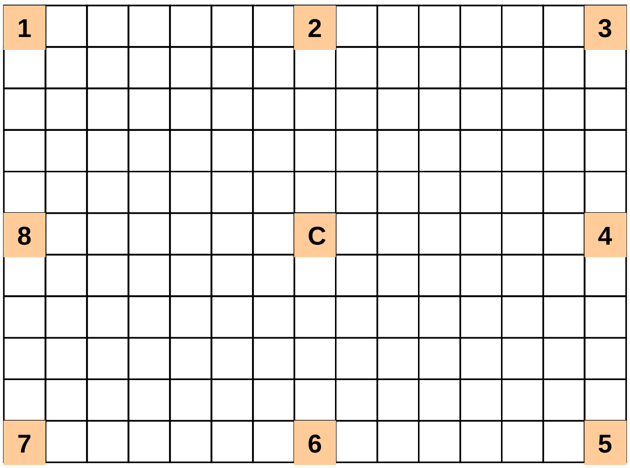
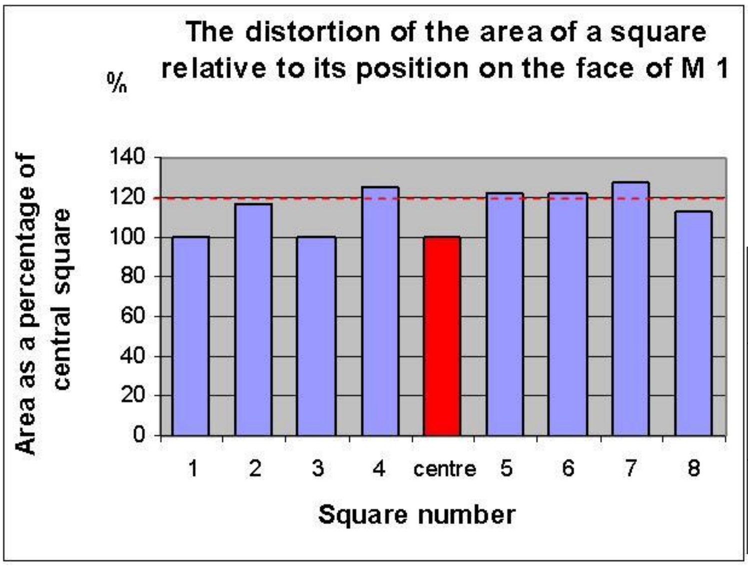


Fig. 5-3. Schematic diagram of squares used in area calculations.

5.3 Results.

The results are depicted in both graphical and plan forms, showing the percentage area of each square filled in pink in figure 5-4 on the following page relative to the central square which was designated to be 100%. Thus square 1 was the uppermost square in the left hand corner which was imaged in entirety. Square 2 was the uppermost square in the centre of the field of view. Square 3 was the upper right-hand corner, and so on, labelled in clockwise rotation round the face of each device. The graphical representation the central square (100%) is highlighted in red and on the plan it is highlighted in yellow.

On the display screen of Mobile 1, as can be seen in figure 5-4 overleaf, two of the squares have a measured area close to that of the central square. This device had the smallest measured difference between any single square and it’s central reference counterpart. The areas of all other squares imaged on this device were larger, two by more than 25%. Enlargement of the perceived areas at the periphery is not surprising, although perhaps the percentage of enlargement may be considered so.



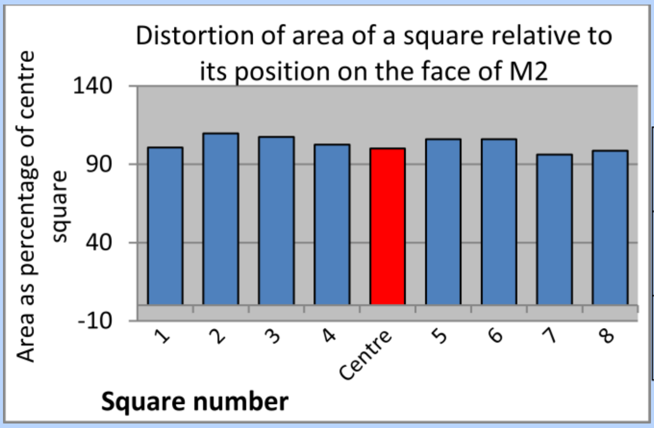
Percentage range
= 100.3% – 127.5%
= 27.2%

1 100.3%	**2** 116.7%	**3** 100.4%
8 113.0%	**C** 100%	**4** 125.7%
7 127.5%	**6** 122.1%	**5** 122.6%

Fig. 5-4 Graph and plan of distortion present on Mobile 1

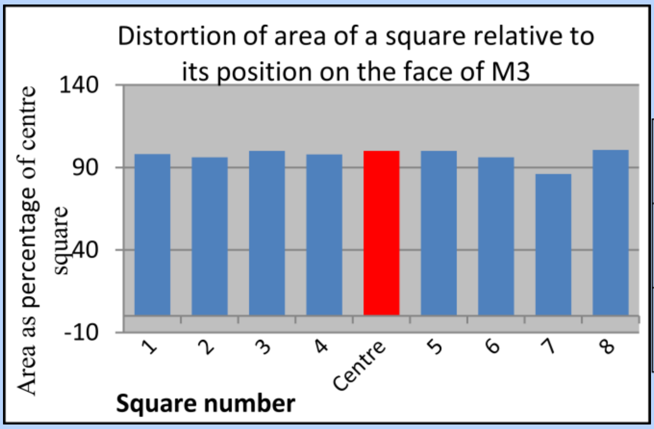
Referring to figure 5-5 on the following page, which demonstrates the results from Mobiles 2 - 4 and the digital camera, it will be seen that the greatest measured difference between any single square and its central reference counterpart occurred in mobile 4, which was the most expensive device and marketed on the strength of its photographic capabilities. There was a measured difference of 28.31%, the outer square being smaller than the central square in this case.

When considering the range of variation displayed across the faces of the devices, the digital camera showed least variation in measured areas, that being just over 10%. Mobile 1 has already been described, the greatest difference in the measured areas being 27.2%. This was almost, but not quite, the poorest performer of the mobile phones, whereas in the colour replication tests it had been one of the best. Mobile 2 was approaching the performance of the digital camera, the greatest difference in measured areas being 13.52%. However it is Mobiles 3 and 4 that provided the greater surprises.



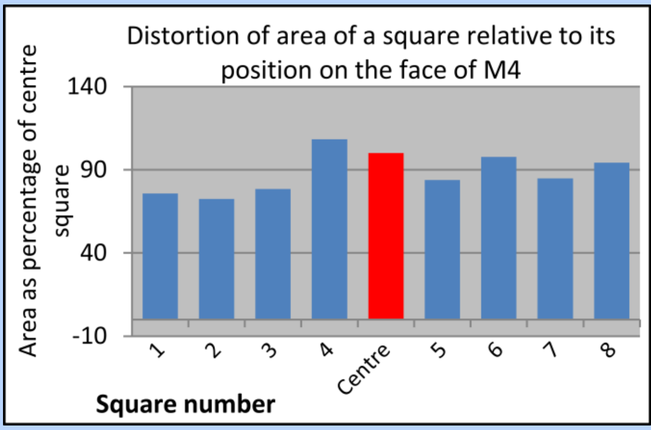
Percentage range
= 96.15-109.6
= 13.45%

100.7%	109.6%	107.5%
98.7%	100%	102.6%
96.15%	106.1%	106.1%



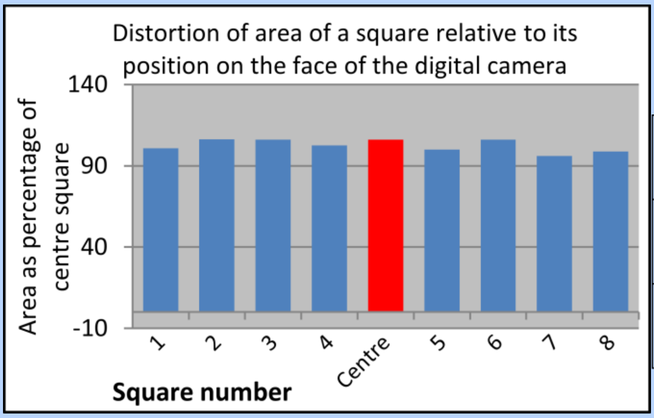
Percentage range
= 86.0-100.8
14.8%%

98.0%	96.2%	100.8%
100.6%	100%	97.9%
86%	96.1%	100%



Percentage range
= 72.37-108.4
= 36.03%

75.7%	72.37%	78.4%
94.3%	100%	108.4%
84.8%	97.8%	83.9%



Percentage range
= 96.1-106.3
= 10.2%

100.7%	106.3%	106.1%
98.7%	100%	102.6%
96.1%	106.1%	106.1%

Fig. 5-5 Graphs and plans of distortion on the mobile phones and digital camera.

From the study on colour replication it will be remembered that Mobile 3 was the device which, although not the cheapest, had consistently performed most poorly in the colour tests. Despite having a percentage range of almost 15% in terms of measured areas across the face of the device, it will be seen from the graph and the plan in figure 5-5 on the previous page that it performed almost as well as the digital camera apart from one outlying result for square number 7. Without that outlier, the maximum percentage difference was only 4.7 however that illustrates the problem of unpredictable distortion rather neatly. Mobile 4 on the other hand was the device considered to be state-of-the-art at that time, and marketed on the strength of its camera capability. It is therefore surprising that the all but one square had a measured area ***less*** than that of the central square, and that the percentages of the area of each square relative to the central square differed by over 36%.

5.3.1Summary of the findings. There was variation in the extent to which distortion occurred across the face of the 5 devices, in terms of the percentage difference relative to the central square.

The greatest difference measured between any single square and its central reference value was 28.31% and occurred in mobile 4.

The smallest difference measured between any single square and its central reference value was 0.3% and occurred in mobile 1.

The largest range of measured areas relative to their central square was 36.03% and occurred in mobile 4.

The smallest range of measured areas relative to their central square was 10.2% and occurred in the digital camera.

5.4 Limitations of the study. Given the manual method used to measure area described in this study, it is inevitable that a degree of error is inherent in the measurements recorded. The problem of measurement error due to the process of manipulating the cursor along the precise line of each square has been noted in the section describing the methodology. In this study the greatest variation found between the series of three measurements taken was 6%. Therefore measurement error may account for some findings but is unlikely to account for the larger variation noted. However since manual tracing is the method usually used in the serial measurement of skin wounds in the clinical situation it was considered important to reflect reality and embrace those errors in the measurements, as being representative of the smallest errors an experienced operator was likely to incur.

A second source of error is related to the technique of photography. It was noted in the method section that small errors of perspective may occur if the plane of focus of each device is not absolutely perpendicular to the object being photographed. To illustrate this effect, figure 5-6 shows a photograph of an earlier version of the test tool (which was later discarded). This test tool was deliberately photographed at an extreme angle to illustrate the point. In it the vertical array of paired squares on the left hand side appear larger than the corresponding paired squares on the right hand side, although they are in reality the same size. This may have resulted in the enlargement or minification of some of the squares relative to each other in the images captured on the devices. Once again however it was felt important to capture such errors as they represented the best techniques of amateur photography, thus strengthening the argument that in many clinical scenarios the results would have been much more variable.

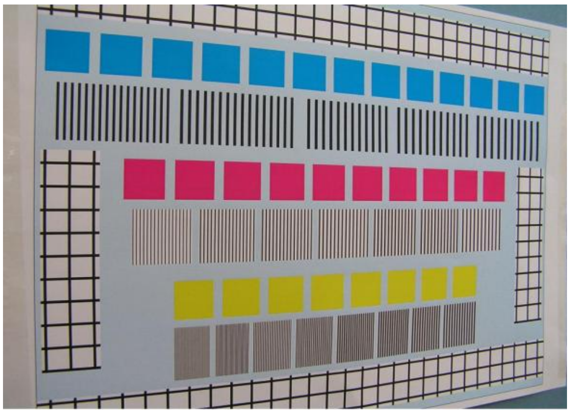


Fig. 5-6 Photograph of test tool illustrating perspective distortion.

Finally, the distortion occurring across the face of each device was not fully mapped by this method. Unfortunately the researcher had assumed that any distortion would occur in a regular pattern across the face of a device, as it does across the face of an imaging monitor. It appears that in mobile cameraphones the pattern is more uneven and it may be useful to make a greater number of measurements across the face of each device to assess the extent of distortion more accurately, as it is likely that the precision engineering of flat screen monitors, which afford excellent image quality in diagnostic imaging departments, is not applied to the mobile phone industry.

5.5 Discussion. It has already been acknowledged that whilst every care was taken to arrange the photographic apparatus perpendicular to the test tool during photography a small error cannot be discounted, and thus small differences in the measured area of each square cannot be assumed to be entirely due to the equipment. However it is the pattern of percentage difference which indicates that the differences may not be due entirely to perspective distortion. If they were, then those further from the camera would always be smaller than those nearest to it, and it can be seen from the plans in figures 5-4 and 5-5 (pp. 139-140) that this is not the case. For example, if in the case of mobile 1 (see figure 5-4 on page 139) the photograph had been taken from the angle of the bottom three squares, the next row up would all have been smaller. This is not the case as one was actually larger. Furthermore the top row would have been smaller still, yet the square above the central one is almost 17% larger. In fact the plan shows that from no direction do the squares appear progressively smaller. One further error may have arisen due to small errors in measurement, although the greatest variation found between the series of three measurements taken was 6%. Therefore measurement error may account for some findings but is unlikely to account for the 36% difference noted in M4, and it is likely that the precision engineering of flat screen monitors, which afford excellent image quality in diagnostic imaging departments, is not applied to the mobile phone industry.

The fact that there is considerable variability in the distortion characteristics of mobile phone display screens is not commonly acknowledged in the marketing literature prepared for the domestic arena. It is likely therefore that busy health care professionals without photographic training are not aware of it either. It has been suggested by a few authors, mentioned in the preceding literature review, that the serial measurement of ulcer wound area from digital images, either by digital camera or by mobile phone, may be viable. That may be possible provided that the image is always transferred to a laptop computer prior to measurement, but that aspect has not been tested here. The purpose of these tests was to demonstrate that shape, and therefore size, is distorted to a variable extent when viewed on the face of a mobile cameraphone, so that the clinical relevance may be considered by healthcare professionals in respect of their own practice and by healthcare managers in respect of policy decisions.

One particular concern was that from the evidence displayed in the results it may not even be possible to rely on the distortion being regular across the face of the device. It has been acknowledged that this was surprising to the researcher, who from years of medical imaging experience had expected a normal pattern of distortion, in which the central areas of the field of view were constant and a fairly regular pattern of enlargement or minification occurred towards the periphery. (This provided a pointed reminder that the researcher was not immune to the dangers of assumption either.) The faces of the devices did not display quite such a regular pattern, indicating that the display capability is probably poorer than that of a flat screen monitor, although that has not been proven. Nevertheless it does indicate that it may be wise to view images on a high quality medical imaging monitor where possible and to ensure that the relevant clinical area is encapsulated within the central part of the field of view, the outer border not being used to image the wound or lesion. This practice has drawbacks of its own, as the smaller the field of view the poorer the resolution, and if the image needs to be magnified to demonstrate tiny features then it could not resolve such fine detail as it could if the entire field of view were used.

Thus once again it is the clinical relevance which dictates the importance of the various aspects of image quality. For example the use of a cameraphone image in some teledermatology scenarios may not rely on shape or size of the lesion. It would appear from the literature that in some cases the increase in size of a lesion may be assessed not by serial photography but by reported account from the patient via the GP. In those circumstances it would seem that the visual appearance of a lesion from a photograph relies heavily on the fine detail and colour components as diagnostic factors and rather less on absolute measurement of shape or size. Furthermore, since mention was made by some authors of including “the surrounding area” it is likely that the lesion, presented in the centre of the display screen, suffered less from distortion than it might have otherwise done. It is of concern however that the successful use of cameraphones in those clinical scenarios may serve to act as supportive evidence for their use by less expert operators working under a completely different set of circumstances. In clinical situations requiring regular serial monitoring of a suspicious lesion, for example, it may not even be the same device which is used on consecutive occasions, which may lead to failures in treatment, as in failing to administer antibiotic therapy in a timely fashion.

It is therefore possible that these devices are being used not only incorrectly but also inappropriately at the present time.

Without a good photographic knowledge of both technique and technology it is understandable for healthcare workers to assume that paying a goodly sum for a cameraphone ensures at least reasonable quality. However, just as cost or claims of technological superiority were not reliable predictors of performance in terms of colour replication, nor do they appear to predict accurate shape replication, as it was the most expensive and technologically advanced device which demonstrated the greatest degree of distortion. Furthermore, there did not appear to be any association between performance in colour replication and performance in shape distortion between the devices, therefore clinicians may have to consider the relative importance of those factors individually if using such devices in their work at the present time.

The idea of instant images assisting in rapid diagnosis and treatment is still a good one however there is a need for objective assessment of the equipment and a method to ensure that the basic principles of competent photography are employed by every practitioner. Without that, the potential exists to get some instances of patient care badly wrong, due to no fault of the healthcare professional except a lack of knowledge of the vagaries of a device which although it undoubtedly has virtues, also has drawbacks. In the longer term it should not be difficult to manufacture cameraphones with better technical specification in terms of screen distortion, if this is what the medical profession needs. Unfortunately that has yet to be defined.

Conclusions

- The devices were very different in the degree to which shape was distorted when displayed on the face of the device.
- The digital camera demonstrated less distortion than any of the cameraphones, having a difference of 10.2% between the smallest and largest measured area.
- Mobile 4, the most expensive mobile cameraphone, and the one marketed on the strength of its camera capability, demonstrated greatest distortion, having a difference of 36.03% between the smallest and largest measured area.

- The pattern of distortion across the face of each device was not regular and was therefore unpredictable.
- Neither cost nor "state–of-the-art" technology in the cameraphones was a predictor of performance in terms of distortion.

Amalgamated conclusions and recommendations for part 1.

- The devices tested appear to demonstrate a relatively poor degree of accuracy in reproducing colour and shape.
- The parameters tested on the devices do not appear do not appear to demonstrate any particular pattern in the irregularities discovered, either in terms of colour recognition accuracy or the distortion of shape, thus it is impossible to draw generalisable conclusions or make recommendations specific to any device or to any specific intended use.
- There did not appear to be an association between the accuracy of colour reproduction and accuracy of shape replication, between devices.

It is recommended that at the present time;

- caution is exercised in the use of photographic images to assist diagnosis.
- staff are made aware of the potential risks and limitations of the devices.
- basic photographic principles are employed in the acquisition of images for telemedicine purposes.
- colour calibration measures are adopted for all telemedicine practices involving the diagnosis, monitoring or treatment of skin lesions.

It is further recommended that in the longer term;

- further research should be encouraged which will identify the most effective method of ensuring that all relevant staff are able to acquire high quality images.
- further research should be encouraged which will identify the technical features required of imaging devices in each clinical scenario.
- consideration is given to the production of a telemedicine image device or devices that will fulfill those technical requirements.

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PART 2

An evaluation of automated weight monitoring via a wireless landline telephone in patients with chronic heart failure

Introduction.

Part two of this thesis describes the evaluation of a remote automated weight monitoring system used by patients with chronic heart failure. Four chapters are presented in relation to this study. The first, chapter 6, provides a literature review which considers the problems posed by chronic heart failure to the individuals concerned and to the health services. The purpose and efficacy of weight monitoring as a medical strategy is addressed, and also the success and limitations of telemedicine weight monitoring initiatives. Finally a case is made for the need to conduct this study. Chapter 7 describes the findings from a series of interviews conducted with patients, their carers and the health care professionals whose duty it was to care for them. The purpose of this part of the study was to illuminate the idiosyncratic factors which impacted on the utilisation of the weight monitoring system under scrutiny. Chapter 8 considers the evidence, ancillary to that above, which provided further support of some of the findings from interview material. The ancillary evidence comprised the state/trait anxiety and quality of life questionnaires and also a short vignette of one family's experiences and their innovative method of coping with the difficulties they encountered. Chapter 9 provides an overview of the limitations of the study, a short reflexive account which explores some personal observations and reflections, and the conclusions and recommendations arising from the findings.

CHAPTER 6: Literature review of weight monitoring in Chronic Heart Failure

6.1 Chronic heart failure ~ costs and care. Chronic Heart Failure (CHF) is "by far the most common form of HF leading to hospital admission, accounting for 80% of cases" (Dickstein, Cohen-Solal, Filippatos, McMurray et al., 2008 p2391). It carries a poor prognosis and is differentiated from acute and transient heart failure in that there is no cure and treatment is palliative (Cowie, Mosterd, Wood, Deckers et al., 1997). Although the prognosis appeared to be improving in the late 1990's (Cleland, Gemmell, Khand and Boddy, 1999), it was, two years later, still "as malignant as many common types of cancer" (Stewart, MacIntyre, Hole, Capewell et al., 2001 p315). It continues to impose a considerable burden on healthcare resources.

The total direct cost of heart failure in the UK was estimated to reach £905million in the year 2000, representing almost 2% of the total NHS expenditure, with secondary and home care costing an additional 2% (Stewart, Jenkins, Buchan, McGuire et al., 2002) . Since these patients are at high risk of early readmission and death (Cleland, Swedberg, Follath, Komajda et al., 2003), hospital admissions were a main component of this (McIntyre, 2000, Stewart, Jenkins, Buchan, McGuire et al., 2002, Ayers, 2005). According to the 2002 report on coronary heart disease statistics there were at that time approximately 880,000 patients with definite or probable chronic heart failure, with 63,000 new cases being identified each year (Petersen, 2002). Although those figures were later revised, in 2006 the number of persons with heart failure was still estimated to be something over 676,000 (Allender, 2006). Since that time the prevalence of heart failure has declined when expressed as a percentage of overall disease, as have deaths from coronary heart disease in the elderly (Fleming, Cross and Barley, 2005), however the actual burden on the healthcare service is predicted to increase, due to an overall increase in population and to an increasing proportion of elderly persons within that growing population (Department of Health, 2004, Allender, Scarborough, O'Flaherty and Capewell, 2008). Paradoxically, this burden is further amplified by improvements in care, as seen in the increasing numbers of patients who survive after acute myocardial infarction (He, Ogden, Bazzano, Vupputuri et al., 2001). The high occurrence of readmission to hospital in this group of patients is often due to causes which are potentially preventable, such as failing to seek medical attention when symptoms worsen, or non-adherence to medication or diet plans (Stewart, Greenfield, Hays, Wells et al., 1989, Rich, Beckham, Wittenberg, Leven et al., 1995, Jaarsma, Halfens and Huijer-Abu Saad, 1996, Michalsen, Konig and Thimme, 1998, Neily, Toto, Gardner, Rame et al., 2002). Treatment is therefore directed towards improving the symptoms or slowing their deterioration (Department of Health, 2000).

6.2 Problems of self-care and symptoms-monitoring in Chronic Heart Failure. The NICE guidelines, developed by the National Collaborating Centre for Chronic Conditions (NICE, 2003) recommend that all patients with chronic heart failure should be monitored, suggesting that education in a number of self-care behaviours would be beneficial to patients. Self-care has been defined as "the decision and strategies undertaken by the individual in order to maintain life, healthy functioning and well-being" (Jaarsma, Stromberg, Martensson and Dracup, 2003 p364). The importance of regular monitoring of the symptoms, and the ability to take effective action when the symptoms worsen, has been emphasised by many authors who have studied the efficacy of disease management programmes (DMPs) in heart failure, the efficacy being measured largely in terms of a reduction in mortality and in the number and duration of hospitalisation events (Rich, 1999, Gillespie, 2001, McAlister, Lawson, Teo and Armstrong, 2001a, McAlister, Lawson, Teo and Armstrong, 2001b, Stewart and Horowitz, 2003, Duffy, Hoskins and Chen, 2004, Gonseth, Guallar-Castillon, Banegas and Rodriguez-Artalejo, 2004, Ofman, Badamgarav, Henning, Knight et al., 2004, Phillips, Wright, Kern, Singa et al., 2004, Holland, Battersby, Harvey, Lenaghan et al., 2005, Roccaforte, Demers, Baldassarre, Teo et al., 2005, Tsai, Morton, Mangione and Keeler, 2005, Whellan, Hasselblad, Peterson, O'Connor et al., 2005, Gohler, Januzzi, Worrell, Osterziel et al., 2006, Jovicic, Holroyd-Leduc and Straus, 2006, Martinez, Everss, Rojo-Alvarez, Figal et al., 2006, Chaudhry, Phillips, Stewart, Riegel et al., 2007, Pare, Jaana and Sicotte, 2007, Seto, 2008).

One of those authors, having conducted a review of the literature available, suggested that heart failure is often selected for DMP's ***because*** those outcomes are easily measured in "standardised and objective ways, such as a decrease in the number of hospitalisations" (Gillespie op. cit., p42). The author further commented that the majority of those studies reviewed demonstrated that the monitoring and treatment of symptoms were highly effective when measured by those parameters. Later authors however evaluated 32 projects and reported that they had differed in effectiveness, commenting on the differences between the studies which they thought might be responsible (Windham, Bennett and Gottlieb, 2003). Two years after that a meta-analysis of the available literature concluded that different DMP methods in heart failure appeared to be equally effective (Roccaforte, Demers, Baldassarre, Teo et al., 2005) thus it was not only the outcomes but also the methods used in heart failure disease management programmes that were variable.

The symptoms of chronic heart failure are numerous and may vary considerably (Ekman, Cleland, Andersson and Swedberg, 2005, Patel, Shafazand, Schaufelberger and Ekman, 2007) but include sudden weight gain, breathlessness, anxiety, loss of memory, fatigue, and the swelling of feet, ankles or abdomen (Carlson, Riegel and Moser, 2001, Lewin, 2005, British Heart Foundation, 2007, Dickstein, Cohen-Solal, Filippatos, McMurray et al., 2008). Since these symptoms can deteriorate rapidly self monitoring is said to require vigilance (Davidson, Paull, Rees, Daly et al., 2005) and such frequent monitoring as to place the burden firmly on the patient or a close carer. However some authors question the efficacy of self-monitoring in patients with CHF, due to age-related disabilities such as the loss of hearing, visual acuity, and functional status (Sweitzer and Warner, 1999, Carlson, Riegel and Moser, 2001).

Cognitive dysfunction is a common adjunct to the condition (Riegel, Bennett, Davis, Carlson et al., 2002, Dunderdale, Thompson, Miles, Beer et al., 2005, Lavery, Vander Bilt, Chang, Saxton et al., 2007) which has been associated with poor participation in outpatient programme (Ekman, Fagerberg and Skoog, 2001). Such changes would naturally affect the patient's self-monitoring ability. For example poor self-monitoring performance has been attributed to patients either having difficulty in recognising the symptoms (Carlson, Riegel and Moser, 2001) or perceiving them as being "of unclear or low importance" (Horowitz, Rein and Leventhal, 2004 p635) and the authors of the Euro-heart failure survey (Lainscak, Cleland, Lenzen, Nabb et al., 2007) demonstrated that patients may misunderstand or may not even recall recommendations regarding self-care management. Self-monitoring is therefore not necessarily easily accomplished by patients with chronic heart failure and many authors have emphasised the importance of patient education and frequent interaction with a specialist nurse in achieving that goal (Hagenhoff, Feutz, Conn, Sagehorn et al., 1994, Happ, Naylor and Roe-Prior, 1997, Ni, Nauman, Burgess, Wise et al., 1999, Riley and Blue, 2001, Stromberg, Martensson, Fridlund, Levin et al., 2003, Dickstein, Cohen-Solal, Filippatos, McMurray et al., 2008).

6.3 The purpose and efficacy of weight monitoring in chronic heart failure. The purpose of weight monitoring is to act as an indicator of the rapid build-up of fluid in the body which is ultimately responsible for the symptoms of breathlessness and swelling of abdomen, feet and ankles. The weight gain due to fluid retention is much more rapid than weight gain due to diet and so can be distinguished from it. It can be detected several days before the resulting symptoms are experienced by the patient by vigilant daily weight monitoring. Thus it can facilitate immediate intervention and its role is preventative rather than curative, being to permit "effective use of lower and safer doses of diuretic drugs" (Hunt, Baker, Chin, Cinquegrani et al., 2001 p 2107). Regular weight monitoring is therefore emphasised as an important self-care activity in a number of respected sources of information and advice on caring for patients with CHF, not only in the guidelines cited above (Hunt et al., op. cit.) but also the Heart Failure Plan of the British Heart Foundation (Lewin, 2005) and the ESC guidelines (Dickstein, Cohen-Solal, Filippatos, McMurray et al., 2008), and in one systematic review the authors concluded, "Experience suggests that, of currently available measures, weight may be the most useful for home monitoring of patients with heart failure..." (Louis, Turner, Gretton, Baksh et al., 2003 p 589) .

It is not recommended entirely without caution however. In one study of 77 patients who were self-reporting their degree of stability or clinical deterioration, a conflicting viewpoint was expressed in which the authors (Lewin, Ledwidge, O'Loughlin, McNally et al., 2005) found that weight gain did not predict clinical deterioration adequately and others expressed concern that in chronic heart failure, reliance on physical signs may result in inadequate therapy (Stevenson and Perloff, 1989). Furthermore, non-adherence to the strategy and non-recognition of symptoms presumably apply equally to weight monitoring as to other self-care behaviours in patients with CHF. In one of the aforementioned studies in which 113 patients were surveyed (Ni, Nauman, Burgess, Wise et al., 1999) approximately 40% of patients did not recognise the importance of weighing themselves daily. Of the patients who did think it was important only 58% actually did it (45% of the total cohort) and 27% weighed themselves only twice a month or less. Similarly other authors, who reported finding benefits from a DMP, also found that sudden weight gain was the least easily recognised symptom, with over 60% of patients not able to recognise it (Carlson, Riegel and Moser, 2001). They reported that most patients said it was not of much importance, (p 356) 20% had no confidence in their ability to do something to relieve their symptoms (p357) and 59% had little or no self confidence in their ability to evaluate their actions (p 358). Another author (Horowitz, Rein and Leventhal, 2004) reported similar findings and cited one patient who gained 9 pounds in one week but took no action.

Adding to the misunderstanding, although recommendations and advice on weight monitoring is freely available, the advice given regarding the purpose and frequency of weight monitoring is often confused and contradictory. For example in their publication "living with Heart Failure" the British Heart Foundation (British Heart Foundation, 2007) recommend weight monitoring every morning, but in their publication "The Heart Plan" (Lewin, 2005) they say the in some circumstances perhaps every two or three days is fine. This is compounded by advice to weigh yourself regularly, without indicating exactly how regularly, but then they go on to advise that the patient's weight could go up and down depending on how much they eat and whether or not they take enough exercise. It is little wonder therefore that patients are confused about both the importance and the reasons for vigilant daily weight monitoring.

That would be confusing enough, but there is some anecdotal evidence that patients and their families read publications such as the NICE guidelines, which are primarily intended for the guidance of health care professionals.[8] The full connotations of the medical terminology may be lost to the layman and in any event the guidelines represent advice, but not a mandate on how to treat patients with heart failure (McDonald, 2005). In the ESC guidelines for example is a table listing the symptoms of CHF (Dickstein et al. op. cit., p 936) which includes "oedema", "ascites" and "fluid overload," but does not specify that patients should record daily weight and recognise rapid weight gain until later in the document, which may well be missed by a patient looking for a quick reference. Similarly, the use of terminology such as "Assessment of fluid status... chiefly by physical examination, changes in body weight..." as is used in the NICE guidelines (NICE 2003,

[8] From an anecdote related by Dr Martin Cowie, on patients presenting for consultation having read the NICE guidelines.

op.cit., p18) is clearly sufficient for the understanding of the health professionals reading the document, but not necessarily for the patient.

Confusion and physical or psychological barriers notwithstanding, most authors have advocated daily weight monitoring, and it remains a key factor in caring for patients with chronic heart failure.

6.4 Telemedicine and weight monitoring ~ successes and limitations. It was perhaps inevitable that telemedicine should be investigated as a potentially useful strategy to improve this, and other, monitoring activities. Provided the benefits claimed for telemedicine can be realised for this group of patients, which according to one group of authors includes empowering patients and their families in addition to “personalising services... strengthening an understaffed and under resourced home health care industry” (Coughlin, Pope and Leedle, 2006 p 196) it is potentially a useful and cost-effective method of improving care.

There is of course no single and universally accepted definition of what constitutes a telemedicine strategy in terms of either the equipment used or the nature of the programme. According to one leading figure in the realm of telemedicine it is an umbrella term that encompasses any medical activity involving an element of distance (Wootton, 2001). Thus as previously noted it could incorporate anything from a single telephone call to the most advanced home-monitoring technology, although there is some indication that perhaps the telephone is now so commonplace as not to be considered “telemedicine,” as some authors have drawn a distinction between “telemonitoring” and “telephone support” (Robinson, Stroetmann and Stroetmann, 2004, Cleland, Louis, Rigby, Janssens et al., 2005, Clark, Inglis, McAlister, Cleland et al., 2007). However, the majority of systems described in previous studies incorporate some method of monitoring weight and some form of telephonic communication with a health care professional, and the terms “tele” and “remote” will be taken to mean anything other than face-to-face contact here.

The models of tele-care proposed in previous studies are many and varied and are often complex as they include a mixture of telemedicine interventions (Jaarsma, Stromberg, De Geest, Fridlund et al., 2006). Many include a more advanced technological approach than a simple telephone conversation between patient and nurse, for example using the telephone to transmit a selection of physiological parameters such as ECG data, transcutaneous oxygen saturations and blood pressure. Weight can also be transmitted automatically in this fashion, but more usually the system incorporates a regular telephone consultation in which a patient verbally reports their self-recorded weight monitoring progress and can discuss any other symptoms (Roth, Kajiloti, Elkayam, Sander et al., 2004, Scalvini, Martinelli, Baratti, Domenighini et al., 2005, Cleland, Louis, Rigby, Janssens et al., 2005, Oeff, Kotsch, Gosswald and Wolf, 2005, Myers, 2006). In some studies the telephone conversation is virtually omitted, for example in one automated telephone system in which the patient used the telephone keypad to report physiological data such as weight, pulse and blood pressure (Spaeder, Najjar, Gerstenblith, Hefter et al., 2006) and in another where similar data were collected but transferred using wireless internet technology in a mobile phone (Scherr, Zweiker, Kollmann, Kastner et al., 2006).

Thus, although an element of weight monitoring is invariably included within the strategies of symptoms monitoring, its place in the “pecking order” and the way it is accomplished are far from homogenous. This makes it particularly difficult to allow comparison of the different types of intervention, a problem which has been noted by a number of authors (McAlister, Stewart, Ferrua and McMurray, 2004, Driscoll, Worrall-Carter, McLennan, Dawson et al., 2006, Clark and Thompson, 2008). One systematic review (Mistiaen and Poot, 2006) included only studies which allowed a telephone follow-up aspect to be analysed separately, but the findings were equivocal and they could not conclude that the telephone follow-up was an effective intervention. Nevertheless, the majority of DMPs suggested have included some form of telephone support, although the objectives and the frequency of that telephone support are variable.

The stated objectives have placed varying degrees of emphasis on education, counselling or reinforcement of self-care behaviour (Jaarsma, 1999, Blue, Lang, McMurray, Davie et al., 2001, Riegel, Carlson, Kopp, LePetri et al., 2002, Dunagan, Littenberg, Ewald, Jones et al., 2005, Grancelli, 2007). The suggested frequency of the telephone support varies widely, with many authors using vague terminology, for example “regular”, “frequent,” or “as needed” (Weinberger, Oddone and Henderson, 1996, Hanchett and Torrens, 1967, Ekman, Andersson, Ehnfors, Matejka et al., 1998, Blue, Lang, McMurray, Davie et al., 2001, Capomolla, Febo, Ceresa, Caporotondi et al., 2002, Kasper, Gerstenblith, Hefter, Van Anden et al., 2002, Krumholz, Amatruda, Smith, Mattera et al., 2002, Laramee, Levinsky, Sargent, Ross et al., 2003, Ledwidge, Barry, Cahill, Ryan et al., 2003, Tsuyuki, Fradette, Johnson, Bungard et al., 2004, Inglis, Pearson, Treen, Gallasch et al., 2006, Rogers, Perlic and Madigan, 2007). Some authors specified the frequency, for example two-weekly or thereabouts, (Vavouranakis, Lambrogiannakis, Markakis, Dermitzakis et al., 2003, Roth, Kajiloti, Elkayam, Sander et al., 2004), or monthly (Robinson, Stroetmann and Stroetmann, 2004) and others suggested that the frequency should depend on the clinical stability of the patient (Grancelli, 2005, Giordano, Scalvini, Zanelli, Corra et al., 2009). Some suggested a schedule of telephone calls for a fixed period of time, for instance a weekly telephone contact for a period of one month (Naylor, Brooten, Campbell, Jacobsen et al., 1999) or telephone contact at only three months and six months following recruitment to the study (Stewart, Marley and Horowitz, 1999). Others investigated the impact of telephone calls at eight and sixteen weeks after the initial prescription (Simon, VonKorff, Rutter and Wagner, 2000) and some specified a phone call from the nurse at one, three, and six months (Koelling, Johnson, Cody and Aaronson, 2005).

Not only are these strategies varied, but most are supported in turn by health care monitoring either at clinic or in visits to the patient's home, and it should be borne in mind that many patients also receive advice from their designated health care professionals in addition to whatever information they may receive from the public arena. Healthcare professionals do not necessarily agree on all aspects of care, and this may apply to weight monitoring and to telemedicine as much as to any other feature. They may hold views which differ from the views of other health care professionals, the views of the patient and from the published advice available (Dracup, Baker, Dunbar, Dacey et al., 1994, Wehby and Brenner, 1999), so it is not surprising that a number of authors have found it difficult to determine to what extent any beneficial effect was due to any one intervention, or indeed to telemonitoring at all. As one group of authors commented, "… the evaluation of telehealth is more difficult than anticipated, because the unpredictability of outcomes makes it hard to assess what component of an intervention is responsible for the change" (Hughes, King and Kitt, 2002 p 37). The consensus was that there were indeed benefits to telemonitoring, but the variability in studies caused the authors of one systematic review to suggest that although telemonitoring programmes were without doubt beneficial, that it was still to be determined which of them worked best (McAlister, Stewart, Ferrua and McMurray, 2004).

It might have been expected that such comments would result in research programmes which sought to disentangle the various elements, but more recently it has been noted that the effects of the different elements of interventions remain undifferentiated (Clark and Thompson, 2008). Thus the question remains, is the beneficial effect due to the monitoring of weight and/or other physiological factors, or to the telemedicine aspect of the telephone support, or to something else entirely?

A further problematic aspect was identified in the dichotomy of a disease-monitoring programme which theoretically should be successful, but which paradoxically is rendered virtually ineffective as the patient's condition deteriorates, due to the physical and mental limitations associated with that deterioration. In other words those patients who need it most are the one least able to avail themselves of the benefits. This was particularly noted by Ekman and colleagues (Ekman, Andersson, Ehnfors, Matejka et al., 1998), who found that in a nurse-monitored outpatient-care programme, in which patients were able to telephone the specialist nurse during business hours but had to visit the clinic for treatment and assessment, was not feasible because only a minority of elderly patients with moderate to severe CHF were able to attend the clinic.

The point, if recognised at all, appears to have been largely dismissed in most studies by simply excluding patients with these difficulties from participation, although few provide the precise exclusion criteria or give precise numbers. For example in their aforementioned study Ekman and colleagues had excluded all patients who could not comply with the vague criterion of eligibility for an outpatient follow-up programme (Ekman et al., op. cit., p1254). Others terms used by other authors for the definition of exclusion included those whom, in the opinion of the authors, were "unable to give informed consent ... or to comply with the intervention" (Blue, Lang, McMurray, Davie et al., 2001 p 715), had significant cognitive impairment (Carlson, Riegel and Moser, 2001 p 352) were unable to hear or had cognitive or psychologic impairment which precluded effective telephone monitoring (Dunagan, Littenberg, Ewald, Jones et al., 2005), or who had dementia (Stromberg, Martensson, Fridlund, Levin et al., 2003, Tinker and Lansley, 2005).

Some authors gave an indication of the number of patients excluded on these grounds, and in one study it they reported that almost 10% were excluded because they were incapable of carrying out the procedures (Roth, Kajiloti, Elkayam, Sander et al., 2004). Almost 28% of patients were excluded in another study because they were not in a stable clinical condition, had dementia or were not on an optimised therapy regimen (Scalvini, Zanelli, Volterrani, Martinelli et al., 2004). Even after excluding patients who were deemed unable to comply with the requirements of regular monitoring, some authors found that of the remainder only 55% had a greater than 80% compliance with twice daily measurements (Cleland, Louis, Rigby, Janssens et al., 2005). The latter authors hinted at the gap in care by commenting that an improvement in the selection of patients may enhance the benefits and lower the costs of therapy further. Although couched in terms advantageous to the perception of the telemedicine intervention, this did go some way towards indicating that a sizeable proportion of patients were not able to benefit from the telemedicine intervention described. Another author supported that point by commenting that the entry criteria for studies were very restrictive, leading them to query whether therapy deemed effective in such circumstances would be similarly effective when given to patients who would have been excluded from those clinical trials (McDonald, 2005).

Despite the heterogeneity of the strategies investigated and the fact that the findings are limited to those deemed able to comply with the requirements, most authors have concluded that remote monitoring does afford some benefits. Whether those benefits are of mortality, morbidity or reduced costs, and whether they apply equally to all patients with chronic heart failure is unresolved and some have urged caution due to weak or insufficient evidence (Mistiaen and Poot, 2006).

6.5 The need for the research study. In critiquing the application of telemedicine, as one author put it, "…On balance, the benefits of telemedicine are substantial, assuming that more research will reduce or eliminate the obvious drawbacks" (Hjelm, 2005 p60). There appear to be two "obvious drawbacks" to the previous studies which have sought to evaluate DMPs. The first is that there is a lack of evidence of the efficacy of weight monitoring as a preventative measure in keeping patients free from fluid retention and the subsequent consequences of it. The suggestion that placing reliance on weight monitoring might result in a patient receiving less than optimum care is an important consideration, and despite more than a decade of investigation the dependability of weight monitoring as a predictive tool for identifying clinical deterioration in this group of patients is still open to question. To what extent this is due to changes in weight being unreliable predictors, or due to a lack of precision and/or vigilance on the part of the patient, is unknown.

The second drawback is that there are a number of patients who are deemed unable to take part in a weight-monitoring programme by virtue of the physical and mental difficulties associated with chronic heart failure. The difficulties may be due directly to the heart failure itself, but this is not necessarily the case, they may simply be age-related. Nevertheless the difficulties caused by those symptoms impact on the patient's ability to participate in a self-care programme and almost invariably worsen with time.

Whilst it has already been recognised that remote weight monitoring might be of particular benefit to patients who have difficulty accessing specialised care, either because they are infirm or because they have transport difficulties due to remote dwelling and the fact that they are unable to drive (Clark, Inglis, McAlister, Cleland et al., 2007), there are more complex issues than those of mere distance which need to be evaluated. Over twenty years ago it was suggested that self-care efficacy was based upon two disparate levels of operation, which the author described as self-care ***management*** and self-care ***maintenance***. Management was considered to require a certain amount of intellectual engagement on the part of the patient, whereas maintenance required only that the patient could respond to direction from a third party (Gantz, 1990). This suggests that the nature of the monitoring programme should be tailored to the individual, and that the details of how the monitoring is achieved may change over time as the patient's cognitive abilities deteriorate. Some years later Field and colleagues further investigated the practical limitations imposed by chronic heart failure (Field, Ziebland, McPherson and Lehman, 2006). They identified 3 levels of awareness in patients, in which only those enjoying the highest level of awareness were equipped to discuss their treatment in detail, thus implying that the remainder required assistance or direction in achieving adequate self-care.

To evaluate this weight monitoring system in terms of rapid recognition and intervention in cases of clinical deterioration is therefore not enough. The evaluation must seek to provide a description and explanation of the phenomena that occur throughout the processes of weight monitoring, both with and without contribution from the telemedicine equipment. In particular, it must provide evidence to demonstrate how such an automated system impacts on the care of the patients in the wider sense, from the perspectives of those living with the condition, their loved ones, and those whose professional responsibility it is to care for them, since “Telemonitoring must not only prove that it is effective but also that it is more effective than simpler interventions” (Louis, Turner, Gretton, Baksh et al., 2003 p 588).

CHAPTER 7: Evaluation of a remote automated weight monitoring system – the participant perspective.

7.1 Introduction. This chapter describes the evaluation of one remote automated weight monitoring system from the perspectives of the patients, carers and staff who use it. The data are varied and complex, therefore discussion occurs throughout the text as the author felt context demanded. A summary of the findings are discussed and the conclusions are tabulated at the end of each topic which had been raised by participants, in order better to clarify the issues. A rather more holistic approach to the discussion is taken at the end of part two and that in turn informs the final conclusions at the end of the thesis.

In the system to be investigated, a pair of digital weighing scales connected to a central call centre via the patient's own telephone landline is the only piece of equipment to be offered, and a comparison of the processes of automated weight monitoring and conventional weight monitoring is illustrated by the following lists;

Normal Weight Monitoring	Automated Weight Monitoring
1) Patient weighs himself	1) Patient weighs himself
2) Patients writes down weight	2) Weight sent to call centre automatically
3) Patient recognises weight gain	3) Weight gain recognised at call centre
4) Patient contacts nurse	4) Call centre contacts either nurse or patient

Thus there are no other confounding physiological data other than weight to be monitored in addition to the usual care. There is no requirement for the patient to see, to record, to assess or to transfer the weight data, as the weight is sent automatically via a wireless connection to a central call centre. There is no absolute requirement to remember the daily weighing routine, because if a weight is not recorded for two days the nurse at the call centre will telephone the patient to remind them and if unable to make contact then the patient's own nurse will be alerted. There is no requirement for the patient to recognise a weight gain, as this is done at the call centre and appropriate action taken, "appropriate action" being variable and proceeding according to pre-determined discussion and agreement between the call centre and the patient's health care professional. Therefore this research study will provide valuable information relating to practical issues surrounding the use of one such service as reported by the patients, their carers and clinicians.

7.1.1 Aims and objectives.

- To evaluate one telemedicine system of remote weight monitoring from the perspectives of patients, their spouse or carer, and the healthcare professionals involved in their care.

  Objectives of the study;

a) To identify differences in beliefs and opinions between users and also between users and previously published material. ("Users" are defined as patients, their carers and clinicians.)
b) To illuminate the factors which act to encourage the successful implementation of the telemedicine weight monitoring strategy and,
c) To expose barriers which act to delay or deter the successful implementation of the telemedicine weight monitoring strategy.

7.1.2 Study design. The overarching design of the thesis has been discussed in chapter 2, and will not be repeated here. The evaluation of the telemedicine weight monitoring equipment rested on a randomised controlled trial which incorporated multiple methods of data collection to validate the findings from each source (interview, state/trait anxiety questionnaire, quality of life questionnaire, a diary of events for patient and carer participants and a comparison of patient outcomes from medical records). The advantages of employing a mixture of methods were introduced in chapter 2 on page 39. The current chapter refers only to the interview data acquired and thus is an exploratory evaluative study yielding qualitative data. The element of randomisation was however lost to some extent, as due to the small numbers of participants recruited all were interviewed where possible.

Definitions of the term "evaluation" usually include mention of "systematic assessment" of the "worth or merit" of some object (Shadish, Cook and Leviton, 1991, Scriven, 1998, Rossi, Lipsey and Freeman, 2004). In many of the previously reviewed studies the worth has been judged in terms of easily measurable outcomes such as the number of hospitalisations and comparative costs. However the intention of this study was to illuminate the experiences of the participants, in order that the full complement of advantages, limitations and detriments from the point of view of each participant may be understood. Thus there was no hypothesis at the outset.

The importance of comprehending the views and beliefs of each participant lies in the need to distinguish between true knowledge and false beliefs. That is not to say that false beliefs are necessarily detrimental, as illustrated by the use of placebo medicine which, when taken by patients who believe it to be of medical worth, report feeling better. They do however exert an effect, detrimental or otherwise and it is important to comprehend how a participants' understanding of circumstances may impact on the effectiveness of the programme under evaluation. In the case of patients with CHF, problems caused by confusion between true knowledge and false belief may be particularly difficult to overcome due to the associated cognitive dysfunction. Not only may this act to confuse what constitutes "knowledge" for each patient, but it also makes it difficult to bring about a change in perception through education, as the patient is likely to forget what was taught just a short time before. Thus a situation may arise in which a potentially valuable intervention, such as the one evaluated in this study, may remain unappreciated if the patient does not "know" of the advantages, or if the patient "knows" (wrongly) that it is not beneficial. In that case compliance may be compromised and as a result the patient's wellbeing may also be at risk. Conversely of course a false belief may be beneficial if it acts to encourage self-care performance. The question then becomes one of ethical judgement to decide whether the encouragement of that false belief is justified in the best interests of the patient, as may be claimed for the use of placebo medicines.

The need to distinguish between true knowledge and false belief was not restricted to the patient. It was equally important to expose the limits of knowledge and justification as they applied to the health care professionals, since they also were in a position to affect the outcomes. Since it was an exploratory study without pre-formed ideas or theory, a post-positivist "bottom up" approach was adopted in an attempt to achieve understanding of the views and beliefs held by each participant. Without that understanding a complete description of the experiences could not be obtained and therefore decision-making based on the data would be inappropriate, at best. Thus an interpretivist paradigm was not so much selected as it simply arose from a natural consequence of the requirements of the study, as a simple comparison of counts of events (or failures of the intervention) offered both by previous studies and also by the complementary data gathered from these participants would be supplemented by an understanding of the reasons ***why*** those events had occurred or why the initiative had failed for some participants. By identifying those reasons it would be possible to evaluate the ***potential*** contribution that the automated weight monitoring system may make to care in patients with CHF and to identify the changes that would be required in order to achieve that potential. The nature of the complementary data was not therefore intended simply to provide a means of corroboration (or contradiction) of certain facts, as is often the claim for methods of triangulation, but rather to illuminate complementary aspects of the same experience.

It follows from the preceding argument that the advantages of the qualitative unstructured interview, described by Cohen and colleagues as affording "unique, non-standardised, personalised information about how individuals view the world" (Cohen, Manion, Morrison and Morrison, 2007 p 354) was the tool most fit for purpose here. Interpretive approaches rely on naturalistic methods in order to construct a meaningful reality between interviewer and participant. The intention here was not to confine the participants to presenting their feelings about a pre-determined number of very specific issues, but to draw from them a description of what the relevant issues were for them, and to understand each respondent's view of those specific issues. As Lincoln and Guba suggested (Lincoln and Guba, 1985 p 269), when a researcher is not aware of what they do not know, but know that they need the participants to tell them, then unstructured interview is the method of choice. Patton phrased this slightly differently, saying "Qualitative designs are naturalistic to the extent that research takes place in real world settings and the research does not attempt to manipulate the phenomenon of interest." (Patton, 2002 p 39) but the message in either case was clear, the method of acquiring the data should ideally reflect the requirement to confine the participant as little as possible, whilst still acquiring data relevant to the evaluation.

The concept "relevant to the evaluation" was equally unidentified as yet, because until words are spoken (and recorded in this case) they cannot be analysed to elicit their relevance to the evaluation in question. Clearly however the completely unstructured "conversational" interview was not an option due to constraints of time and geographical location and some direction must be given to the topics addressed during the interview. Whilst a comparison of the interview with alternative methods of data collection does demonstrate the superiority of the interview for obtaining "obtaining access to and describing the lived everyday world" as experienced by the subject (Kvale, 1996 p 124), according to McNamara it also demonstrates its better performance in getting the story behind a participant's experiences and permits the interviewer to pursue in-depth information to further investigate a participant's responses (McNamara, 2006). This would provide the opportunity to explore further with participants the topics as they arose, whilst still directing the conversation towards the foci of the interview. Patton suggested that there are several types of questions available to the interviewer, addressing descriptions, experiences, behaviours, opinions or values, feelings, knowledge, sensory effects and demographics (Patton, op. cit. p 358). Clearly participants' behaviours were important, specifically those behaviours relating to weight monitoring and self-care. Their experiences, both positive and negative have the potential to affect those behaviours and inform opinions and feelings on the topics of weight monitoring and the telemedicine system. The concept of knowledge as it applies to many patients with chronic heart failure has already been discussed on page 170 and is important as it also has the potential to affect behaviours and opinions, and be affected in turn by experiences. Therefore interview schedules were constructed which invited the participant to reflect on those aspects as they relate to loosely defined concepts of illness and/or well-being, weight monitoring and telemedicine, whilst at the same time leaving the specific topic open for the participant to define. Those interview schedules are given in appendix 2.

7.1.3 Data collection and interview techniques. In order to elicit the information described above, the timetable previously described in the flowchart figure 2-3 on page 32 was developed, however difficulties in recruitment resulted in that timetable being adjusted. The final format is shown in more detail in figure 7-1 on page 176 but in brief, baseline interviews (0months) with the specialist nurses, patients and their partners were intended to elicit experiences related to the illness, to weight monitoring *per se* and to any expectations which might exist of the telemonitoring system. The interval (3 month) and end-of-study (6 month) interviews were intended to elicit data which would enable a comparison of the participants' experiences of the telemonitoring system with their earlier assumptions. Thus the total complement of data would reveal;

- issues related to the telemonitoring system which were of importance to the staff, patients and partners, which may therefore inform decision-making related to the use of automated weighing scales in the future.

- A comparison of the perspectives of health care professionals and service users, in order to discriminate between perceived and actual impact of the system.

Although the participants were geographically distant from the researcher, face to face interviews were the method of choice, despite being costly in terms of both time and money. This was primarily for reasons of establishing credibility, because as explained on the preceding pages the research question demanded insight into aspects which were of importance to the users. Although some illumination regarding the problems of the elderly, the infirm and the condition of heart failure was possible from the literature this was usually presented from the purely medical perspective and did not attempt to describe the users' perspective. In order to address the research question it was essential to approach data collection with as few preconceptions as possible and "The overpoweringly positive feature of the interview is … it enables you to *see* and understand what is reflected" (Gilham, 2000 p 10). There were four supplementary reasons for conducting the interviews face-to-face rather than by telephone. The first was that telephone interviews are often subject to time constraints and the researcher was keen not to obstruct or curtail the data flow unnecessarily, because previous authors had stressed the "need to listen to older people" (Tinker and Lansley, 2005 p 1). The telephone was therefore rejected as a communication method, at least for the early interviews. The second reason for choosing to conduct face-to-face interviews was that the possibility that social cues, observed within the home, may further illuminate the participant's verbal communication. Thirdly, it has been shown that patient's tend to offer a more critical response when addressing issues of satisfaction, or possibly more importantly dissatisfaction, during an interview than via a more remote method of communication (Bauer, Bohrer, Aichele, Bach et al., 2001). Lastly, it has been shown that trust is more easily developed during face-to-face communication, as some telephone respondents may be more suspicious about the interview process than those approached in person (Holbrook, Green and Krosnick, 2003). Since it was recognised that there may be issues relevant to the participants which were of a sensitive nature (for example heart failure is known to be associated with sexual dysfunction) the issue of trust was thought to be of relevance, as according to Gillam (op. cit., p 15) both trust and confidence are involved in making such disclosures. For similar reasons of establishing credibility, each interview was allocated a time span of a "session," this being defined as a morning, an afternoon or an evening, according to the participant's preference. Developing rapport with participants requires sufficient time to allow the participant to feel comfortable in disclosing information and also to allow the researcher to observe the setting, in order to understand the context of the data emerging.

Early interviews were recorded onto audio tapes. Later a digital recording device was purchased and used specifically for this study. Open questions were formulated for the reasons given earlier, on pages 171-172, for example asking patients and their partners to "describe their illness and self-care routine," with prompts about weight monitoring if needed. Staff were asked to describe how they used the weight monitoring behaviour in their care of their patients and what impact, if any, they felt the telemedicine scales may have on patient care and on their own role as a specialist heart failure nurse.

Follow-up interviews, those conducted during and at the end of the study period, began with open questions such as "how have you been?" and if necessary this was followed by prompts to elicit more information such as "has your weight changed at all during the last three months?" "Has the cost of telephone calls been a problem?" Interspersed between the topics of conversation the phrase "... last time I think you said....?" and after the participant's response the interviewer followed with "... and is that the same now or has it changed..?" or a similar phrase. In that way the researcher was able to check the validity of current concepts and also those recounted previously.

The recordings were transcribed verbatim and NVivo software was used to facilitate data analysis. The analysis of the content is, according to Krippendorff , "a research technique for making replicable and valid inferences from texts (or other meaningful matter) to the contexts of their use" (Krippendorff, 2004 p 18). The technique used to conduct an analysis of the content was thematic analysis, as described by the same author (Krippendorff 2004 op.cit.). Thematic analysis has been described by many authors in relation to a medical context for several decades (Benner, 1985, Leininger, 1985) however Boyatzis depicts it as a "process for encoding qualitative information" (Boyatzis, 1998 p 6). The process of thematic analysis described aspermitting relevant themes to emerge from the data, after which process those themes are applied back to the data to accomplish a better understand of their meaning within their original context (Tesch, 1990, Wright, 2000). In conducting thematic analysis the themes are constantly compared and contrasted in order better to understand the distinctions or commonalities between categories (Corbin and Strauss, 2008, Thomas and Harden, 2008).

The first three recordings (one patient, one partner and one heart failure nurse) were analysed by two researchers who listened independently to the recordings, transcribed the verbal material which was then subjected to analysis in the manner described above, in order to identify themes, assign codes (labels) to the themes and subsequently to group those themes into categories. The codes and categories developed by the researchers were compared, concepts defined and labels agreed at this stage, in order to ascertain reliability of the coding. The researchers then independently arranged the categories into a branching tree of thematic classifications. The resultant thematic trees were compared, discrepancies discussed and amended to achieve agreement. The researchers then listened to two further recordings (one patient and one carer) and again coded them from the transcripts, using the thematic classifications previously agreed and adding others as they emerged. When compared, although minor differences in the labelling of new themes had occurred no major discrepancies were identified. The remaining transcripts were coded by the lead researcher who added thematic categories as they emerged and consolidated or refined others. The second researcher reviewed two later transcripts to confirm the validity of the resultant thematic trees. The findings from six interviews (3 patients, two carers and one nurse) were reviewed with the relevant participants and confirmed as representative of the participant's views. The final coding scheme is presented in appendix 3.

7.1.4 Participants. Twenty patients with a mean age of 75 years and age range between 66-83 years were included in the data arising from this study. Twenty four originally signed the consent form but four withdrew prior to commencing the study. Of the twenty contributing participants, two were female and eighteen male. Ten of those had spouses who also participated and in addition the son of one male patient, the sister of one male patient and the carer of one male patient also participated. All patients were Caucasian and local to the area. All but one was retired and none had other weight-changing illnesses. It was not possible to obtain further medical information as the researcher was not able to gain access to medical notes, and that issue is explored further in chapter 9 on page 253. Of those recruited, fifteen patients and thirteen carers were interviewed. It was noted that the five patients who could not be contacted were those without either spouse or carer, although it is not known if this was an influential factor . Nine of the patients interviewed were in the telemedicine group (receiving usual care and also the telemedicine scales) and six were in the control group (receiving usual care alone).

Of the healthcare professionals, four heart failure nurses contributed the majority of the interview information. However one GP practice which had consented to participate, but which did not ultimately recruit any patients to the heart failure study, included specialist cardiac nurses who wanted to volunteer their views, which they chose to do as a focus group. The contribution of each participant to the interview data is summarised in figure 7-1 below. In addition comments received from individuals from eight general practices, relating to reasons for declining the invitation to participate, are included in the analysis.

HF nurse	HF nurse	HF nurse 1 (replaced by) HF nurse 2	5 HF practice nurses
(Secondary Care)	(Community)	(Secondary Care)	(Primary care)
1 interview start of study	**1 interview start of study** **1 interview end of study**	**1 interview start of study** **1 interview end of study**	**1 Focus group interview**
Did not recruit patients	Recruited	Recruited	Did not recruit patients

Recruited 24 patients (40%) out of which 4 withdrew immediately, 15 were interviewed plus 13 carers as follow;

9 patients telemedicine group (1 start and end, 8 single interviews) = 10 interviews
8 carers telemedicine group (1 start and end, 7 single interviews) = 9 interviews
6 patients usual care group (3 start and end, 3 single interviews) = 9 interviews
5 carers usual care group (2 start and end, 3 single interviews) = 7 interviews

Plus……
notes made during telephone calls with participants choosing to withdraw half way through:-

- 1 patient from the telemedicine group
- 1 patient from the "usual care" group.

Fig. 7-1 Breakdown of interview data collected.

7.1.5 Ethical considerations. The research was funded by the Diagnostic Futures Programme of the Department of Health and supported by voluntary loan of telemonitoring equipment and services, free of charge, from Broomwell Healthwatch Ltd. The clinical research lead, who was working as a GP in the North West of England, identified three heart failure specialist nurses who agreed to recruit participants from the patients in their care. Unfortunately one was not able to obtain the necessary approval from her hospital to recruit patients to the study but was able to contribute as a participant herself. The academic input was provided by two members of the TeleHealth Research Group at Buckinghamshire New University, one of whom is the author of this thesis and who was responsible for all data collection, analysis and interpretation of the results. The research proposal was the result of collaboration between all members of the team and received the approval of the ethics committee on 20th April 2006, REC reference number: 06/Q1309/1 (Appendix 4.) An overview of the proposed research study was presented as a flowchart in figure 2-3 on page 32, where it can be seen that, in addition to medical data, ethical approval related to the interviewing of patients, carers and clinicians. In the case of GP practices, following consultation with staff members the senior GPs' decision to contact the researcher and accept the invitation was taken as consent for that practice, although members were free to abstain from participating if they so chose.

There is little doubt that any information on the impact of a telemonitoring system such as the one evaluated in this study would be a useful contribution to the debate on policy formulation and would therefore be of value to society as a whole. The views of the patients and their spouses or carers have the potential to inform the work of the healthcare professionals, whose views in turn may reveal aspects of their work hitherto unrecognised by higher levels of management, thereby improving the service for patients and staff. Thus although individuals may have a vested interest in putting forward certain views, and many of those views may conflict, it was thought to be important that the funding bodies should have access to the full range of views. The result was that in some instances it may be possible for an individual healthcare professional to be identified by someone familiar with his or her unique working practices, through a particular view that he or she had expressed and which the researcher wanted to report verbatim. This was discussed with the interviewees in question and assurances received that this did not present a problem, indeed the healthcare professionals were particularly keen for their views to be heard. Similarly any verbatim reports of comments made by patients or their spouses were checked by the interviewee prior to inclusion in the report, with particular care to point out any reference that may potentially identify the speaker. Again, the patient and spouse participants were very keen that their views be presented in exactly the form that they had expressed them and none requested any point to be removed or amended.

As in any circumstance in which items or services are provided free of charge by a commercial company, the telemonitoring company naturally hoped for a favourable report of the weight monitoring system. Assurance was requested, and freely given, that the researchers were free to publish any finding, whether or not detrimental to the public perception of the system.

A particular ethical concern regarding patient involvement was related to the recruitment and participation procedures. Due to the nature of chronic heart failure it was important to ensure that the patient had a full understanding of the purpose and nature of the study without feeling under pressure to participate and to understand that they were free to withdraw from the study at any time. Therefore measures were incorporated to allow the participants the fullest opportunity to discuss and consider the implications prior to making the decision whether or not to participate. Those measures are described in the next section. Furthermore permission was obtained from the telemonitoring company to continue to use the equipment and services after the study had ended, in order to offer access to telemonitoring to those patients in the control group who would not otherwise have had the opportunity.

7.2 Procedure. Due to the strict legal, ethical and medical requirements imposed by the nature of research, the researcher was not able to contact the patients directly until after informed consent was obtained in which participants provided their contact details to the researcher. Therefore recruitment was a multi-step procedure which had to be completed in entirety before the patients could receive the automated weighing scales. The steps were as follows:-

i) Between sixty and sixty-five patients with Class 2, 3 or 4 Heart Failure who, in the opinion of their specialist heart failure (HF) nurse required regular weight monitoring as part of their care, were invited to participate in the study by that nurse. The exact number is unknown as one nurse left post and the final five consent forms were not received by the researcher. It is not known whether they were given to patients and not returned, or if they were discarded when the nurse left post. At the same time the partner or carer was also invited to participate, although it was made clear that a partner's refusal to participate did not preclude the patient from doing so. The purpose and procedure of the research was explained by the nurse, with an opportunity for patients and partners to ask questions or request more information.

Patients were excluded if they;

- were in heart failure class 1 (class 1 was considered by the clinical members of the research team to be too mild to require weight monitoring. This view was later challenged by one heart failure nurse and is reported later).
- were unable to stand to be weighed. (There was no facility for the weighing regime to be undertaken other than by standing. However if the telemonitoring system proved beneficial it would not be impossible to adapt it to accommodate a chair or sling.)
- had dementia. (Whilst the purpose of this study was to evaluate the telemonitoring system for all patients, in the hope that it may overcome the limitations of other systems, the restrictions imposed by the ethical considerations of including this group of particularly vulnerable people precluded their participation at this time. If a positive benefit were to be proved during the initial study, later evaluations with particular participant groups may be conducted.)
- had other weight changing conditions. (Confusing data arising from other conditions have the potential to obscure the benefits or limitations of the system. Once again if a positive benefit of using the telemonitoring system were proven in the initial study other participant groups could contribute to later evaluations.)
- were aged less than 18 years. (Although heart failure in the young is a serious matter it is extremely rare. None of the healthcare professionals had any patients in this group under their care. However, once again if the telemonitoring system were to prove beneficial in this study there is no additional risk to young patients if it is included in addition to their usual care. Therefore later evaluations including this group of participants would presumably not present a problem.)
- were unable to speak English. (The telemedicine company has no facility to communicate in languages other than English at the time of writing.)

ii) The nature and purpose of the research, and in particular the details of the participants' role were explained, allowing time for questions and further explanation if necessary.

iii) Patients who agreed to participate were given a prepared pack containing administrative documents and explanatory information for themselves and their partners or spouses, and they were asked to consider them carefully before signing and returning the participation agreement. The documents comprised;

- information sheets for themselves and their partner / carer (appendices 5& 6).
- consent forms for themselves and their partner or carer. It was explained that it was not a necessary requirement for the partner or carer to participate and that the patient could participate in a solo capacity if preferred (appendices 7 &8).
- contact details of the researcher, including a telephone number, in case they wanted further information either before deciding whether or not to participate, or at any time during the study.
- a letter to inform the patient's GP of participation (appendix 9).
- a stamped addressed envelope to return the signed consent forms to the researcher. "Informed consent" was achieved when the signed documentation was received by the researcher.

Very few patients were recruited to the study and the recruitment period was extended by ten months. However even after an extended period low recruitment was a matter of concern therefore following discussion the research team agreed that the clinical lead would extend the invitation to GP practices within the health authority. The letter of invitation is reproduced in appendix 10. No patients were recruited via this method and the reasons offered by the GPs are discussed in section 7.3.1 on page 182.

Patients who returned the signed consent form were randomised 1:1 either to receive the telemedicine electronic weighing scales in addition to usual care (TM group) or to receive usual care alone (UC group). This was achieved by means of assigning the consent forms to one or other of the groups alternately, in order of receipt. Thus the first, third, fifth and so on, signed consent forms that were received were assigned to the telemedicine (TM) group and those patients received the telemedicine weighing scales. The patients returning the second, fourth, sixth and so on consent forms which were received were not allocated the telemedicine scales and they continued with usual care alone. All participants were sent an introductory letter from the researcher telling them whether or not they would receive the automated weighing scales and instructions relevant to completing the first of the questionnaires. The questionnaires are reproduced in appendix 11.

The details of patients to receive the automated scales were sent to the nurse in whose care that patient lay. The nurse then;

- made a judgment of the value of weight change in kilograms occurring over a stated period of time which was clinically significant for that patient
- defined a working practice. For example the nurse could specify how often they would receive the weight data relating to each patient, or in cases of sudden weight gain whether they wanted the telemedicine company to contact the patient directly or simply alert the nurse in the first instance, and whether the task of conveying information relating to clinical matters to the patient's doctor should be carried out by the company or left to the specialist nurse.
- completed a call-centre questionnaire about the patient's medical history and sent it to the telemedicine company, so that their staff were able to make appropriate clinical judgements in the event that urgent action were required.

Once the first questionnaire had been received, the patients in the experimental group received the weighing scales from the telemedicine company and proceeded with the telemedicine monitoring. Data were collected according to the schedule already described in figure 7-1.

7.3 Results and discussion. When asked open questions about the study and about the monitoring and treatment of heart failure, the participants chose to address very similar topics and those are presented below. However they demonstrated fundamental differences in opinion and reasoning, which in turn raised practical and ethical questions about appropriate care for these patients. Some of those differences were identified not by verbal report during interview but by observation of their practice, as for example when defining a working practice for each patient. Those differences are also explored here as and when they are relevant to the issues addressed.

7.3.1 Recruitment and participation - GP practices. At least fifty-one GP practices throughout Cumbria and Lancashire were invited to participate. The exact number is not known as the clerical officer responsible for issuing the invitations left post before recording the final invitations to be issued. Eight GP practices replied to the invitation, expressing an interest in participating and requesting further details. Full details of the telemedicine system, the choices available to staff at the practice and the requirement of staff participation were given. In some cases several pieces of correspondence passed between the researcher and the practice managers. In addition a personal visit by the researcher was offered, to explain the requirements of participants and the implications for staff. Only one practice accepted that offer and only that one went on to participate in the studies. That practice did not ultimately recruit any participants to the weight monitoring study, but did recruit participants for the ECG study described in part three of this thesis. Six cited the unacceptable extra workload for themselves and their staff as reasons for not participating. The required workload entailed identifying suitable patients, explaining the study prior to inviting participation and giving the prepared information pack to the patient. If the patient agreed to participate there would be a short medical questionnaire about the patient's symptoms which the telemedicine company required the GP to complete. A fee of £50 was offered for this by the company as standard practice.

Two practices gave other reasons, the first reporting that;

> "(we) do not feel the heart failure/weight side is of particular benefit as we have a good heart failure nurse who is already overseeing these patients and there are obvious benefits for patients having local contact/specialist support."
>
> The second replied;
>
> "I've asked my partners and it doesn't sound as though anyone has any patients with heart failure who are at the stage where they would benefit from daily weighing."

The latter comment neatly demonstrates the differing concepts of "knowledge" insofar as that GP "knows" that there is a particular stage at which patients require weight monitoring, prior to which there is no benefit. This was an assumption also made initially by the research team, but it is by no means a universal view and was specifically contradicted by one heart failure nurse (see comment on p. 184). From the responses received, both from the GPs and later from the focus group of practice nurses, it appeared that it was the GPs who took the decision in every case and without recourse to the specialist nurses.

The GPs' comments implied that it was the prospect of an increased workload which deterred the clinicians from becoming involved with the research. This is not unknown in healthcare. Although much of the literature has focused on links between workload and a failure to utilise research findings, a survey of the key barriers to clinical research, undertaken in the Central and East London region by the Comprehensive Local Resource Network (CLRN) noted a lack of engagement by GPs as long ago as 1980, identifying a high level of bureaucracy and lack of administrative support as contributing obstacles, quoting, "Clinicians do not want to take part in clinical research if that involves spending hours of their time filling in tedious paperwork even before the first patient is recruited" (CLRN, 1980 p 9). At present it is a major drawback of collaborative research that, due to confidentiality and data protection issues, non-research clinical staff must gain the patient's informed consent before the researcher is permitted access to patient details and can take over the administrative burden. Interestingly, in a paragraph which appeared in the news section of the Imperial College (University) website (ImperialCollege, 2008) reporting the integration of Imperial College and St Mary's and Hammersmith Hospitals NHS Trusts, included the comment that, due to the integration "artificial barriers between research and clinical practice are removed." The nature of the barriers was not specified but it supports the notion that such obstruction is commonplace.

In addition to the unacceptability of increased workload, or perhaps because of it, some GPs still held the impression that remote monitoring would take away support and/or control from the local nurses, again demonstrating the power of a false belief. This belief prevailed, despite the GP having received both verbal and written explanation regarding the flexible nature of the call centre, for example that the data could be sent directly to the GP practice or relevant nurse without the call centre staff having direct contact with the patient. There was no way of identifying whether the GPs had sought the opinion of their nursing staff or if this was simply their own view, a "top down" approach to management perhaps being prevalent in some practices. It may of course be related to the workload aspect and that GPs did not have time to read or assimilate all the information concerning the research project. However in the case of one practice which had declined to participate in the heart failure study because they saw no advantage to the service, reporting that they already had good heart failure care in place, a focus-group interview with five heart failure nurses from that region revealed that these nurses saw remote weight monitoring as having potential benefits to their own work. This appeared to support a point made by other heart failure nurses, and which is explored later in this chapter, that the roles of nurse and doctor address very different issues in the care of heart failure patients, and the nurse's role is the better position from which to make decisions on issues of day-to-day patient care.

These findings indicated that:-

- Telemedicine trials in primary care may be obstructed because of the extra administrative workload on clinical staff in the early stages. This in turn may obstruct the dissemination of even the most advantageous intervention, as funding is not generally approved for new initiatives (such as telemedicine monitoring) in the absence of research evidence.
- The decision of whether or not to participate may have been different had it been made by the nurses responsible for the day to day care of CHF patients, instead of the GPs.
- Misconceptions or false beliefs about the nature of the telemedicine system and untested assumptions related to weight monitoring (which may ultimately prove to be correct) imposed a barrier to even the most rudimentary evaluation of this telemedicine initiative, by creating a circular argument in which;

they don't believe it will be of benefit
or they misunderstand the concept

because therefore

they refuse to experience it

7.3.2 Recruitment by the heart failure nurses. Of all the patients who had verbally expressed agreement to the nurses (approximately 60) only twenty-four returned the signed consent forms following the period of reflection. This represented 37 - 40% of patients originally identified as meeting the inclusion criteria, although exact figures cannot be given as one nurse left post without recording the final number of patients invited to participate.

This recruitment figure initially appeared to be unusually low, however closer investigation of some of the literature already reviewed (Roth, Kajiloti, Elkayam, Sander et al., 2004, Scalvini, Zanelli, Volterrani, Martinelli et al., 2004) indicated that it may not be unusual. For example in the former study almost 28% were "excluded" but this did not give any indication of the numbers refusing to take part, and in the second study almost 10% were excluded because they were "incapable of carrying out the procedures," which does not take into account those excluded for other reasons or those refusing to participate. It is likely therefore that the participation rate of 40% was not far from the norm. More recently a similar study (Dar, Riley, Chapman, Dubrey et al., 2009) indicated that their participants represented only 40% of those originally identified as having chronic heart failure. In that study the respective percentages of those not meeting the inclusion criteria, declining to participate or "excluded for other reasons" differed from those in this study, which may be due in part to the differences in demographic mix between patients in the rural North West and patients in the London area, however the point to note is that the findings of both studies relate to only approximately 40% of the relevant patient group. This supports the implications raised in the literature review of earlier studies that the benefits claimed in terms of reductions in cost, in-patient stays or time, relate to the minority of heart failure patients, and not to the majority as they appear to infer. For example, if a 25% cost reduction were claimed for an intervention of this kind in chronic heart failure, it is probable that in real terms that represents a cost saving of 25% applied to only 40% of the chronic heart failure suffers, representing only a 10% saving overall, which is a very different picture to the one initially implied. Nevertheless, a 10% saving of a budget of over £900,000, as mentioned in the literature previously reviewed in chapter 6, may still present a very attractive prospect to those concerned with funding issues.

The heart failure nurses were not surprised by the low recruitment, saying that many patients who had verbally agreed to participate when invited during a face-to-face consultation, had subsequently said that they had mislaid the information sheets and then forgotten about it, or "didn't want to bother." It was not clear whether the patients did not want to bother becoming involved in the study or, as the nurses suggested, found it onerous to read and comprehend the information. As with other issues, the researcher was not able to pursue this as consent had not been given (reasons volunteered by patients themselves are given in the next section) however it may be significant that a number of consent forms received had to be returned to the participants, often several times and requiring a number of telephone calls from the researcher, before they were completed correctly. For example some patients had signed the consent form relating to their spouse, although these were printed on different coloured paper for clarity. Others had ignored the separate components which required their initials, simply putting a single signature at the bottom. This might indicate that the nurses were correct in their view that the documentation was a problem for this group of patients who, as previously noted, are known to be at risk of some degree of physical or cognitive disability, either from the effects of heart failure or advanced age. It was not thought that it was likely to be due to flaws in the production or presentation of the documentation, as it did not happen in the study involving participants suffering from arrhythmia, which was conducted at the same time and used virtually identical forms. That study is described in part three of this thesis.

There was a further issue which emerged from the nurses responses as a consequence of reporting on recruitment. At least one nurse held an unacknowledged preconception about their doubt of some patients to comply with the requirement to monitor their weight during the study. Although only one patient was formally identified as meeting one or more of the exclusion criteria not all patients had been invited to participate, with that nurse commenting;

> *"I know* (this patient) *would not comply ..."*.

The same nurse later added;

> *"I've asked about nineteen patients … but some people come to clinic and you know they're not somebody whose weight fluctuates anyway…or somebody who cognitively would get in a real pickle about it ... I mean, there are patients I'm deliberately not putting in the study for you, just don't weigh themselves …"*

A second nurse referred to having similar thoughts and coined the term "cherry picking" of participants, which appeared to be a manifestation of that nurse's "knowledge" of patients, based on the past experience of patient behaviour according to existing working practice. Whilst their view might hold true for the existing working practice, it cannot be assumed that it would necessarily hold true for the different working practice associated with telemonitoring. For example in normal weight monitoring, which does not include supervision by a remote telemedicine system, the HF nurse would not know until the next clinic visit that the patient had not been monitoring his or her weight. Patients who habitually forgot would be excluded from that safety-net of care. If enrolled in the telemonitoring system, the patient would be telephoned and reminded if the weight was not received for two consecutive days. Thus the nurse's difficulty in comprehending a different working practice was obstructing the opportunity to investigate the potential benefits and almost certainly compromised the impartiality of the study.

The findings thus implied that approximately 60% of patients with chronic heart failure were not able to have their engagement with this telemedicine intervention assessed under conditions normally associated with research, due to the very problems of age and heart failure that the intervention seeks to alleviate. A further undefined percentage of patients were not able to have their engagement with the system evaluated due to some preconceived notions (which are not necessarily incorrect) on the part of the health care professionals, or because of restrictions imposed by inflexible working practices which inhibit change.

These findings led to the conclusions that research and/or patient access relevant to this telemedicine initiative will continue in one of three ways;

1. These patients will continue to be excluded from the enquiry intended to reveal how they might benefit from the intervention, or,
2. Items of equipment which are initially perceived as useful to decision-makers will be introduced as service tools in small and disparate areas, but will not be properly evaluated. Other items of equipment, which the decision-makers regard as having little or no use (even if they are mistaken), will not reach the stage of evaluation and will therefore be omitted from the potential to contribute to care Or,
3. Current practices, both in professional care and in research, may have to be reconsidered to enable evaluation of telemedicine monitoring for the full complement of patients with CHF. This is not to suggest that ethical practice should be compromised. Indeed imposing barriers which preclude those with cognitive disability might be considered to be unethical, but it perhaps suggests that there is a need to bridge the gap between the initial agreement to participate and the later administrative requirements following the recommended "period of reflection."

7.3.3 Patients' reasons for non-participation. Of the twenty-four patients who signed and returned consent forms four withdrew prior to completing any questionnaire or interview, indicating in the main that they perceived either the weight monitoring routine or the completion of the questionnaire as a burden rather than contributing to their care. Patients' comments included;

> *"I'm afraid it is just a little too much as it takes all of 2 hours per morning for medicines and pills etc. – we just cannot add to it."*
> *"I am reluctant to accept any more commitments."*
> *"I am unable to participate in your research as I have enough to contend with at the present time … I do not want any other commitments."*

Two of these patients had been randomised to receive the telemedicine scales and the interesting aspect of this response was that these patients had already received education and advice from their specialist nurse with a recommendation to monitor their weight. The mechanisms and role of weight change had been explained to them and a review of weight changes was a normal part of the regular clinic or home visit. Thus it might be tempting to assume that it was solely the extra tasks involved in the data collection, such as completing the questionnaires and keeping a diary of significant events that was responsible for the decision not to participate. However, subsequent interview material revealed that the patients did not necessarily understand, retain or comply with the nurse's advice on daily weight monitoring (see sections 7.3.4 & 7.3.13) and furthermore that the nurses accepted their non-compliance as a necessary reality. Once that was understood it became clear that even those patients who received the automated scales might reasonably perceive the daily weighing procedure to be an extra task rather than the opportunity to make an existing chore easier by automation. Exploration of the reasons might have usefully informed future research design in order to gain increased cooperation, but as the participants had withdrawn it was not possible to pursue this.

Four patients withdrew or were lost to the study after completing the first questionnaire. Three of the four were randomised not to receive the weighing scales and offered no reasons for withdrawing. Again it was not possible to pursue the reasons as the participants had withdrawn from the study. One patient had received the scales but withdrew on receiving the second questionnaire which was returned uncompleted, although his spouse did complete and return hers. Whilst this may support the notion that people who suffer from CHF find such tasks more difficult than those who do not, no reliable conclusions can be drawn from such small numbers.

Of the patients who agreed verbally to participate but did not return a signed consent form following the period of reflection, only one offered a reason, writing;

> *"The process of an automatic recording of information from within my home is a worrying harbinger of things to come."*

As the patient had expressed his refusal to participate it was not possible to explore this comment, but indicates that there may be factors other than time or administrative concerns that impact on patients' perception of technology and its benefit to their care. It is not known if this was an isolated case or if it related to any of the other patients who simply had not returned the consent form, but it should be noted that of the studies previously reviewed in chapter 6 which claimed a successful outcome for telemedicine monitoring, a substantial number of the authors over a period of forty years had included a specified schedule of telephone communication in their monitoring methods (Weinberger, Oddone and Henderson, 1996, Hanchett and Torrens, 1967, Ekman, Andersson, Ehnfors, Matejka et al., 1998, Naylor, Brooten, Campbell, Jacobsen et al., 1999, Stewart, Marley and Horowitz, 1999, Simon, VonKorff, Rutter and Wagner, 2000, Blue, Lang, McMurray, Davie et al., 2001, Capomolla, Febo, Ceresa, Caporotondi et al., 2002, Kasper, Gerstenblith, Hefter, Van Anden et al., 2002, Krumholz, Amatruda, Smith, Mattera et al., 2002, Laramee, Levinsky, Sargent, Ross et al., 2003, Ledwidge, Barry, Cahill, Ryan et al., 2003, Vavouranakis, Lambrogiannakis, Markakis, Dermitzakis et al., 2003, Robinson, Stroetmann and Stroetmann, 2004, Roth, Kajiloti, Elkayam, Sander et al., 2004, Tsuyuki, Fradette, Johnson, Bungard et al., 2004, Grancelli, 2005, Koelling, Johnson, Cody and Aaronson, 2005, Inglis, Pearson, Treen, Gallasch et al., 2006, Rogers, Perlic and Madigan, 2007, Giordano, Scalvini, Zanelli, Corra et al., 2009). It is possible therefore that a patient may perceive increased automation without personal contact as a threat to in-person care from their specialist nurse. The issue of personal contact with and attention from a named heart failure nurse was later shown to be an important issue for patients in this study, (see sections 7.3.12 on pages 214-215, and 7.3.15 pages222- 224).

The findings thus implied that patients may be unable or unwilling to perform the additional tasks that are necessarily associated with survey research at the present time, and furthermore that they may be unable persistently to recognise that daily weight monitoring is one of the measures which may help to safeguard their health. There may also be issues or beliefs, as yet unidentified but perhaps associated with the technology, which deter patients from interacting with it from the outset. The outcomes are that consistent performance, in terms of weight monitoring measures and research data provision, were obstructed in the circumstances under which they were evaluated in this study.

These findings led to the conclusions that:-

- A comprehensive evaluation of interventions in the care of patients with CHF may not be possible under the conditions currently imposed. It could be argued that those patients who agree to participate in such a study, and who comply assiduously with the requirements, may be those least in need of the intervention, as they are physically and cognitively able to perform the required tasks of monitoring self-care in any case.

7.3.4 Nurses' views of routine weight monitoring as a self-care stratagem. The nurses were unanimous in the view that weight monitoring was "the most important thing" in the early detection of fluid retention and thus in reducing the risk of hospitalisation and exacerbated damage to the heart, saying;

> *"Weight monitoring is fundamental, I think."*
> *"It's the first thing that changes of course."*
> *"They (the patients) start to build up fluid in their lungs, wake up, they can't breathe, it's a 999 situation."*
> *"You're trying to prevent someone coming in with two stone of fluid onboard and they'd have to be admitted then to get that off."*

It was interesting therefore that the nurses differed in their opinions about many of the details of routine weight monitoring, including whether it should be used in every case. For example, one nurse thought that it was not necessarily important for all heart failure patients, as;

"Not all of them suffer from fluid retention, with heart failure being quite a complex condition with many causes it means not all are at high risk of fluid retention…"

Some even considered weight monitoring to be counterproductive in some cases;

"… the least fuss and bother, the better the patients buck up I find"

This nurse thought that twice-weekly weight monitoring was appropriate for many patients, but suggested that the routine should be tailored to the individual, saying;

"A lot of the time I think we try to put things into boxes and it's not possible with people is it?"

A strongly opposing view was proposed by another heart failure nurse who said;

"… that routine of weighing themselves daily … it's a huge component part of heart failure… and even though they haven't got any symptoms … I would still suggest to those patients that they are in the routine of weighing themselves daily" (because) "you may find patients who are maybe a 2 (NYHA) can go up to 4 and it can be quite a … a relatively short space of time ..."

The same nurse offered a supporting argument in favour of daily weight monitoring in even the earliest stages of heart failure;

"It's good practice for them, so that if the condition does deteriorate they already know that weighing themselves daily is a part of their management programme … so I'd have thought that NYHA1 patients need to weight themselves daily as well."

As previously noted this comment was particularly surprising as the research team included two specialist heart failure nurses and a GP who, having examined the design of similar earlier studies, had agreed with very little discussion that patients with stage 1 NYHA disease would be excluded from the study on the grounds that the symptoms were too mild to demonstrate any benefit from the equipment.

The multi-purpose view of weight monitoring was echoed even by nurses who thought that daily monitoring was not always appropriate, with one nurse saying;

> *"You're encouraging them to weigh themselves* ***and to learn to manage their condition."***
> *"At the same time it maintains contact with the patients. It's useful in that way because you periodically have patients speaking to you about their weight. So that's a useful opportunity to check out that everything's alright."*

This of course relates to the routine of weight monitoring per se, and not to ***automated*** weight monitoring, which might arguably be said to remove the last two of those useful additional features, as;

a) the management of the condition may pass from the patient to a third party, and
b) there would be no need for the patient to discuss the weight record with their nurse, and so that opportunity for discussion would no longer exist.

Although the nurses were in agreement that daily weight monitoring would be beneficial if patients could accomplish it, they were reluctant to place any great reliance on patients' reports given during clinic visits, because as one nurse commented;

> *"…they could write anything down on that piece of paper that they bring to clinic, they could make out they've been weighing themselves every day,"*

The findings thus implied that although the heart failure specialist nurses agreed that weight monitoring has a very important role to play in the care of their patients they disagreed on almost every aspect of the procedural details, such as;

- the patient group to which it should be applied, i.e. all patients or just selected individuals.
- the schedule, whether it must be daily or should be tailored to the individual patient.
- at what stage of the disease it should be introduced, from the very earliest stages of diagnosis or not until weight fluctuation became symptomatic.
- its function, whether it is to identify physical change, to educate the patient in learning to manage the condition, to train the patient so that weight monitoring continues even if dementia ensues, or to provide a framework for discussion between nurse and patient.

The comments from the nurses and GPs regarding the role and weight monitoring provided the earliest indications that the concept of heart failure care was not a universal constant in which the only variable was the patient. Individual health care professionals appeared to have individual perspectives of the best way to treat patients with heart failure, although whether those perspectives arose from experience or from individual traits of personality, or even ability, was not apparent. If due to experience then it should presumably be possible, with the appropriate exploration, to identify the best mode of care. If however those perspectives arise from an individual's own cognitive, affective or even psychomotor domains[9], then doubt must be cast on the effectiveness of any evaluation which imposes a strict control of operating procedures.

These findings led to the conclusions that:-

- Either there is a single "correct" process of weight monitoring, in which case some of the heart failure nurses are wrong in some of their beliefs and the case for daily weight monitoring of all patients can be established,

… or…

- The "correct" process varies for each patient and is a function of the individuals involved, the individuals being both the nurse and patient, and possibly any others who interact with that area of patient care. In that scenario the case for daily weight monitoring of all patients is not established and consideration should be given to find a regimen more appropriate to the prevailing circumstances.

7.3.5 Nurses' views on the potential value of the telemonitoring system (prior to using it). Even before they incorporated the telemedicine system into their work there is little doubt that the nurses saw potential benefits in having an early alert system.

> *"that's the idea with heart failure ~ that you get in quick to do something about it before you get this huge amount of fluid building up."*

It was seen as propping up a limited service where staff was in short supply;

> *"I mean … there's just been myself in post, in …a large area … with one of the highest rates of heart disease in the country ... they* (managers) *would find that quite beneficial because it's one way of keeping that monitoring system going and the support system going…"*

[9] For explanation of these terms refer to information on "Bloom's Taxonomy."

Examples from their caseload were often given;

> *"I've just turned around a patient this week who* (I) *suspect he has been ill for at least six weeks, it's taken us two or three weeks to get him anywhere near normal … whereas if it had been recognised earlier… I think it would have never got as bad as it got."*

The nurses were of the opinion that telemonitoring would alleviate some of the problems for patients who could not read the scales or record their weight due to physical disability, or who had socio-psychological issues, because;

> *"… monitoring would be still ongoing and you'd still get the call or could just review it yourself without the patient worrying too much about what their weight is, or what they should do about it."*

They saw the transference of the task of comparing weight to previous measures and assessing the need to summon help as providing useful support for more vulnerable patients, such as;

> *"those who have cognitive problems and can't quite comprehend the importance of monitoring weight or what to do."*

The potential they envisaged for the telemedicine scales reflected their views on weight monitoring, thus they identified a potential role for them during periods of fluid balance instability, specifically for people 'in and out of hospital' and during the early stages of titration (adjustment of medication). Two nurses also identified the potential for increasing compliance in patients who;

> *"… are motivated by getting involved in technology,"*

or who;

> *"…might think 'well I have to get on the scales because* (nurse's name) *is going to get the reading'…"*

The latter comment came from the same nurse who subsequently "cherry picked" patients for the study, passing over those whom she thought would not comply. A mismatch between the philosophical and conceptual standpoints had occurred at some stage. Her actions undoubtedly impacted on the current research to some extent, by excluding some patients who arguably had greater need than those predicted to comply. However they also suggest that the adoption of telemonitoring systems by a wider audience of clinicians may not be easily achieved and that beneficial outcomes may not necessarily be able to be generalised to other circumstances.

The previously expressed concern about the effect of daily weight monitoring on a patient's emotional state was revisited;

> *"sometimes ... patients can be a bit obsessive and they live in absolute dread of this weight going up and ... I just wonder if that's there if that would make them more obsessive and if that would exacerbate those feelings."*

However cost implication was the main reason offered for assuming that the equipment would have to be rationed rather than used for every patient, even though the nurses admitted they had no idea what that cost would be;

> *"In the real world of the health service, I would suspect we won't be able to get electronic scales for everybody because ... it would cost about, I don't know how much a system would be, but I assume it would be in the tens of thousands of pounds if not more."*
>
> *"... it rather comes down to resources and if we have limited resources, we need to target people who would benefit the most."*

Unfortunately, from the preceding evidence offered it would appear that specifying those people is an almost impossible task, due to the idiosyncratic nature of care which depends not only on the individual patient but also on the individual health care professional.

Two nurses were very sceptical of funding being available without;

> *"... hard outcomes evidence ... we wouldn't get that purely on the basis of patients finding them satisfactory and feeling that their anxiety levels decrease by using them.*"

These two nurses demonstrated their knowledge of research from other sources to suggest potential benefits to the telemedicine scales which, if applied to their immediate daily practice, may support the case for the equipment to be provided for them. One nurse, for example, based in a large hospital clinic, commented;

> *"The United States, Harlem, have been doing telemonitoring … the key was the bilingual worker …and it does make you wonder, we have a large Asian population…"*

This nurse was the only one to mention a culturally diverse patient caseload and unfortunately was the nurse who was not able to recruit participants to the study. The other nurse appeared to have only a local and very elderly patient caseload, but nevertheless suggested issues which she thought relevant to improvements in the efficiency and effectiveness of her own workload. For example;

> *"It would be interesting to see, if they do put on weight, if there is something happening or how often it happens, how long does that last? I think you could pick up quite a bit ~ and concordance, what do they perceive, have they got this message over, do they understand it, and yeah just to see what happens to them…"*

Of the nine heart failure nurses interviewed (four individual interviews and one focus group of five persons) only the two quoted immediately above were in the habit of reading research papers regularly. Their comments in this section support the argument that the use of telemedicine scales depends not only on the variations between patients, but also on the differences between health care staff.

The findings thus implied that all nurses predicted potential benefits which were related to their immediate practice and to their views on the role of weight monitoring, therefore they offered different examples such as the regular close monitoring of "brittle" patients, helping those at physical disadvantage and encouraging compliance. The appreciation of potential benefits which required a change in working practice, or a shift in perspective such as identifying trends related to the disease, or widening the access of care to those patients who were currently disadvantaged due to language difficulties, was rare. Nor did all nurses translate the potential benefits they had envisaged into appropriate action, for example in the case of the nurse who thought that telemonitoring may encourage patients to comply but did not try to recruit non-compliant patients. Entrenched attitudes or patterns of behaviour in current nursing practice appeared to override the theoretical potential envisaged for the equipment in this case, which in turn precluded an unbiased evaluation.

These findings led to the conclusions that:-

- Nurses are likely to use the telemedicine scales in an idiosyncratic fashion, according to their differing levels of knowledge, experience and entrenched working practices, at least in the early stages.
- The measurable outcomes from the early idiosyncratic use of the equipment may have implications for the perception of the "success" or "failure" of the system and the subsequent deployment or rejection of automated remote weight monitoring.
- The achievement of "best practice" in the employment of the telemedicine weighing scales will require adjustments in staff perspective. This will in turn require planning, motivation and time as staff need to embrace different working practices which the telemedicine technologies make possible.

7.3.6 Differences in deployment of the telemonitoring equipment by staff. The telemedicine service could be tailored to the requirements of the individual user, negotiating specifics such as the schedule of weight monitoring and the nature of the action to be taken in the event of a patient's weight rising. There was a proviso that in the event of not being able to contact the nurse then they were free to inform the patient's GP or take whatever other action was required to ensure the patient's safety.

The remit of the study was to evaluate daily weight monitoring therefore the nurses could not opt for weekly or bi-weekly monitoring for any patient, even if they thought it preferable. This was, with hindsight, an error, as with more flexibility to conduct weight monitoring as she saw fit, the nurse who had "cherry-picked" patients may have invited a wider audience to participate. The nurses were free to negotiate all other details and they elected to deploy the facility in different ways. For example one nurse retained control of all patient contact. Thus she received a list of patients' weights by email, and reviewed all of them herself. She chose to take the lead as first-line contact in the event of an identified weight rise in one of her patients, saying;

> *"Personally I think it best if* (the company) *let us know about changes rather than the patients direct as I think this could muddy the waters and increase patient anxiety."*

Conversely the second nurse delegated a substantial part of the burden to the call centre from the outset. Although all weight data were received by email and available for review, this nurse chose to receive an alert to a weight rise outside pre-defined limits for each patient and permitted the specialist cardiac nurses at the call centre to contact the patient in the first instance to carry out an initial review. That review included checking that the weighing procedure had been carried out correctly, whether there was an increase in other symptoms and discussing an adjustment to medication. Full report of alerts and the actions taken by the call centre staff, including a précis of conversations held with the patient were sent to the heart failure nurse, who then made a decision about follow up action. The "normal" weight data were also reviewed by the nurse, but only intermittently when it was convenient to do so. Not surprisingly the nurses' perceptions of the implications for their workload and working practices were very different and this is discussed in section 7.3.9.

The findings thus implied that staff can and do deploy the telemedicine facility in very disparate ways. They may not feel comfortable in having a particular working practice imposed upon them in relation to their first contact with the telemedicine facility and a mutually acceptable working relationship between call centre staff and the heart failure nurse may take time to develop.

These findings led to the conclusion that:-

- Consideration must be given to the best methods of introducing the telemedicine equipment if it is to be introduced into nursing care, as early negative experiences may lead to reluctance to deploy it, giving rise to false perceptions to those responsible for the policy decisions on its employment.

7.3.7 The value of the system after six months experience of using it. Despite the very different methods of deploying the telemedicine facility both nurses with patients enrolled in the study were enthusiastic about the potential to use the telemedicine weighing scales in their professional practice. It has already been noted on page 186 that nurses "cherry picked" patients and that this had acted to preclude some patients from participating in the study. It was equally obvious that, following some months of experience of using the telemedicine weighing scales, the nurses also wanted to select patients whom they specifically thought would benefit from monitoring via the telemedicine system, for example the patient who;

> *"Stopped diuretics and went bizarre … could've monitored quite closely with automated scales"*

Another example offered was of a patient who returned home from holiday with fluid overload and had to be hospitalised. His heart failure nurse thought that telemedicine monitoring on discharge might allow him to be discharged from hospital earlier than otherwise expected. This unfortunately did not happen as the study ended before the patient was able to be provided with the telemedicine equipment. However it is a strong indication that the nurse saw a real and practical use for telemonitoring within the remit of her own work. This view was repeated on a number of occasions, for example;

> *"I'm glad* (patient's name) *has gone on the scales because he's somebody whose weight really does fluctuate and who I see regularly."*
>
> *"I have a patient lined up for when we go live again."*

One of the nurses commented that they would have preferred to remove the weighing scales from some of the participants and to have given them to patients whom they felt would have benefited, because;

> *"the patients recruited to this study stabilised very quickly … so the direct medical benefits were not strongly demonstrated in this group"…*

This was not possible, partly due to the randomised nature of the selection process for those who received the scales, but largely to the fact that many patients did not want to be participants in the study. The nurse did note an unpredicted benefit for those patients who had received the weighing scales, in that the weights recorded by the telemedicine company were discussed with the patient at each clinic meeting and the nurse found this useful in reinforcing the monitoring aspect of self-care. It is an interesting thought however that in this case the essential elements of a randomised controlled trial might have inhibited the demonstration of certain advantages of the equipment. That notion was supported by another nurse who commented;

> *"… if we were just saying to people 'would you like these scales* - *this is what we have on offer? then obviously a big chunk of that time would disappear…"*

Both nurses whose patients were included in the study experienced instances of being alerted to a patient's weight gain by the call centre. On one occasion it transpired that;

"the weight gain was not due to heart failure, ***but could have been****..."*

The nurse in question therefore still perceived advantages to the telemedicine system, despite the inconvenience of an alert which was, in this instance false.

In general the advantages identified with the benefit of hindsight were the same as those which had been predicted. For example nurses continued to express the view that a certain patient would not benefit because;

"... he's pretty much on optimum heart medication,"

They also suggested that the system should be used for;

".. a rolling programme .. through the titration process ..."

"...patients who had been in (hospital) *a couple of times, who need close monitoring,"*

In at least one case the nurse appeared to appreciate an opportunity that had not previously existed, saying;

".. somebody you had concerns about who ... it's more of a gut instinct, intuition that would make me think 'Oh yeah, let's try those scales'."

The findings thus implied that the nurses viewed the potential benefits of telemonitoring largely in relation to specific preferences in their own existing working practice, and particularly in relation to their existing patients. Realisation of the benefits may be inhibited by the research process, which appears to act to discourage both the patient's involvement and the nurse's ability to exercise clinical and analytical judgement.

These findings led to the conclusion that :-

- Appreciation of the full complement of benefits and/or detriments inherent in using the telemonitoring weighing scales may require two prerequisites.
    a) that the nurses are able to utilise them in their preferred manner. This includes the method of working relationship with the call centre and also their method of treating heart failure, which is dependent to some extent on their approach to care and their beliefs related to weight monitoring, and

b) that they use them for a prolonged period of time to allow their practice to evolve within an environment where telemonitoring is readily available.

7.3.8 Nurses' views on the importance of telemonitoring relative to the clinical review. Despite the nurses agreeing that the telemedicine system would be a useful additional facility, they were keen to emphasise that it could not replace the clinical review. The face-to-face relationship, they said, was needed for physiological assessment such as detecting symptoms via smell, colour, lung sounds and Jugular Venous Pressure. It was also essential in establishing a relationship with the patient that would facilitate later discussions related to sensitive topics associated with heart failure, such as erectile dysfunction or end-of-life issues. More importantly, in the context of this study the relationship established would also provide the knowledge on which to base their decision of the appropriate action to be taken in the event of an alert from the telemedicine company to a patient's weight gain.

> *"I am re-familiarising myself with that patient's normality…"*
> *"If it's somebody who I don't really know very well … I wouldn't say to them 'increase your water tablet by such a thing today, drop it tomorrow,' because I wouldn't feel confident."*

Whether the alert had come from the call centre or from a patient, the process of care by the nurse from that point on would be the same;

> *"I would still contact the patient … how quickly I contact the patient would rather depend on who it was…if there's a patient I knew that was at risk and I was concerned about I would probably ring that patient quickly... if it's somebody who I felt was much less at risk I would probably wait for another day or two recordings to see what they were."*

Thus the action taken by the nurse following a recognised weight gain appears to rest more heavily on their knowledge of the individual patient rather than on the objective weight data. In the nurses' view the detail of that knowledge is what makes them valuable in the care of patients with CHF;

> *"I think that's why heart failure specialist nurses do such a better job than doctors at managing heart failure, because it's not just about the heart and the*

lungs, it's about the whole issue, diagnosis, you've terminal illness, end of life issues, family support, benefits, diet, smoking, alcohol, maybe lifestyle changes for some people."

The findings thus implied that the nurses believed that objective telemonitoring data were inferior to subjective assessment of the individual patient in terms of evidence used to formulate appropriate care. They would therefore use telemonitoring to support and enhance the individual and subjective aspects of their patient care rather than to prescribe uniform action.

These findings led to the conclusions that:-

- if remote automated weight monitoring were to be utilised in areas where there is no heart failure nurse provision in place at that time, it is likely to require the development of some form of patient / health care professional relationship, either with the staff at the call centre or elsewhere, rather than a simple provision of objective data, if it is to be effective.
- if it is used by heart failure nurses it is likely to be an addendum to current care, rather than replace any feature of it. Therefore it would be unlikely to decrease their workload to any significant degree and thus not afford an opportunity to increase their caseload to include greater numbers of patients. The nurses were aware of this and their concerns related to workload are the subject of the next section.

7.3.9 Nurses' views on the implications for workload. The additional support provided by the telemonitoring facility was not without its problems and the nurses expressed concerns about how it might impact on their existing workload and working practices. There were three junctures in the process of introducing telemonitoring into their daily practice when the nurses could see a potential for increases in workload. These were;

a. the initial stage of establishing a new patient on the telemedicine system
b. the process of installing the equipment in the patient's home, and
c. the continual process of data review.

In the initial stage of establishing a new patient on the telemedicine system the company required the nurses to complete a medical health questionnaire for each patient, using information from the patients' medical notes. For one nurse this presented no problem, partly because this nurse had clerical support and partly because, being based in the community instead of in a hospital situation, the patient's notes relating to heart failure were stored in the nurse's office and not in a central filing department.

> *"I've my own records here which already contain all that information, so … probably about two, three minutes … not a big deal"*

Conversely, the nurse whose job was based in a busy hospital clinic did not have clerical support and;

> *"I haven't had time to do it … I have my own notes but I don't keep the medical records. So it's just that time factor thing."*

This nurse had identified this as a problem at the outset, and when asked to complete the medical questionnaire required by the telemedicine company, commented;

> *"I just know I'll be having to find case notes from all over the place…"*

This was the first intimation that specific features of their job which were not under their control would affect the nurse's perception of whether the telemedicine system was an advantage or an encumbrance. However this nurse was able to query the current research practice, which was for her to see the patient in clinic and request the weighing scales if appropriate, after which the company would send the questionnaires to her for completion. She pointed out that if she had a stock to hand she could complete them instantly because the patient's medical records were available to her at each clinic appointment. Thus the nurse had successfully adjusted one working practice to provide a solution in this case, although this was an isolated example and was related to the research practice and not to heart failure care. Examples of how the nurses' perception of the telemedicine system was influenced by the nature of the post they occupied are offered below.

The second area of concern was the stage at which patients had to install the equipment in their home. The community-based nurse was prepared to undertake that task during a normal home visit to patients, seeing this as an acceptable addition to workload in order better to help patients, but pointed out that not all specialist heart failure nurses visit patients at home as part of their general duties and so this might not apply to all situations. Furthermore they predicted that changes to working practice might be imposed which would restrict the time available for home visits;

> "(Nurse's name) *is only doing 2 or 3 clinics a week but that will alter ... will do 5 or 6 a week the way things are going politically. It's not nice…"*

The two nurses who worked sequentially in the hospital-based post both expressed reservations about their ability to undertake the task, even if the time were available, one of them saying;

> *"I'm going to have to get (person's name) to show me that because I've not seen it physically set up."*

The fact that intelligent health care professionals felt the need for a demonstration of the installation process, rather than simply using the instructions that were supplied with the equipment, lent credence to the notion that patients suffering from the effects of CHF were not likely to accomplish this easily and that a high percentage of them may require assistance. Furthermore nurses who conducted most of their work within the hospital setting would have little opportunity to take on this task, because;

> *"...I don't think we'd be allocated time to do it…"*

Whilst representatives of the telemedicine company had helped participants in this study, the nurses doubted that would be possible in the long term, not only due to the numbers of patients but to the distance of some patients from the company headquarters.

> *"The company reps have been out and seen patients in Manchester which is where the company is, but ... they aren't going to come up here"* (referring to a practice in a remote part of the county).

In this example a potential problem had been identified but not solved, perhaps because the problem was as yet only "potential" and not realised in practice. One nurse did suggest however that this was possibly one area in which family members might assist.

The final stage in which the nurses discussed the implications for their workload was related to the review and processing of the daily weight data. They held opposing views which arose mainly out of the different ways in which they had chosen to deploy the telemedicine service. In the case of the nurse who retained control of all data review and patient contact, this took time which was currently allocated to other duties. It was, she said, equivalent to a clinic, and was not reasonable to reduce the service by one clinic per week in order to;

> *"end up looking at two hundred normals … it's a potential kind of negative outcome for me"*

This nurse was not able to explain why she had retained control of the data to that extent, but after six months experience of the system concluded;

> *"… say it was something that we adopted, then I would probably say, 'I just want you to send me abnormals.'"*

It appeared that devolving some of the tasks to a third party was difficult in the beginning for this nurse, but that increasing familiarity with the service over a period of time had allowed the necessary adjustments in procedure to take place. This period of adjustment had not been required by the second nurse who delegated a substantial part of the burden to the call centre from the outset. This nurse also reviewed the data, although only occasionally and when convenient, finding this;

> *"… a relatively quick* job *- the information's there on the computer, It's just a case of looking at it… if there were hundreds of patients using them, I don't feel it would be a huge increase in work load."*

The reasons for differences in the way the nurses used the facility at first, and their respective difficulties in viewing the data, are not known. It may be due to differences in training, experience in the job, competence in associated skills such as interrogating data spreadsheets, or any other unidentified factor. The important aspect is that both arrived at the same point eventually, managing the data flow to best advantage. However none of the nurses felt that they could predict long term implications for their workload with any degree of accuracy, because the eventual outcome of an improved data flow was unknown to them. It appeared to be dichotomous. If, for example, there was a tendency to identify weight gain more readily then more patients may require follow- up procedures;

> *"…are you saying those are the people who might come to the clinic more often … and then they've got to have this full review?"*

That, they could see, would involve them in extra workload, but;

"The flip side of that is that it may save work load, in that if a patient goes several days before they ring me, on the traditional system they'll be several days worse off and ... it usually it takes the same amount of time to get somebody back to normal as it has taken them to deteriorate."

Because most patients who agreed to participate in the study had remained stable throughout, there was limited information about the course of events that would occur following an identified weight gain. The nurses were therefore unable to predict whether their workload would increase or decrease as a result of telemonitoring, because although the early detection of fluid overload would probably save nursing time in the long term, the investigation of weight rise which was not ultimately due to fluid overload might be considered to be time wasted, adding an unnecessary burden to an already overstretched service. The cost of not responding to a recognised weight gain cannot be quantified and nurses were very conscious of a need to present measurable outcomes of their work, but felt that much of that work was not recognised;

"…in today's economic climate ... you have got to prove just how (cost) *effective you are being*" and;

"The workload for heart failure nurses has not been counted, only bed days (in hospital)*"*

In a situation where a reduction in bed-days is the measure of effectiveness, there is a danger in being too efficient in recognising a patient's deteriorating condition because;

"*We do also contribute to admissions ... maybe keeping patients well reduces the workload of the heart failure nurses, not necessarily bed days."*

Attempting to assess the impact of telemonitoring on workload therefore, at least from the nurse's point of view, was a pointless exercise because;

"... it's (workload) *always going to be difficult to measure because of the unknown variables…"*

"It's going to be technology which we may feel is a benefit but perhaps struggle to prove in the sense of hard outcomes but I think we will be able to prove in terms of patient cope-ability and acceptance."

However although they were not able to predict from their experiences of telemonitoring how the quantity of work might change, it was readily acknowledged that telemonitoring might effect a practical change in the pattern of work;

> *"I don't think it would probably save on visits. It might allow the visits to be scheduled slightly differently. It may bring forward or delay a visit to a more appropriate time."*

The findings thus implied that the effect that telemonitoring would exert on the workload of heart failure nurses appears to be, at least in the early stages, dependent to some extent on job-specific factors. The workload may undergo an increase at first, but would probably diminish to some extent over time, as new working practices evolve to accommodate the requirements of inducting patients into the telemonitoring system. The ultimate effect of telemonitoring on workload for heart failure nurses is virtually impossible to predict and will be impossible to quantify, at least in the foreseeable future. This is because there is at present no complementary measure of patient "wellness" with regard to fluid / weight variation, thus no way to predict at what point nurse intervention is required. There is no reason to doubt that the number of hospital in-patient bed days per patient would reduce, as it has done in other studies, however the number of patients being admitted may increase due to early diagnosis of weight increase which might otherwise have resolved.

These findings led to the conclusions that:-

- working practices are likely to evolve as staff develop effective interaction with the data provided by the automated weighing scales and remote monitoring system.
- an evaluation of the impact on nursing workload could not reasonably be properly conducted until that process of evolution has occurred.
- research is required to determine the most appropriate points of change during weight monitoring, and the most effective strategies to be applied in remedial nurse intervention which will produce the best outcomes.

7.3.10 Implications of the nurse/patient relationship for working practices. Apart from the slight practical changes to the normal pattern of work described above, the benefits of telemonitoring were portrayed mainly in terms of the ways in which it could corroborate the patient/nurse relationship. For example the patients' desire for a higher level of attention and contact from their heart failure nurse was well known to the nurses, one remarking;

> *"A certain patient I know, if I say three months* (until the next clinic visit) ... *her face says… three months? ... and I can put a month's wages on the fact that they will ring me up* (before then)*... about a minor query … they want to have that contact."*

The nurses saw some benefit to fulfilling that need;

> *"if that keeps them at home and stops them occupying hospital beds or taking up the GPs time by an inappropriate appointment, then to me that's fine..."*

It was not always possible to do so however, as one nurse who had been asked by a patient to visit her more often commented,

> *"I said 'Of course I will' … probably the wrong thing to say, I can't do it, too many clinics."*

From the nurse's point of view telemonitoring could address the need for contact, at least partially, insofar as it was a tangible reminder of the nurse's care, using it for;

> *"…patients who you try and put them on six weeks review but…they're used to regular contact with you...six weeks is too long for them."*

In that example the daily weight monitoring was introduced in a way that emphasised the nurses' watchfulness of their condition;

> *"They've all accepted my thinking of a way to improve their safety and that's how I've been discussing it with them."*

The nurses felt that this was a two-way interaction, as emphasis of the nurse's surveillance also made the telemedicine more acceptable to the patients. In the nurses' opinion the inclusion of third party researchers in the process created a psychological barrier between the telemonitoring system and their nurse, impeding patient acceptance;

> *"…if it comes from outside they don't want it…"*
>
> *"the gap between the participants and the carers* (nurses) *is too remote I think…"*

The nurses accepted that policy makers may raise a possible criticism of the automated weighing scales, in that;

> *"Theoretically you could make an argument that it's making the patient dependent and less independent. I personally wouldn't go for that being true I can see that would be one possible criticism."*

However, as they also pointed out, a high level of dependency of a patient on their nurse was an inevitable feature of CHF, to the point that;

> *"...I personally suspect they* (physical findings) *are less important than people feel more looked after"*
>
> *"...if they feel they're being looked after, that's what's different, they're becoming reliant on you, can't discharge them."*

Although the nurses did not see telemedicine as permitting them to discharge patients, they suggested that it might provide a sort of "half-way house" for patients deemed well enough not to require frequent clinical review. The reluctance to discharge patients was particularly important to one nurse who suggested that there might be;

> *"...a definite hierarchy of outcomes dependent upon what level of interaction you have."*

It is not surprising therefore that, in addition to providing a useful resource for their clinical practice, nurses saw telemonitoring as an opportunity for patients to perceive an increased level of support and individual attention from their nurse, which they were in reality unable to provide. They also envisaged potential opportunities, which in the present circumstances would be lost due to the political arena in which they operated. One such was the suggestion of shared holiday cover, that nurses;

> *"might be able to check for 'reds'* (alerts from the telemedicine company of patients in danger of fluid overload) *when someone is on holiday for three weeks."*

This was not possible at the present time, they said, because;

> *"* (nurse's name) *is PCT and I'm secondary care, which is very political isn't it, when we work together, it's the way it's funded.."*

Lost opportunities notwithstanding, there is no doubt that the nurses recognised both potential and actual value in the telemedicine scales, as evident in this final comment made by the most senior nurse;

> *"I think I would need a maximum of 12 scales. I would imagine around 6 being in use at any time 12 would allow more flexibility for surges in demand."*

The findings thus implied that the nurse/patient relationship is necessary to the acceptance of the telemedicine scales by patients, and conversely that the telemedicine scales may have the potential to at least partially fulfil the patient's need for greater nurse contact. The potential criticism that telemedicine scales increase dependency in patients could be considered to be irrelevant in the context of chronic heart failure, as dependency is an inevitable consequence of the disease as it progresses. Some political and/or administrative factors inherent in the current working practices of nurses inhibit the full potential of the scales. These factors include funding and administrative mechanisms of healthcare provision and the requirements of the research process.

These findings led to the conclusions that:-

- in addition to the daily monitoring of weight and early alert in the event of a rapid weight gain, automated weight monitoring has the potential to fulfil a secondary goal of providing assurance of care to patients.
- if telemonitoring is to become a normal part of care for patients with chronic heart failure, particular attention will have to be given to the issues surrounding the healthcare provider/patient relationship in situations where there is no heart failure nurse in post, for example where the first-line monitoring care is in the hands of a GP or devolved to the telemedicine call centre.
- some potential benefits to telemedicine weighing scales, such as the facilitation of emergency cover during periods of absence of the regular nurse, may remain unfulfilled due to the organisational and administrative structures in place at the present time.

7.3.11 Patients' and carers' perspectives. The views of the patients and their spouses, or other close relative or carer who had agreed to participate in the study, are addressed together as the participants were generally interviewed together. The intention had been to interview the participants separately but they were unwilling to do this and both partners contributed to the discussion, frequently interjecting to confirm or emphasise further what the other was saying. It was noticeable that some patients looked to their partners to remind them of certain events which they wanted to relate but which they had forgotten as they lost track of the conversation. There were some issues, not immediately concerned with telemonitoring, on which the patients felt the need to express themselves and those issues are explored as the wider implications may impact on the use of a telemonitoring system.

Many patients expressed a negative, but arguably realistic, view of their condition,

"It's a miserable existence and I'm sick of it."

"*There is no cure for this condition … medics can't do any more … told it's just old age … they've all said 'we can't do anything for you'*."

On describing his symptoms to a cardiologist in the hope of finding a remedy, one patient reported being told,

"she (the doctor) *said no, it's just old age, and that was that."*

Participants were quick to offer examples of how having CHF affected their daily life. Decline in cognitive function was the most frequently reported issue for all participants. This is a frequent finding in elderly patients with chronic heart failure (Spiecker, 2006) and affected participants' lives in a number of ways, for example in contributing to a loss of confidence,

"*I can't think … I'm flaming stupid, I feel stupid. I hate it"*

" *… I'm rapidly losing any confidence … I can't cope anymore*."

"I used to run machines … now I fall to bits."

In most cases patients reported that the cognitive dysfunction acted to restrict their normal daily activity.

"…somehow or another I didn't feel confident … I didn't like walking out by myself for quite a while."

"I didn't understand how to fix it … up with the rest" (referring to a "freeview" box.)

Carers however indicated that perhaps patients were not always aware of their confusion;

"He doesn't sort of remember you know, he keeps asking what are we doing, when are we going to, what time are we going to …"
"He said to me … 'Ethel (name changed) *will want it when she comes in and I said 'I'm Ethel…'"*

The loss of independence and a leadership role within their relationships was also a common thread, with partners tending to take over this role,

"*Good job she's (spouse) got the brains you know*."

The partners were aware that this was sometimes a source of frustration to the patient;
" *… he doesn't like to ask you see* … (he says) '*I can do it, I can do it'."*

The patients too were aware of their frustration and that it was sometimes the cause of anger.

"I get angry then and I start shouting, I don't know how she put up with me all these years."

One way in which they struggled to retain control was in refusing to relinquish the responsibility for scheduled tasks such as taking medication,

"I did it at one time, but then he said "I can do it" so he does it now. We have four little pots … he's got them lined up … and puts them out every night."

Such desire for independence sometimes caused friction within relationships. For example one spouse said,

"*he wants to do it, he won't let me do it*"

and the patient interjected,

"*I get in trouble with her and we have a row*…"

Depression and anxiety, also common adjuncts to heart failure, were mentioned by two patients.

"They asked me if I get depressed …I always have bad days."
"I get very emotional … if Tom and Jerry started fighting on the telly I'd cry. You know, it takes nothing, nothing at all."
"I just feel agitated."

"She knows I get stressed."

Another common manifestation of the problem was the fear of being alone and either socially or physically unable to cope.

"*What if I was on my own? … I get a bit scared at that … (puts) fear of God into me*,"

"*I couldn't imagine there not being anybody.*"

At least two participants, both of whom were in their early eighties, had found a solution to that problem by developing internet friendships which, they felt, gave them time to construct their responses and review them before making them public, so;

"*It doesn't matter if I make a slip*-up."

This neatly encapsulates both the vulnerability of the patient and the fact that they can adapt their behaviour to find solutions which are at least partially satisfactory. As one patient said;

"… it's (the internet 'chat line') *saved my sanity…"*

It was interesting that one of those internet friendships, sought and actively sustained by the patient, was with a nurse in America with whom he "chatted" online on a regular basis about his heart failure.

A second patient also raised the issue of need to;

"talk to somebody who knows what they're talking about … there's a lot of ignorance about it… I just say heart failure and they say oh yes … a bypass… a pacemaker … to them it's all the same."

This patient used a friend who was a retired nurse as a source of information, as did two other participants who referred to nursing friends who could;

"tell me in effect what was going to happen."

"help us by explaining what was happening to him."

The findings thus implied that the knock-on effects of the physical and cognitive problems common to sufferers of chronic heart failure manifest themselves in ways that may make it difficult for the patient to access either the professional or the social contact they need. For example, many patients demonstrated a conflict between wanting to retain power over decisions in their everyday life and awareness that they were ill-equipped to do that. This made it difficult for them to access the knowledge they needed about their condition and presumably casts doubt on their ability to be "empowered" in terms of making healthcare decisions. Because they were often aware of those problems, and distressed by them, they lacked the confidence to initiate a discussion. Useful strategies to overcome the problem centred round removing the urgency to conduct the whole discussion within a short time-frame, as exemplified by the use of the internet chat line and also by utilising trusted friendships whereby frequent contact allowed the discussion to take place in "bite-sized" chunks over a period of time. Spouses too, whilst willing to take on the mundane tasks such as control of medication, felt the need for knowledgeable medical support. These roles have traditionally been the remit of the heart failure nurses, however it is the immediacy of contact at unsocial hours and the necessity of conducting the discussion over a protracted period of time which may present a problem for busy staff.

These findings led to the conclusions that;

- Patients and spouses desire a level of support that is not at present completely fulfilled by the heart failure nurses and which according to at least one nurse (on page 204) may become less available in the future.
- Given that the automated weight monitoring system has both a decision-making function (to adjust medication, or in extremis go to hospital) and a supportive function (discussion with a cardiac nurse) at all hours, it may be able to fulfil the requirements for medical care whilst at the same time affording the continuous supportive care which is desired by vulnerable patients.

7.3.12 Patients' and carers' perceptions of the role of clinicians. Patients were unanimous in their dissatisfaction of the care they had received in the hospital environment. They expressed the view that clinicians have no interest in them or their illness and they felt themselves to be treated with a lack of dignity and respect.

"*We've been sat out there half an hour and she* (the nurse) *turns up late, ...*"

"*… people with broken legs get a wheelchair and they're* (the fracture clinic) *just inside the door, we have to walk … they never offered*."

"and she (the doctor) also called me a stupid old man…"

In contrast, patients and carers expressed high praise for the care received from their heart failure specialist nurses.

"*Only need to ring* (Nurse's name) *and I get straight through … She's made it clear she's available any time*."

"*I realised how lucky I am, treated like royalty*."

Carers in particular emphasised the importance of feeling that medical support was available to give advice and care at all times,

"*She's got to keep him on the books in case ... anything happens".*

One carer reported that her spouse (the patient) had been asked by the heart failure nurse how they felt about the prospect of being discharged from the clinic. There is no record of the patient's opinion, but the spouse said firmly;

"I wouldn't be happy, we need somebody on call."

The support was clearly at least as important to the spouse as to the patient, and both the spouse and the patient emphasised that they wanted the medical support, particularly from the consultant, to be directive and not collaborative. They did not want to be empowered.

"… doctor said 'do you want them (tablets) altering?' and I said 'I'm asking you, you're the doctor' ... pushing the onus onto the patient ... it should be on the doctor ... the patient doesn't know what it should be doing."

The findings thus implied that the patients valued the close relationship with "their" heart failure nurse but were frustrated by interactions with less familiar health care professionals. It seems odd that since many were unable to cope with decision making and self-care behaviour in relatively mundane matters such as taking medication daily, that a specialist consultant in the condition should expect a patient to make decisions relating to treatment options. Although only one example of that was reported, and it may have been a gesture to respect and courtesy to a frustrated patient, it was common to find that patients wanted medical care to be directive rather than collaborative, and available at all times.

These findings led to the conclusion that there are marked psychological aspects associated with CHF which need to be considered in relation to the successful introduction and mode of employment of any system of care. This is perhaps particularly so in the case of a remote and automated telemedicine intervention, which by its nature has the potential to be perceived by patients and their spouses either as evidence that supportive care is always accessible, or alternatively as evidence that an unsympathetic health service has replaced their care with a "quick fix" surveillance system.

7.3.13 Patients' experiences of weight monitoring as a self-care stratagem. One author has described the goals of treatment for patients with CHF as being "*to increase survival, reduce symptoms, and improve functional status and quality of life*" (Gillespie, 2001). Only one patient recognised that weight monitoring was an important factor in achieving those goals however. This patient had been a nurse, had been proactive in reading recent literature on her condition and was in the habit of monitoring both her fluid and salt intakes. Furthermore only one of the patients interviewed was in the habit of weighing himself daily prior to participation in this study. The majority of patients weighed themselves intermittently, often shortly before a clinic visit, and one patient was not in the habit of weighing herself at all.

> *"I never used scales, I hadn't scales in the house before* (participation in the study)*"*

Two patients reported only being weighed when they attended the clinic, which was approximately every three months and two patients were weighed weekly by a visiting nurse as they were unable to weigh themselves due to failing eyesight. All other patients reported that they weighed themselves approximately weekly, although very few of them recorded their weight. No-one indicated that either they or their nurses were dissatisfied with the schedule they were using, and as previously mentioned the nurses appeared to accept that whilst this was less than ideal the patients were doing the best that could realistically be expected of them.

In the early stages of the study, during the first round of interviews, the lack of vigilance in weight monitoring appeared to be due to either a lack of understanding or a lack of awareness of the role of weight monitoring, on the part of both the patients and their spouses or carers. Most interviewees reported that they had not received any information or recommendations regarding weight monitoring, with one commenting;

> *" it wasn't mentioned until…he said would you be interested in taking part* (in this study)*?"*

One patient indicated that he had received information related to weight monitoring, but that he had not fully understood the recommendation to weigh himself at home, either daily or even less frequently, saying;

> *"they gave me some charts to record the weight … well apparently she told me and I didn't realise I had to do it every day, so I was getting weighted when I went to the clinic."*

However despite reporting that they were not aware of the recommendation to monitor their weight, and being unable to explain the rationale for it when asked, most interviewees could recall having received the information about fluid retention and its relationship to an increase in weight when prompted. They also remembered the fact that it signalled a need to contact their nurse. One patient did comment that it had been explained,

> *"somewhat, but … I still wasn't understanding it all."*

Whilst tempting to assume that the lack of comprehension was due at least in part to a lack of education or information given by the nurses, the nurses themselves were not at all surprised by the phenomenon, indicating that they were familiar with the need to repeat the information on a regular basis. Whilst this does not confirm the quality or quantity of education, the researcher found that when she began to give the explanation the patients were able to recall having received the information and in many cases they continued the explanation unaided. Furthermore, when discussed again with the same patients in the next round of interviews after a period of approximately twelve weeks, they exhibited the same level of ignorance as they had on the previous occasion, followed by the same level of recall on prompting. This was taken as evidence that the problem lay more with a patient's memory than with a lack of information from the nurses.

However, there was also some evidence that the patients and their spouses were failing to convert their knowledge of the theoretical concept of weight monitoring into practical action within their own situation. For example, one spouse was very clear about the fact that if her husband's weight increased by five pounds in three consecutive days, then;

> "*That was drastic and that we should ring*… (the nurse)".

This interviewee saw nothing odd in the fact that her husband weighed himself only once a week, and therefore it would be impossible to identify a weight gain over three consecutive days. They had also stopped recording the weight anywhere and it is questionable whether they would remember previous weights with any degree of accuracy, and so be unlikely to recognise an early weight gain prior to experiencing other symptoms. In fact interviewees appeared to rely more on the physical signs that weight monitoring is intended to prevent, as indicated by one spouse's comment;

"*… he can also tell looking at his feet and legs*…"

Only one patient said that they would contact the health centre due to a change in weight alone, even then saying;

" *(I)… wouldn't bother unless it were drastic ... would prefer to leave it until I visited the clinic*."

It is therefore perhaps not surprising that two patients became very ill with fluid overload even whilst participating in the study. One of these patients had the telemedicine monitoring scales in his home, but despite advice from the call centre had not taken action because his heart failure nurse was on holiday and he preferred to wait for her return. (This situation is described in more detail in section 7.3.15 on page 223.) The second patient who had become ill with fluid retention was holidaying away from home at the time. This was the only patient in the study to monitor his weight daily and keep a written record, affording weight monitoring a high priority in his regime of self-care. It was interesting therefore that he had never considered continuing to monitor his weight when he went on holiday. Since he usually visited family it presumably would not have been difficult to do so, and even more important than usual as he was remote from his heart failure nurse and GP practice. He appeared to be surprised by the suggestion that he should do this whilst on holiday although he was careful to ensure that he had sufficient medication to cover his absence from home. The question arises therefore, is there a difference in the patient's mind between ***taking an action*** (tablet) to become well, and ***monitoring*** wellness without an associated remedial action taking place?

The findings from this section suggest that patients have difficulty in comprehending the purpose of monitoring as distinct from diagnosing. Therefore the need for a regular routine of weight monitoring is not understood and so compliance is commonly poor.

Furthermore the nursing staff had accepted that they were unable to effect further improvements in the current circumstances, as it would be unlikely that staff would be able to increase the number of visits per week to those patients who were unable to weigh themselves, and even more unlikely that funding would be available to visit patients at the weekend. Even when correctly conducted and a weight gain identified, the heavy reliance placed by patients on close personal contact with "their" heart failure nurse may act to inhibit the self-care action of seeking immediate help from sources other than that specific nurse.

The findings led to the conclusions that;

- With the facility to contact patients and remind them to weight themselves, the automated telemonitoring system may help to overcome some of the issues of irregular monitoring but further research is required to ascertain this.
- The automated system would initiate the necessary remedial action, thus avoiding delay which may otherwise occur due to prevarication on the part of the patient. However, compliance with directions from call centre staff cannot be enforced if patients insist on ignoring those directions in favour of waiting for interaction with their preferred nurse (although secondary remedial action in terms of informing the patient's doctor may avert severe problems).
- At the present time the automated system could not perform a monitoring function from anywhere other than the patient's usual domicile, due to the specificity of the telephone connection which is a requirement of the system.

7.3.14 Factors contributing to confusion in weight monitoring. A number of factors appeared to contribute to a general discouragement to be vigilant in weight monitoring. Many interviewees mentioned that they had reduced the frequency of weight monitoring because there had been no discernible change in their weight over a period of weeks. Since they were "well" they saw no reason to continue the daily monitoring.

> *"... my weight hasn't changed much it only varies a pound either way and I just don't know these few days I've not taken it."*
>
> *"…he's all right he's quite back to normal now."*

The inference is that they would only monitor their weight daily if their condition was deteriorating to the point that they were becoming ill, which of course completely negates the point of monitoring. One patient however gave an indication that some element of regular feedback about her weight would have encouraged continued compliance, possibly because it would have afforded reassurance that she was receiving the level of attention she desired.

“ *... nobody looked at them or bothered about them so I just stopped doing it.”*

Several patients and spouses supported the notion that it was important, as far as they were concerned, that;

“ ... the nurse keeps an eye on it.”

This was despite the fact that weight monitoring might be occurring as infrequently as three-monthly.

There was a high incidence of confusion between the issue of weight gain due to fluid retention and a need to control diet.

“I have weighed myself, but with not eating for the last....”

“I don’t put a lot of weight on ... I know that if I’ve been eating too many pies ... ”

“I mean, with not eating, I’d have been going down (in weight).”

“...because I like chocolate and ... I watch it to make sure that I don't gain too much.”

Confusion such as this is perhaps not surprising, as dietary guidance is a recognised feature of management (Ershow and Costello, 2006, Khan, McAlister, Rabkin, Padwal et al., 2006). It is one of the measures usually discussed by nurses and, as confirmed in the literature review in chapter 6, is evident in the information relating to self-care in chronic heart failure (Dickstein and Jaarsma, 2005, British Heart Foundation, 2007, Dickstein, Cohen-Solal, Filippatos, McMurray et al., 2008), so it is easy to see where confusion might occur in considering a gain in weight. Furthermore diet is not usually considered to be a matter of urgency, so even patients who recognise a weight gain may not take prompt action, and as mentioned previously this happened in at least one case (see section 7.3.15 p 222). However patients also confused the purpose of weight monitoring insofar as they saw weight *loss* as a symptom of illness. They did not in general perceive weight change as being connected with fluid retention and in some cases regarded fluid retention as a separate medical problem quite unconnected with heart failure;

"…that was my second problem… I put on a lot of fluid you know."

"I've had some problems with my leg … but nothing to do with the heart it's the leg surface you see" (referring to severe swelling and blistering, which are symptomatic of decompensation in heart failure).

Even patients who did monitor their weight (although misconstruing the purpose) did not always have confidence in the legitimacy of the monitoring because they felt that their own weighing scales were not of sufficient quality to ensure accuracy.

"Mind you it's only ordinary bathroom scales."

"I've got a pair of scales that are definitely not right, I'd have to buy a very expensive pair you know, if you wanted to carry on that weighing business."

A further complication was that patients were confused by the differences in weight recorded on their own weighing scales at home and those in the clinic;

"The only thing I find is that I get weighed at the hospital I might weigh different to what I weigh at home because of the scales so I don't see where the comparison is…"

Thus the patient had not appreciated the fact that it was the trend in weight gain that was important and not the absolute measurement.

Lastly, it appears that the patients do not perceive that vigilance in weight monitoring is reinforced by the nurses and possibly they believe themselves to be receiving an "all clear" signal from the nurses when they are allowed to discontinue daily monitoring.

*"At first (*nurse*) gave him a paper to write it down on, but he never varies more than a pound… so instead of doing it everyday we've gone to doing it once a week, and he doesn't write it down and (*nurse*) doesn't ask for it now."*

One participant in the control group was subsequently offered the weighing scales, but said;

"I'm not going to take part again because I did put weight on …I rang (the nurse) *… but she didn't think it was anything to worry about."*

It may be a factor of the nurse's belief in the negative aspects of daily weight monitoring described in section 7.3.4 that resulted in "permission" for the patients to abandon daily weight monitoring, or it may be that the patients have misinterpreted their nurse's intention. However both patient and nurse appear to accept that it is a satisfactory situation if the patient reports that weekly monitoring is taking place, despite the nurse's acknowledged scepticism, previously mentioned on page 192, that *"they could write anything down on that piece of paper…"*

The findings thus implied that patients almost invariably misunderstood both the purpose and the importance of weight monitoring. The reasons for non-retention of knowledge appeared to be due partly to factors commonly associated with both CHF and age, i.e. poor memory and/or poor comprehension but were possibly compounded by other factors such as a lack of positive reinforcement when their weight remained unchanged and a lack of absolute clarity in the presentation of information from varied sources.

These findings led to the conclusions that:-

- The lack of vigilance in weight monitoring is not likely to be improved by simple measures such as increasing the quantity of education provided by the heart failure nurse because, given the resources available at the present time, it cannot occur frequently enough to offset the problems of memory retention.
- Other measures may improve compliance, such as frequent positive reinforcement, particularly during periods when there was little or no change in weight, and it may be necessary to consider the most appropriate ways of incorporating those measures into a telemedicine system if it is to be successful in caring for patients with CHF.

7.3.15 Patients' and partners' views of telemedicine weight monitoring. Many patients felt that the telemedicine system had been of no particular value to them, which is not surprising given their negative views on the concept of weight monitoring in any form. Much of the comment offered however indicated that the reasons for their lack of enthusiasm over the telemedicine weighing scales were not related to the telemedicine weight monitoring as such, but to a preference for greater personal attention from their heart failure nurse. For example, many participants did not see the telemedicine scales as a major contributor to healthcare but as a redundant exercise, the importance of which was overridden by the reliance they placed in their heart failure nurse.

> *"They haven't really been much good to us…* (because) *he's being kept an eye on by* (nurse's name)*"*
> *"I do keep an eye on his weight… but* (nurse's name) *is keeping a close eye on him all the time as well."*

This was common to the majority of participants and was emphasised by the example of the patient who was contacted by the call centre due to an identified weight rise, but who refused to contact his GP, instead insisting on waiting until his heart failure nurse came back from annual leave. The staff at the call centre informed the patient's GP and continued to monitor the situation, contacting the patient as necessary. In this case the patient came to no harm, but required an increased level of nursing supervision to stabilise his condition when the heart failure nurse returned. This could have been avoided if the patient had followed the advice of the staff at the call centre, but given the cognitive problems already identified it is debatable whether or not it is reasonable to expect patients to perform actions advised by someone who is to all intents and purposes a total stranger to them.

It is an odd paradox that this scenario actually confirms the usefulness of telemedicine weight monitoring, as a weight gain was recognised before the patient was aware of it. The patient reported that had he been aware, either by noticing swelling or feeling ill, he would have contacted the doctor, but had felt no urgency because he was not experiencing symptoms. This perhaps highlights the necessity of putting appropriate working practices in place before introducing a telemedicine system. Had another nurse been delegated to receive the alert from the call centre in the absence of the patient's own nurse, or if a patient / health carer relationship between the patient and the call centre had been established at the outset, the patient may have remained well. This would have avoided the cost of the extra resources which were subsequently necessary,

Although the patients had been informed at the outset that their heart failure nurses would monitor the weights received by the telemedicine call centre, they had not fully appreciated the fact until the nurses gave them evidence. For example one nurse noted;

> *"The patient was pleased to receive confirmation that her condition was indeed being monitored and her nurse informed."*

Thus further evidence appears to support the idea that the successful introduction of a telemedicine weight monitoring system for this group of patients would depend to a large extent on preserving, or even enhancing, the patient's perspective of the personal patient/nurse relationship. This idea was further reinforced when patients who were originally in the control group were offered the opportunity to trial the scales at the end of their first 6 month period. Only one accepted the offer, the other five saying that they did not see any point. However, following conversation with their heart failure nurse, who made it clear that she had received the data from the call centre, reviewed it weekly and confirmed that there had been no need to visit the patient, two of those patients later expressed a desire to use the automated scales because,

> *"My nurse wants to keep an eye on me."*

Patients did not necessarily limit their search for the kind and level of care they wanted to a single specialist heart failure nurse however. In at least one case a patient with access to the telemedicine resources had fulfilled the need for more frequent contact by creating his own supportive relationship with the nursing staff at the call centre. (Patients are free to call the staff at the centre at any time to discuss concerns about their weight or about heart failure matters generally.) This patient in particular appeared to have developed a strong rapport and was on first-name terms with most members of staff at the call centre. He was, interestingly, the same patient who "chatted" online to other nurses. Although only one patient created quite such a comprehensive network of knowledgeable support for himself, and this may be a function of his "larger-than-life" personality, it demonstrates that such measures are possible, even within the telemedicine call centre system. Therefore it would presumably be possible for others to benefit in a similar way, although with less gregarious patients some encouragement and assistance may be needed to initiate that relationship in the first instance.

The findings thus implied that negative views of telemonitoring held by patients are frequently caused by its being contrasted against nurse contact, rather than seen as a complementary measure. When it is viewed as part of the nurse supervision it is accepted much more readily. Technical success can be, and in practice sometimes was, defeated by the patient's strong dependence on their identified heart failure nurse, but it may be possible to transfer an element of that dependence to a wider support network such as is offered by the telemedicine system.

These findings led to the conclusions that:-

- If, as seems likely, the strong culture of dependency in this group of patients cannot be converted to "empowerment", due either to age or to the nature of the illness, the introduction of automated technologies may have to rely on strategies which include an element of personal attention if patients are to use it effectively and consistently. However we have already shown that current working practices would have to undergo some adjustment if effective monitoring is to be achieved and determining the best method of providing motivational feedback is just one of the issues to be addressed in that process of change.

7.3.16 Patient and partner experiences ~ positive aspects. Despite the majority of participants intimating that more frequent personal care from their heart failure nurse was what they wanted, and was greatly preferable to automated surveillance, patients did see a benefit to automated daily weight monitoring.

> *" well I suppose it's reassuring to the back of your mind that things could be flagged up sooner than maybe if you were left to your own judgment."*
>
> *"She* (call centre staff) *kept saying regular when things were going wrong, let me know and everything has been great with them."*
>
> *"... anything that happens they'll let me know and keep my nurse and doctor supplied with information."*

The last two comments again reinforce the importance of feedback and of reassuring the patient that 'his' nurse and doctor are in control of his care.

In addition to the intended benefit of an automatic alert on detecting weight gain, patients and carers mentioned associated benefits which had not been considered either by themselves, by the heart failure nurses or by the researchers, prior to their experiencing the equipment. For example, one carer reported feeling relieved each morning when she heard the faint sound indicating that the weight data were being transferred, because she knew;

> *"He's up and about and all right."*

All patients were aware that the telemedicine system was not simply for one-way data transference but that they could also telephone the call centre at any hour of the day or night. Although patients did call during the day none used this facility during the night, except one who confessed to feeling great fear that something would happen to him outside normal office hours, when his heart failure nurse was not available. He said;

"I think possibly knowing that there's somebody there at… the right time, I get a bit scared of that… I mean this is twenty four hours…"

Another surprising finding was that a patient who was experiencing depression, a common adjunct to CHF, said he had;

"… found the scales useful in getting me up when I did not feel like it."

He acknowledged that the motivation to get out of bed was due partly to his feeling of responsibility to the research study he had agreed to take part in, but mostly to the fact that he knew the telemedicine company would telephone him and prompt him to weigh himself, as in fact they had on one occasion. It could be argued therefore that even though there had been no benefit in terms of the early recognition of fluid retention, the system had effected a therapeutic function in addition to encouraging compliance with the daily weighing routine.

The findings thus implied that patients were greatly reassured by having 24 hour access to help and advice. This was not quantified in terms of resource savings in this study as no patient became so acutely ill that they telephoned the call centre in favour of summoning an ambulance. There were a number of associated benefits to patients and their partners which are neither easily recognised nor easily quantifiable.

These findings led to the conclusion that:-

- In deciding whether or not to introduce this telemedicine system, such unquantifiable benefits are likely to be unrecognised unless the decision making processes include anecdotal evidence from those with first-hand experience.

7.3.17 Patient and partner experiences ~ negative aspects. In most cases the cost of the daily telephone calls which transferred the data to the central call centre was not of concern to patients. One however did remark on it. Although the patient was aware that it would be one call per day, his bill was presented quarterly, which meant that just over ninety calls were registered to the call centre. Although the total cost was only £3.74 and did not represent a hardship to the patient, who was in any event reimbursed, it highlights the fact that the consequences of an initiative such as this one are not always fully appreciated by patients until they have experienced it for themselves. In this case it was the very long list of calls to the same number that had shocked the patient and when asked, other patients also commented that although they had not noticed any rise in costs they had noticed a lot of calls to “a number in Manchester.” It appeared that the patients had not connected the written and verbal explanations of the daily telephone call transferring the weight data to the call centre with a call appearing on their telephone bill. Therefore the issues associated with CHF in the introduction of the telemedicine system had not been sufficiently addressed and possibly contributes to some of the negative perceptions voiced by patients. In addition it highlighted the special ethical considerations of conducting this study with a group of patients who, although not “vulnerable” in the normally accepted sense of the word within the research community, nevertheless probably were.

A second patient found that he had to replace batteries in the weighing scales more frequently than expected. This had not been foreseen and therefore had not formed part of the initial explanation and consent procedures. In this case the patient bought and replaced batteries when the warning light indicated that the battery level was low. Because the weighing scales continued to work correctly in terms of the transference of weight data, the problem was not identified until the patient mentioned it to his nurse. The company investigated promptly and it transpired that the weighing scales failed to go into “standby” mode when the patient stepped off them. They were replaced immediately, the patient was reimbursed for costs and no further problem occurred, however the fact that the patient disclosed the problem to his nurse and not to either the telemedicine company or the researcher, endorses the belief that a close patient /nurse relationship will still be a necessary part of the care plan for patients with CHF.

One patient was perturbed that the weighing scales displayed weight in kilograms because he did not understand the metric system. In the same way that patients had been confused by the difference in weight displayed by their own weighing scales and by those in the clinic, this patient was not able to monitor a change in weight, being concerned only with the absolute value. The display mode was altered to show the weight in stones and pounds and he reported no further problems. Two patients found that they had to stand on the weighing scales for several minutes before they stabilised and the weight recorded and transferred. This was found to be due to soft carpeting underneath the weighing scales and was solved in both cases by placing a small piece of plywood underneath them.

One patient expressed concern that he had been weighing himself inconsistently as he awoke at different times each morning. He was reassured that the time was irrelevant as long as he weighed himself before dressing or having breakfast and after having been to the toilet. However this had to be reinforced a number of times, indicating that patient education and reinforcement is still necessary to alleviate those concerns, even with the telemedicine system, which has checking procedures in place as a first-line precaution intended to identify exactly this sort of error in the weighing routine when weight changes occur.

In each of these examples the patient had chosen to discuss the problem with their heart failure nurse rather than with the call centre staff, reinforcing the point made previously that the relationship between patient and nurse is particularly important for patients with chronic heart failure.

Three patients requested help with the installation of the weighing scales, even though their partners considered them to be "mechanically minded" and attributed the need for help to their medical condition and prescribed medication.

> *"All his tablets that he's taken in the past have, you know, affected his brain somehow and he's very slow to take things in. He would never have got it, he would have never have got it all plugged in and sorted out on his own, never."*

The help required was not technically difficult, relating to the insertion of a small plug into the telephone socket to accommodate the data transfer. The difficulty for the patients was either not being able to get to a socket inconveniently placed behind furniture and at floor level, or because the patient was afraid of doing damage to either the telephone line or the weighing scales. It was a task that any agile family member or neighbour could have done easily and in one case was done by the heart failure nurse. Whilst this problem occurred in the minority of cases and should not be difficult to overcome, it clearly demonstrates an unacceptable risk that elderly patients with heart disease should move furniture and crawl on all-fours to install the equipment. In common with many of the points raised in earlier sections, the problem appears to be not with the technical aspects but with the procedural details.

There were two instances of the equipment causing inconvenience. One of these was related to physical disability in that the patient could not read the display on the weighing scales due to poor eyesight, therefore his wife read it for him each day, but remarked;

> *"For 6 months I had to come in every morning ~ before my breakfast. When he stood on it he couldn't see the figures on it, when it had stopped and to record the weight. So I had to watch it for him."*

This participant was irritated by the inconvenience caused by her husband's poor eyesight, although this is one of the problems that the telemedicine system is intended to overcome. The data are read and logged at the call centre. There is no need for the patient to read their weight, but it appeared that the patient felt he should do this even though he had not previously been in the habit of monitoring it. It is not known whether it was the novel telemedicine equipment or the fact of it being a research study which made the patient want to monitor his weight himself, but had he done so prior to the study his wife would presumably have had to read the normal bathroom scales for him. If the telemedicine system is acting to encourage the patient better to monitor his own weight, then possibly consideration should be given to ways in which that might be made possible, for example by the inclusion of voice simulation to "speak" the weight, or some alternative form of feedback mechanism, perhaps by telephone either from the telemedicine company or from the heart failure nurse.

The second inconvenience was related to the nature of the housing, commonly chosen by the elderly specifically for ease of daily living. Accommodation tends to be compact and this contributes to the difficulty of locating and accessing the telephone socket, but also makes it difficult to site the wireless gateway without wires trailing to the socket. Furthermore it affords limited space to site the weighing scales and as the telemedicine scales are specific to one user there were reported instances of "weight watching" spouses having to forego their own weight monitoring as there was not room for two pairs of weighing scales in the bathroom. Whilst enduring these inconveniences for the duration of the study the participants were unlikely to accept this as a permanent discomfort, as one patient clearly demonstrated. This patient, already prone to the frustration that CHF often engenders, found it was exacerbated by the telemedicine equipment to the extent that he withdrew from the study. His complaint received by email is reproduced in entirety below.

> *"This morning I was typing your e-mail address when a note appeared on the screen saying that the study was over. For six months I have unplugged the computer to use the scales and then later plugged it all back and to be honest I was delighted to see it was over. Plus we get rid of all the wires etc., we have had trailing all over that room. The wife and I ,she being age 70 me aged 76 and also very tired with heart failure crawled all over those wires for best part of an hour By the end of that hour I had to lay down on the bed but we are still unable to use together the phone and the computer. That means I cannot speak at all on the other phone because I am deaf. Left alone in the house, I have no phone. Mrs (X) rang your number* (she actually rang the call centre, not the researcher) *and explained and asked for assistance, after a lot of explaining the Lady suggested that as we had done it it wasn't your (their) fault and we should get BT to sort it out ... BT ... the last time we called them out for a minor fault it cost us £50, If you or anyone else connected to this research study think we are paying BT you can think again.*
> *I also make it clear that if we don't get the phone and the computer working again (as it was before we undertook this test) all the electrical equipment will, make no mistake, be thrown outside the front door to rot away.*
> *As you may have gathered I am simply FURIOUS, therefore at the same time as I throw that lot out I will contact the press to warn others not to get involved with the likes of you and your colleagues. This is the first time I have been duped but believe me it will be the last.. The cheek of it after all we did.*
> *I want that phone working and the computer working in two days Time is of the essence.*
> *Kindly reply in the morning."*

The patient was contacted the same evening and found to be entirely charming. His frustration (he reported) had been alleviated by the act of writing the email, but it is clearly not acceptable that any telemedicine application should cause such distress and is another indication that even the most successful technology should be introduced in a carefully considered manner and the consequences monitored. This origin and content of the note which the patient says appeared on his computer screen was unknown to the researcher. Neither she nor the heart failure nurses have ever seen it, or anything similar and no other patients reported seeing a similar note.

The findings thus implied that the technological success of automated weight monitoring is not in itself sufficient to ensure that it will be consistently and effectively used by patients. There are some aspects of the system which, if made more “user friendly,” would alleviate some minor problems of using the equipment, although these might be complex to introduce and possibly apply to only to a minority of patients. Even if used correctly, technological success alone is not sufficient to achieve the goal of ensuring timely remedial intervention in every instance of fluid build-up. The main factor contributing to failure is the patient’s reluctance to undertake self-care tasks which are not seen to be directed and assessed by the health care professional with whom they have developed a dependent relationship. In addition there are a number of associated factors, mainly to do with the practicalities of installing, siting and comprehending the weighing scales, which proved problematic to the patients and some have the potential to cause great distress. In most cases the problems were easily resolved, but often required assistance from others. Those factors would therefore need to be considered at the point of introduction of the equipment into a patient’s home.

These findings led to the conclusions that:-

- If this system is to be introduced into patient care, it is necessary to incorporate an on-going evaluation of the patient’s experience in order to remove obstacles before they act to inhibit the monitoring process.
- Whilst solving the practical problems related to the installation and operation of the automated weighing scales is necessary, those problems are relatively minor compared to the need to present the execution of the weight monitoring routine and its associated requirements in a manner that will encourage patient compliance.

7.3.18 Summary discussion ofusers’ views. The value of research evidence in a study such as this one is dependent upon the position of the consumer of that evidence within the sphere of research activity. In this case the consumers comprise the commercial company whose technology is undergoing assessment, the policy makers whose job it is to consider cost-effectiveness, the end-users of the equipment and lastly the researchers who must evaluate the research process. This study has yielded evaluative evidence on two fronts. The first includes the benefits, detriments and considerations which have to be taken into account for all participants if implementation of the technology is to be implemented successfully. The second, and arguably the more important of the two, is the value of the research evidence which has been offered in this and other studies.

In considering the technology, there can be no doubt that, although the number of participants in this study was small, the evidence has supported previous claims that remote automated weight monitoring can identify early instances of fluid retention in patients with CHF. Specific incidents have been described which have proved that the automated weighing scales have the potential to prevent a patient’s condition from deteriorating by providing an early warning system, even though that potential was not entirely fulfilled in this study, due not to technological shortcomings but to the dependence of the patient on his named nurse. There were minor instances of equipment malfunction, however even in those circumstances the accuracy of the weight recorded was not compromised, there was merely an inconvenience in either the time taken to achieve the weight recording or in the number of battery replacement actions necessary. Therefore the technology has been shown to be sound.

The nurses for their part have acknowledged that they would value the automated weighing scales as one of the tools used in their care of their patients, although individual nurses may utilise those tools in different ways. They agreed that for certain patients the weighing scales would help them to provide better care by virtue of closer monitoring without a significant increase in their workload. Better patient care and best utilisation of healthcare resources do not therefore appear to be in doubt with respect to this telemedicine equipment. Furthermore there is no reason to doubt that the system evaluated in this study has the potential to reflect similar cost savings in terms of emergency admissions and bed-days in hospital as have been reported in similar studies reviewed earlier in this document.

Such savings were not specifically demonstrated in this study, due partially to very low participant numbers and also to the fact that all patients remained relatively stable throughout the duration of the study, or at least did not require admission to hospital. However this study was not intended to analyse costs, but to evaluate the telemedicine system in terms of its appropriateness as one strategy in the care of patients with chronic heart failure, and from the perspectives of the end users the research evidence is much less clear. Although the technology has proved to be sound and therefore ought to be beneficial, the interaction between the technology and the end users (patients, carers and staff) caused the potential benefits not to be fully realised. The problems have been shown to be partially in the preconceptions held by staff and partially in meeting the patients need to feel individually cared for by appreciating that the weighing scales are intended to contribute to that care, not replace it.

In considering patients' views, it must be borne in mind that the level of nursing attention that they desire is not necessarily available to them at the present time and that it will probably decrease further in the future. Thus there is a need to find ways in which effective care is not only taking place but also to find ways in which the patients are receiving the assurance they need, whilst at the same time the human and financial healthcare resources are utilised in the most effective manner. It is possible that this need may be met, at least in part, by the careful introduction of this technology, provided attention is paid to the details of appropriate and frequent communication with patients.

What constitutes either appropriate communication or the necessary frequency has not been explored in this study, but from the evidence offered it appears that it may vary, not only from person to person but also throughout the duration of care for each individual. Further research is needed to explore the possibilities of feedback mechanisms to the patients, either from the heart failure nurses or possibly via automated feedback from the telemedicine equipment. "User friendliness" is a concept familiar in the development of automated communications such as internet banking, bill paying, social networking etc., and may possibly be used to advantage in the further development of the weighing scales trialled in this study. For example some items of telemedicine equipment incorporate an LCD message display which greets the patient by name each morning and confirms that the data recorded are within normal parameters. The equipment evaluated in this study does not have this facility and nor was a system of feedback by the nurses imposed, as the intention was to evaluate the system as it operates at the moment. However it has already shown that some adjustment to working practices have to occur if effective monitoring is to be achieved and determining the best method of providing motivational feedback is just one of the issues to be addressed in that process of change.

In considering the health professionals' views, it is possible that not all heart failure nurses are immediately able to incorporate the telemedicine technology, as it exists at the present time, successfully into their patient management. This may be because staff are required to effect a change either in their beliefs and/or attitudes about weight monitoring, or in their behaviour, as in for example being required to adopt a more remote managerial stance for some aspects of care, such as devolving some of the mundane tasks to a third party (the call centre staff). To relinquish control of the day-to-day weight data and assume managerial expertise may require a degree of job-related professional development for some staff, whilst others already have those skills and could use the system effectively.

A similar change would be necessary in other professions if some patients were not to be unfairly excluded from the benefits of automated weighing scales. It was shown in this study that in some GP practices a "top-down" approach exists in which the majority of decisions regarding care for chronic heart failure patients are decided by the GP. The barrier of human assumption, particularly relating to the role of weight monitoring, prevented this equipment being trialled by the nurses and patients in those practices, and possibly led to the omission of some aspects of care which are important to the patient, though not necessarily from the strictly medical standpoint.

From the evidence offered when nurses were interviewed it would appear that the wider social and emotional aspects of a patient's wellbeing were considered by the nurses to be an important part of their role, also extending to the care of the family of their patients. It is not easy to imagine a busy GP or consultant having the opportunity to explore issues of faith or the importance of hobbies with patients, even though they may constitute an important contribution to the patient's quality of life. Nor is it realistic to assume that their time permits such frequent assessment of symptoms as is required during titration. It begins to emerge therefore that there may be aspects of heart failure, important to the wellbeing of the patients and their families, which are only recognised and addressed by the heart failure nurse and not by any other health care professional in any capacity. If this is the case then it follows that those healthcare professionals should be the ones trusted with the decisions regarding the selection and use of tools, such as the automated weighing scales. From the responses to requests for recruitment received from the GP practices it appears that this is not always the case. It further follows therefore that those patients suffering from chronic heart failure who do not have recourse to a heart failure specialist nurse may be disadvantaged in their care to a greater extent than is generally acknowledged.

From the research perspective, the merit of the evaluation has been diminished to a great extent by prescriptive requirements imposed by the research process. In the first instance, in common with many other studies it has addressed only a relatively small percentage of the population of chronic heart failure sufferers, that is those considered by some individual to be physically and cognitively able to interact with the equipment in the prevailing circumstances of medical care. Targeting that small population could be considered to be an easy financial strategy to adopt, as it requires no adjustment to existing working practices or, more relevantly, no adjustment to existing policies relating to health or research. Therefore it is an attractive option to embrace the technology for a few, but ignore the majority. It is a further temptation to base that decision on only those measures which are the simplest to identify, such as a reduction in in-patient stays, and not to address the wider, but unquantifiable benefits of wellbeing.

Being unable to identify every concept of importance to patients, it follows that it is impossible to measure them at the present time, and a further issue of particular relevance in chronic heart failure is that of obtaining the evidence necessary for a comprehensive assessment of the equipment. However from the responses received to the request for recruitment to this study, it appeared that approximately 60% of patients with chronic heart failure were not able to have their need for this telemedicine intervention assessed under any circumstance, due to the conditions associated with research. This was because the very problems that the intervention seeks to circumvent, for example problems of non-comprehension or forgetfulness, were exactly those problems which inhibited the procedure of gaining informed consent.

If that situation persists it is probable that the patients most in need of telemedicine support will be those least likely to have the opportunity to experience the potential benefits and one of two equally unacceptable situations may then arise. Either those items of equipment which are initially perceived as useful to decision-makers (even if they are mistaken) will be introduced as service tools in small and disparate areas, in which case they are unlikely to be properly evaluated or made widely available. Alternatively, items of equipment which the decision-makers regard as having little or no application (whether they are mistaken or not) may never be tried at all. It would be useful therefore, in discussing the process of change, to include issues surrounding the collection of evidence from cognitively disadvantaged patients. This is not to suggest that ethical practice should be compromised. Indeed failing to include those with cognitive disability might be considered to be unethical in itself and perhaps suggests that there is a need to bridge the gap between the initial agreement to participate and the later administrative requirements following the recommended “period of reflection” which caused such difficulty in recruiting participants to this study.

In the second instance the remit of the study was to evaluate ***daily*** weight monitoring, therefore the nurses could not opt for weekly or bi-weekly monitoring for any patient, even if they thought it preferable. It is not reasonable to expect health care staff to change their level of expertise, their beliefs and their working practices overnight. It may not even be possible to do it at all for individuals who are currently in post. It would presumably require time for training and experience, features which were missing in the early stages of this study and which are known to be important due to the changes which occurred in staff opinions throughout the duration of the study. In any event it may be an inappropriate expectation, since although there is evidence regarding the medical efficacy of daily weight monitoring there is no evidence to suggest that nurses are incorrect in their contention that for some patients a daily regimen may create greater psychological and medical problems than it alleviates.

It appears that, in the evaluation of the telemedicine technology in patients with chronic heart failure, it is the strength of the relationship between the nurse and the patient which is both the strength and the weakness of the programme of care. This is particularly the case when attempting to introduce an "outsider" (the telemedicine intervention) into that close relationship. The outsider in this case can be perceived either as strengthening that relationship or as interposing between the parties involved. That perception is dependent to a large extent on the way it is introduced and subsequently utilised.

Referring back to the circular argument previously illustrated on page 184, in which the equipment is not given a trial period by some because of prevailing misconceptions, and so the misconceptions perpetuate because the equipment has not been trialled, is not a completely accurate representation of the experience at end-user level (although holding true for the more remote tier of management, such as the GPs in charge of large practices).

they don't believe it will be of benefit or
they misunderstand the concept

because

therefore

they refuse to experience it

The situation for the end user was almost invariably that;

The technology works and
would potentially benefit care
and reduce costs to the NHS.

but....

Some elements associated with
using the technology make the
system is unwelcome in its current
form.

therefore.

The technology is resisted
in the early stages.

therefore

Adaptation is not possible and
end-users never perceive using
the technology as a positive
experience.

Even though.

There exists therefore a "chicken and egg" situation, which has to be broken at some point to encourage the process of remote weight monitoring to occur throughout a sustained period. The only point at which the barriers can be breached is at the point of experience. Education and information have consistently failed to persuade some patients of the value of a weigh monitoring routine and imposing the experience against the will of either the patient or the nurse will, as has been shown in this study, result in resistance, non-compliance and “cherry picking”. Therefore there is a need to provide encouragement for patients and motivation for staff.

Permitting the member of staff most closely associated with each patient to negotiate the use of the automated weighing scales with that patient, reaching agreement as to the mode of use they feel most appropriate, is possibly the best method of providing such encouragement and motivation. This may result in the technology not being used at all for some patients, if both parties agree that that is the best mode of care. If both patient and nurse are motivated to use the system for a sustained period, time will permit them to become familiar with the technology, to adapt and to amend their relationship and working practices to include its greatest benefits and avoid undesirable consequences.

Alternative they may reach the ***informed*** decision that automated weight monitoring does not make a contribution to care, but only after a sustained period of adaptation will evaluation yield useful information truly representative of the impact that such technology has on the care of all patients with chronic heart failure. It is strongly suggested therefore that a comprehensive and conclusive evaluation of this telemedicine system, via randomised controlled trials on a widespread scale is not possible at the present time, and in particular that any negative impressions left by this or other studies should be considered carefully in the light of the limitations of the research process.

A summary of conclusions and recommendations arising from the three contributing sources of data are presented in chapter 9 at the end of part 2 of this thesis. Also presented in that chapter is the appraisal of the limitations of the evaluation study and a reflection on the research process.

CHAPTER 8: Ancillary evidence for automated weight monitoring in chronic heart failure

8.1 Introduction This chapter considers the evidence arising from the quality of life and anxiety measures and also explores the innovative use of the automated weight monitoring system by one family caring for a patient suffering from chronic heart failure, but who had no recourse to a specialist heart failure nurse.

8.1.1 Aim of the study.

The aim of this study was to assess the extent to which the automated weight monitoring system may affect the quality of life and anxiety experienced by patients and carers, by a comparison of scores in each case between;

- Patients and carers, regardless of whether or not they had access to the telemedicine equipment.
- Participants in the experimental group and participants in the control groups (those with access to the telemonitoring scales and those without).
- Participants at the start of the study and the same participants at the end of the study.

8.1.2 Study design. This study contributes to an overall evaluation which was described in chapter 7. The reader is directed to chapter 2 and to pages 169 and 175-178 of chapter 7 for a detailed description of the underpinning design, but in brief it was an exploratory evaluative study based on the precepts of a randomised controlled trial, insofar as the patient participants were assigned either to the control group, in which they received their usual care, or they were assigned to the intervention group in which they received the telemedicine equipment in addition to their usual care. The research instruments used for this part of the data collection were the MacNew Heart Disease Quality of Life Questionnaire and the Spielberger State-Trait Anxiety Inventory (both reproduced in appendix 11). They were administered to participants at the start of the study, again after a period of 3 months and finally at the end of the study period (6 months).

8.1.3 Measures used in the evaluation of quality of life and anxiety. The MacNew Heart Disease Quality of Life questionnaire has been widely validated across a number of heart-associated diseases (Hofer, Lim, Guyatt and Oldridge, 2004, Lane, Baxter, Jenkins, Tsang et al., 2006, Sansgiry, Chien, Jayawant and Raju, 2008) but also specifically in heart failure (Hofer, Schmid, Frick, Benzer et al., 2008). It is a self-administered instrument consisting of 27 items which fall into the three domains consisting of physical limitations, emotional function and social function. There are 5 items that inquire about symptoms. It may be scored either by calculating the average of each of the domains separately or by calculating the average global score. In this case the global score was used in an attempt to explore the patients' and carers' overall perspective of the effects of heart failure on their life before and after the introduction of the automated weight monitoring equipment, and also to compare those with the views of participants in the control group who did not have access to the automatic weight monitoring equipment. The State/trait anxiety measures comprise two parts. The first asks about immediate feelings of anxiety, specific to that moment when the participant is recording his or her responses. The second asks the participant to consider how they feel generally throughout the course of daily life.

8.1.4 Participants. The participants are the patients and carers described in the previous chapter. The essential information is repeated here for ease of reading. Twenty patients with a mean age of 75 years and age range between 66-83 years were included in the data arising from this study. Of the twenty contributing participants, two were female and eighteen male. Ten of those had spouses who also participated and in addition the son of one male patient, the sister of one male patient and the carer of one male patient also participated. All participants were Caucasian and local to the area and none had other weight changing conditions. Eleven of the patients (nine with partners) were assigned to the telemedicine group (receiving usual care and also the telemedicine scales). Nine patients (four with partners) were assigned to the control group, receiving usual care alone.

8.1.5 Ethical considerations. The ethical considerations in relation to the evaluation of the automated weight monitoring system in patients with chronic heart failure have been discussed in the preceding chapter. It will not be repeated here in full as the studies described formed part of that evaluation, was conducted on the same participants and included in the ethical approval received (shown in appendix 4). The reasons for the decision to measure anxiety, particularly in preference to depression, are not easily clarified, except that clinical members of the research team hypothesised that having the telemedicine service may reduce anxiety, especially for carers. Both depression and anxiety have been associated with heart failure (Rutledge, Reis, Linke, Greenberg et al., 2006) and have been shown by some to be highly correlated when using the Spielberger State-Trait Anxiety Inventory (Jiang, Kuchibhatla, Cuffe, Christopher et al., 2004), which was the instrument chosen in this case. Other authors however have suggested that although depression is significantly affected by heart failure, anxiety is not (Nab, Manousos, Clarke and Cleland, 2006). The main reason for choosing to compare anxiety measures however was that whilst depression is commonly treated with pharmacological intervention, anxieties (which may ultimately contribute to depression) are more likely to be discussed with, and addressed by, the heart failure nurse rather than by the doctor. From the initial discussions relating to the formulation of the research proposal it was clear that the nurses saw dealing with anxiety as part of their role and that they extended that to dealing with the anxieties of family members, therefore it was agreed that it would be useful to know to what extent the telemedicine system may affect that aspect of the nurses' role.

8.1.6 Procedure. State-Trait anxiety and Quality of Life questionnaires were administered to patients and their partners or carers at the beginning of their involvement in the study (0 months), during their period of participation (3 months) and at the end of their participation (6 months). A summary of the questionnaires returned is given in figure 8-1, page 242 in which it can be seen that only ten patients and eight partners in the experimental group and six patients and three partners in the control group completed two or more questionnaires.

Therefore the limited data which exist are not sufficient for statistical comparison and are described in simple terms of;

a) the mean global score for each participant in the state anxiety, trait anxiety and also in the quality of life assessments, at the start of the study (20 patients and 13 partners or carers), to show the range of scores which were recorded at that time.

b) the change in the scores of state anxiety, trait anxiety and quality of life which occurred during the study for each participant who completed at least two questionnaires (16 patients and 11 partners or carers).

Breakdown of sets of questionnaires returned, (each set containing state anxiety, trait anxiety and quality of life components.)

- Completed on two or more occasions - experimental group = 10 patients + 8 partners
- Completed on two or more occasions - control group = 6 patients + 3 partners
- Completed on one occasion only - experimental group = 1 patient + 1 partners
- Completed on one occasion only - control group = 3 patients + 1 partners

Fig 8-1 Breakdown of questionnaires returned by participants.

8.1.7 Results and discussion of quality of life and anxiety scores. The column graphs showing the range of state anxiety, trait anxiety and quality of life scores at the start of the study (fig. 8-2 page 244) are depicted using the maximum mean score which would have been achievable on the Y axis, in order that the reader may make an approximate visual comparison of the severity of response with relative ease. Thus the anxiety scores have a possible range of between 1 and 4 whilst the quality of life scores have a possible range of between 1 and 7. The graphs showing the changes in the state anxiety, trait anxiety and quality of life scores (fig. 8-3, page 245) are depicted using a vertical scale equivalent to ***half*** the maximum mean score which would have been achievable, as the changes recorded were small. This makes viewing easier but still permits the severity of change to be compared between participants. Also to assist the comparison of the experimental and control groups, the results have been arranged so that those for the experimental group occur on the left hand side of the graph depicted in shades of orange, whilst those for the control group occur towards the right hand side of the graph in shades of green. In cases where participants responded but there was no change in mean score, that is signified by a cross of the appropriate colour on the horizontal axis next to that participant's identification number. In some graphs the participant identification numbers are directly below each participant's result rather than on the horizontal axis, to avoid confusion in viewing. The data are supplemented by the unsolicited written comments which were received from some participants when the questionnaires were returned.

With reference to figure 8-2 it can be seen that the level of anxiety reported differed between participants, with many reporting quite low levels of anxiety and only approximately one third of participants recording a score of level 2 or higher, out of the four levels possible. In each case the degree of state and trait anxiety was similar for each participant, except in the case of participant 7, who reported a very high trait anxiety, although much lower state anxiety at that time. From a purely visual scrutiny it appears that in many cases the patients and their spouses or partners reported similar scores, and also that there may be a negative relationship between the level of anxiety experienced and their perception of their quality of life (for example patient 24) as perhaps could reasonably be expected. However as previously noted the numbers are too small to draw robust conclusions. Furthermore, of the thirteen patients who had a partner or carer contributing to the study only ten of those were marital partnerships. The remaining three were either more distant relatives such as a sister or daughter living at a different address or in one case was a semi-official carer paid to carry out this role. These three carers therefore had life priorities elsewhere and so their own wellbeing would arguably be less affected by changes in the patient's circumstances than would those of a spouse.

The changes which occurred between the beginning and end of the study, as shown in figure 8-3 on page 245, are similarly difficult to interpret although the change in state anxiety appears to be mirrored by a similar result in trait anxiety. A change in trait anxiety may reflect the participant's general view of the anxiety state during the previous few months, as the interval between responses varied between 3-7 months. Alternatively it may be that patients suffering the associated effects of chronic heart failure, particularly depression or cognitive dysfunction, may have difficulty in differentiating between the "state" and "trait" perception. There are no convincing data to indicate a difference between the experimental and control groups, as roughly half in each group recorded an improvement in these measures of wellbeing and half recorded either a reduction or "no change" in scores. The reader is reminded that in this figure "no change" is denoted by a large cross in the appropriate place on the horizontal axis.

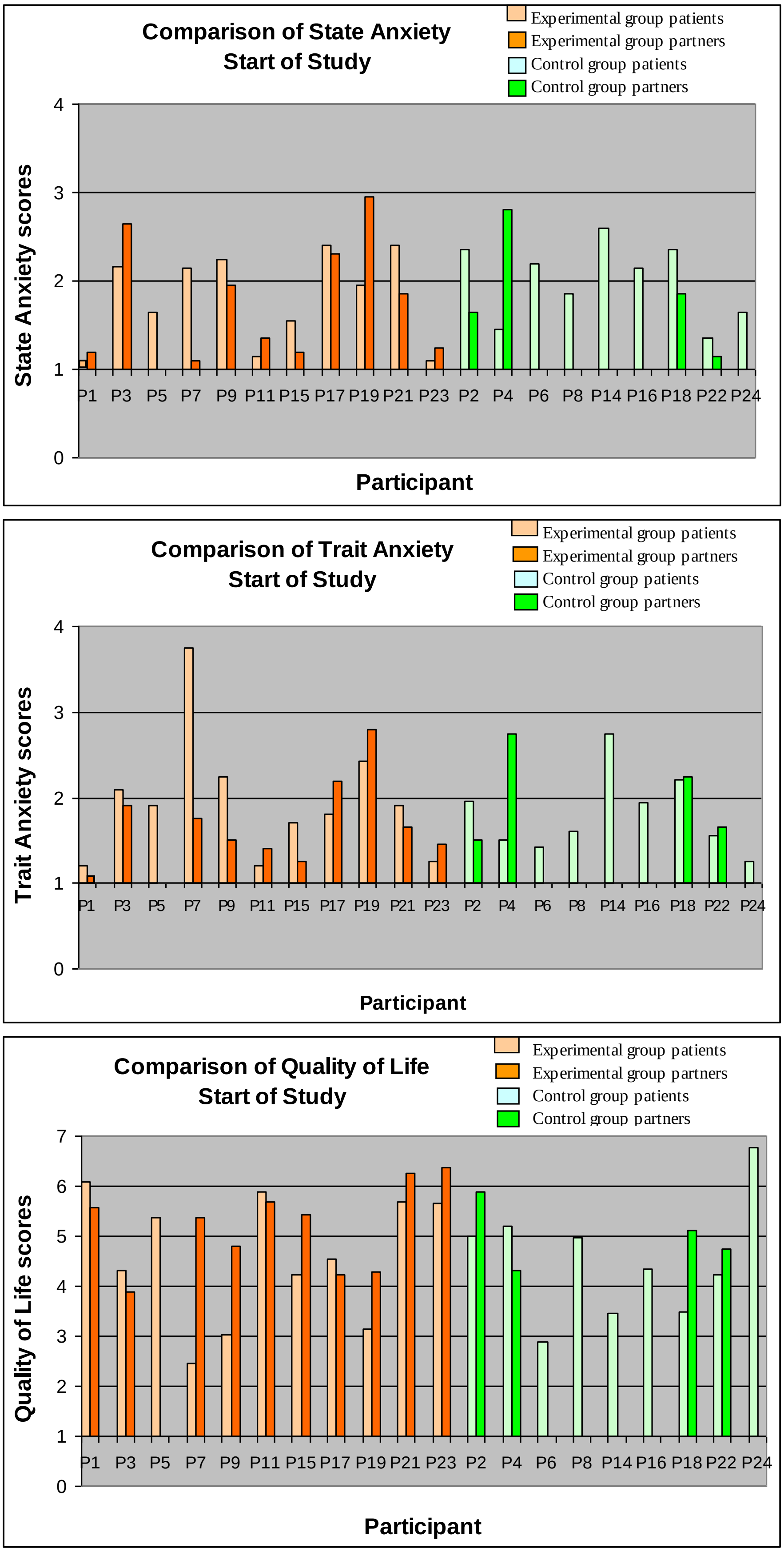

Fig 8-2 Anxiety and quality of life scores at start of study

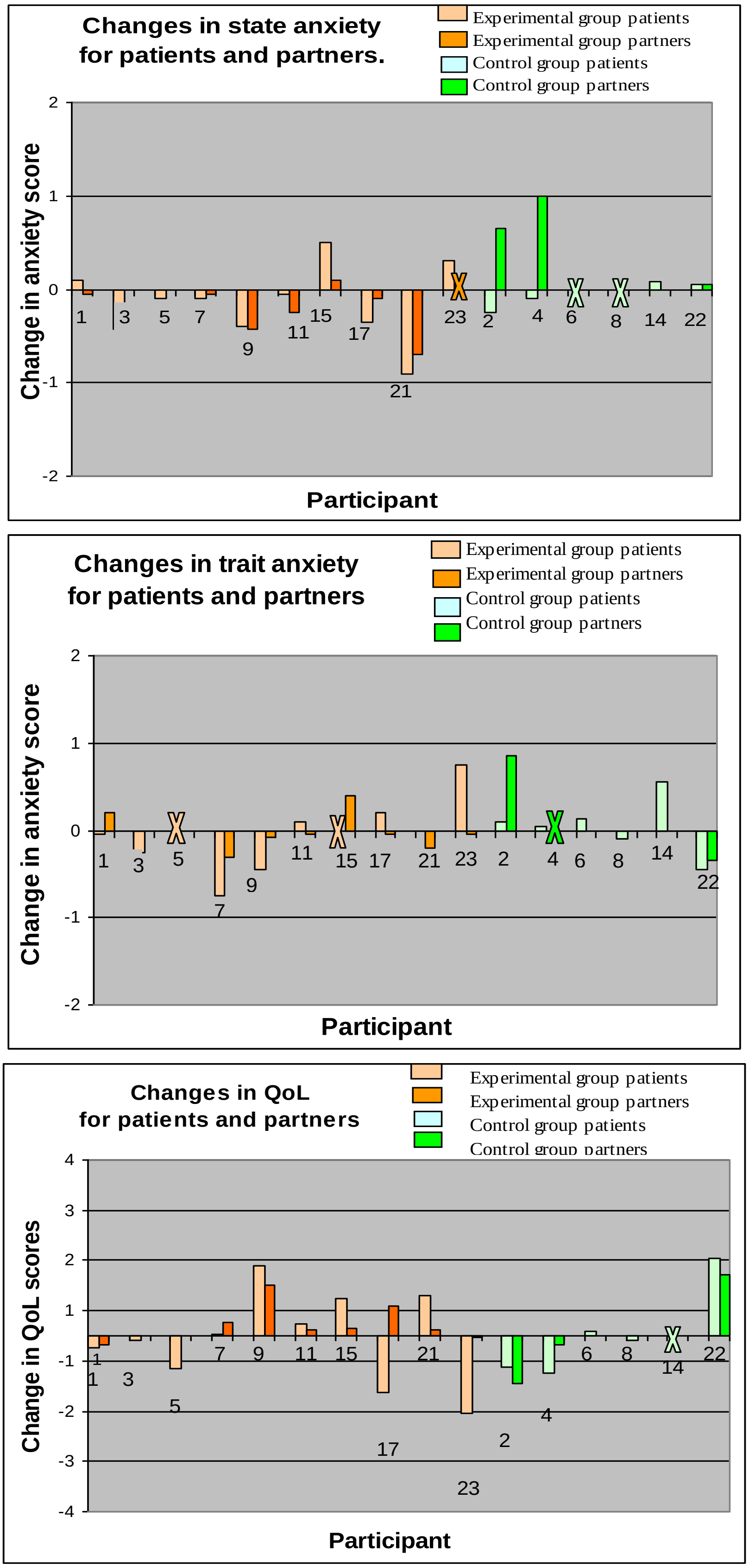

Fig 8-3 Changes in anxiety and quality of life scores between the start and end of the study

*** NOTE A large cross on the horizontal axis signifies "no change" in that participant's score.**

8.1.8 Summary discussion of anxiety and quality of life findings. It is not known how each patient perceives his or her overall wellbeing. Some responses may have been greatly affected by a participant's loss of physical ability, for example if a large part of their enjoyment had previously been derived from walking or dancing. Other responses may have been affected by emotional trauma, for example spousal death which is quite likely to occur in the age group associated with chronic heart failure. In fact the spouse of one patient in this study did die during the period of the study and two participants (married couple) reported the unexpected death of a son. The reported changes in anxiety and quality of life for these three participants in all probability reflected those incidents as much as, or even more than, changes due to the effects of the heart failure. However two patients offered unsolicited comment on returning their questionnaires, which offer evidence of both effects, the first (P 17) writing;

> "*If I had been asked these same questions two months ago there would have been many different answers. I put this down to the alteration of my tablets that I had been on for years and was changed by Hospital (X) from when I was transferred from Hospital (Y), for example loss of breath, dizziness and quite a few more things*"

The importance of the physical condition is clear in this patient's statement. It also reflects the importance of the initial medication, which may arguably be said to be the remit of the GP or consultant, and the later titration which may arguably be said to be the role of the heart failure nurse. This perception of the nursing role was stressed by the nurses in their interview responses and lends support to the validity of their view that they would find the automated weighing scales useful during the titration period. However the second participant (P16) wrote;

> "*I have tried to answer these questions honestly, though these types of questions and answers make me feel very frustrated. My answers would be completely different if I did not have a strong faith and a good hobby (family history) which though in itself can be frustrating it is very challenging*."

Unfortunately there was not an opportunity to explore this comment further with this participant, as he chose to withdraw from the study at that point, but it is interesting that the physical condition was not the focus of the comment. "Faith" was an issue for two other people who had been invited to participate in the study, one of whom refused the invitation, but wrote giving an explanation for his refusal. However both of these comments would seem to underline the importance of the nurses' contribution to heart failure care in different ways.

The patients' comments also implied that a single focus of distress, such as may result from sub-optimal medication as described by patient 17 on the preceding page, may mask more subtle improvements in other areas of the patient's wellbeing. Thus a reduction in quality of life or increase in anxiety due to other factors may disguise any improvement effected by the weighing scales. This strongly suggests that the timing of these assessment methods is of paramount importance in the accurate assessment of the telemedicine facility. However, even with perfect timing it may not necessarily be possible to discriminate between the effect of automated weight monitoring and the effect of better titration for example, as it could be argued that the meticulous monitoring of weight contributes to the titration process. Thus once again the value of the evidence is called into question when so-called objective methods are used.

As with the data from chapter 7, conclusions and recommendations from this section of the study are presented in chapter 9 at the end of part 2 of this thesis, as they draw from the three contributing sources of data. Also presented in chapter 9 is an appraisal of the limitations of the evaluation study and a reflection on the evaluation process.

8.2 Arnold's story. A vignette of one family's experience of the equipment

This is a descriptive account of the use of the automated weighing scales by a patient diagnosed with chronic heart failure, but who was not under regular review by a specialist heart failure nurse. He is identified as patient 23 in the data previously provided in section 8.1. It is an unconventional contribution to the original evaluation of the telemedicine intervention because it occurred as an incidental finding. Thus there was no initial aim or design, this participant was simply one of the twenty patients enrolled into the research study, but whose experiences of the automated weighing scales were thought worthy of reporting more fully.

8.2.1 The participants. Arnold (real name withheld) was a widower in his early seventies. His heart failure care was dependent on his taking action to go to the doctor if he felt unwell as he was not under regular review by a heart failure nurse. He lived alone and had two married daughters living nearby and one married son who lived in Australia. One of the daughters played the major role in caring for Arnold and fulfilled the role of "carer" for the purposes of completing the anxiety inventory and quality of life questionnaires, and as an interview participant. Neither daughter was knowledgeable about heart failure. Their roles were mainly assistive, for example in driving their father to the hospital when required or collecting his prescription from the chemist, rather than demanding first-hand information or directing his care. During the interview process with Arnold and his daughter, it came to light that Arnold's son (who shall be called Arnold junior for the purposes of clarity here) had taken a close interest in his father's participation in the telemedicine study and had become involved in the monitoring process. Arnold junior was by far the most academically successful member of the family, having attended university, been involved in a variety of medical studies and at the time of writing owned a multi-national company whose sphere of operation was in medical devices. He was already knowledgeable about telemedicine initiatives and felt that it could be beneficial to his father's healthcare, therefore he requested that he be consented as a participant and so chose to express his views.

8.2.2 Procedure. The procedure for this participant followed that of other participants as described in section 7.2 on page 178. Thus questionnaire and interview data were elicited and in addition unsolicited contributions via a series of emails and a video recorded commentary were received from the participant's son in Australia. The epistemological and ethical arguments are therefore identical to those previously described for other patients.

8.2.3 Results. It can be seen from the data relevant to patient 23 in figures 8-2 and 8-3 on pages 244 & 245 that Arnold's anxiety measure increased and quality of life measure decreased slightly during the period of the study. The reduction in quality of life for Arnold was not explained, Arnold himself volunteering very little information during interview (which in this case was conducted via telephone) and restricted himself to generalities, saying that he felt "alright" but was "getting older." This apparently was normal for Arnold, according to his son and daughter. His daughter's recorded scores remained virtually unchanged. As discussed previously, this was not necessarily surprising, given that caring for Arnold was a relatively small part of the daughter's life, as she had a family of her own and other life priorities.

When asked about weight monitoring both Arnold and his daughter recalled on prompting that when Arnold was first diagnosed with chronic heart failure he was given advice on weight monitoring, but neither appeared to have appreciated either the reason or the importance for this and it was not part of a regular self-care regimen. The purpose and procedure was explained to both Arnold and his daughter by the researcher and Arnold was provided with the telemedicine equipment. Because Arnold had no heart failure nurse assigned directly to his care it was agreed that in the event of a weight gain Arnold would be contacted directly by the staff at the telemedicine company and the information would also be passed to the researcher who would contact Arnold's family. (This proved unnecessary as no significant weight gain occurred during this period.)

After a period of some weeks Arnold stopped using the scales because, in his daughter's words "his weight didn't change so there was no point." It is an interesting point that the daughter, who does not suffer from any form of cognitive dysfunction as far as is known, still exhibited the same flawed reasoning as many of the patients, despite having appeared to understand and even reiterate the explanation at the outset. Arnold himself echoed the view of there being no value to the weight monitoring if his weight did not change, but he also said that there was often a delay of several minutes before the display screen of the weighing scales "stopped rolling" and transferred the data to the call centre, after which he could step down from the scales. It was, he said, particularly unpleasant standing in an undressed state as it was winter and he often became extremely cold.

However, at this point Arnold junior intervened. He was already aware of the role of weight monitoring as an early-warning sign of a deteriorating condition and was keen for his father to continue the procedure. He reported the problem with the weighing scales to the telemedicine company and this was found to be due to the thick carpeting underneath the scales. The scales were positioned on a piece of plywood and the problem solved. Then, following discussion with his father and his sister, Arnold junior developed an idiosyncratic system whereby his father’s daily weight data were sent to him in Australia. He then included a discussion about weight and other symptoms in his regular telephone call to his father. The receipt of the weight data, he reported, “provides a basis for a conversation” which has led to his father having better understanding about the need to monitor his own health in general and weight in particular. In addition Arnold junior reported being reassured that any adverse event would be recognised and could be dealt with at an early stage. Furthermore, if he has any concerns about his father’s health in the future, arising from either the weight data or from other reported symptoms he has arranged to contact his sister who will then take their father to his doctor.

In terms of remote automated weight monitoring surveillance the telemedicine system had not therefore demonstrated clear beneficial medical advantages from the point of view of early warning notification of weight gain, because this patient remained stable throughout the study period. However the study did usefully demonstrate that the telemedicine system was able to;

- provide a monitoring facility for the patient, which had not previously existed since the patient was not under regular review by a heart failure nurse.
- provide reassurance to the immediate family.
- demonstrate the potential for some, but not necessarily all, family members to adopt useful roles in the care of patients with chronic heart failure.

8.2.4 Summary discussion of one family's innovative solution. A situation such as that described here cannot be prescribed for every patient, or indeed every family member. There were two particular occurrences in the case of this family's use of the automated weighing scales which stimulated particular areas of concern. The first was the fact that Arnold's daughter was as confused about the nature and purpose of weight monitoring as was her father. It raises the possibility that the problem with appreciating the importance of it in the regimen of care is not solely due to cognitive dysfunction associated with the disease, as the daughter certainly did not appear to be less intelligent or less knowledgeable than any average lay person.

The second matter of concern was that neither Arnold senior nor his daughter reported the problem with the scales, although they had the contact details of both the telemedicine company and the researcher, with whom they had spoken on a number of occasions. Had Arnold junior not taken control of the task of communicating with the telemedicine company the telemedicine system would not have been used and the evaluation would probably have recorded that in this instance the equipment was not beneficial. Thus, as with the participants' experiences described in the preceding chapter, the successful deployment of the telemedicine system appears to depend on the existence of a relationship between the patient and someone who is able to direct the process of care in some way. Whilst for other participants that person was the heart failure nurse, in Arnold's case that role was accomplished satisfactorily by his son. The important factor however is that it was not able to be accomplished by the daughter. Thus although Arnold's story provides an excellent example of how family members may be able to contribute to care, it also provides an indication that it is not a simplistic solution which every family member could accomplish successfully, and it would not have succeeded in this particular circumstance had it not been for the knowledge and skills of the one family member who was motivated to devise and implement procedures which made it acceptable to the patient.

The idea of family being called on to assist was introduced by one heart failure nurse (on page 204 of the preceding chapter) when it was suggested that family members may be able to assist with the installation of the equipment. A collaborative approach such as that developed by Arnold's family had not been predicted however, lending support to the argument proposed in the previous chapter that only the most comprehensive evaluation of this system can yield the true extent of benefits and detriments.

It is possible that there are a number of roles able to be filled by persons other than the heart failure nurse, or alternatively that with careful exploration some aspects of that role may be undertaken by the heart failure nurses at the call centre. From the example provided by Arnold and his son it suggests that those roles would have to be matched to the circumstances and abilities of those involved, which perhaps reinforces the notion that although the telemedicine system is perceived as one single strategy by those viewing it from afar, for those intimately involved it is a unique phenomenon. Thus support is added to the weight of evidence which suggests not only that the automated weight monitoring system has real potential to enhance care for patients with chronic heart failure, but also that it must be permitted to evolve under the control of those most closely associated with its operation before its worth may truly be evaluated. This is particularly emphasised by the fact that Arnold's participation as a member of the experimental group was a matter of random chance, without which it would never have been recognised that the most ambitious claims for telemedicine, such as enabling trans-global care, are being acted out successfully in practice by a small family in Lancashire.

As with the data from chapter 7, the conclusions and recommendations arising from this small part of the study are presented in the following chapter, together with those from the other two contributing sources of data an appraisal of the limitations of the evaluation study and a reflection on the evaluation process.

CHAPTER 9: Limitations of the evaluation study, reflections on the research process, conclusions and recommendations.

9.1 Limitations of the evaluation study. The randomised controlled trial (RCT) is generally regarded as the strongest form of research evidence (Guyatt, Sackett, Sinclair, Hayward et al., 1995, Walker, 2003, Franks, 2004, Berwick, 2005) and evidence which does not encompass the element of randomisation is not generally considered sufficient basis on which to base practice (Sackett, 1993, McKenna, Cutcliffe and McKenna, 2000, Morse, 2006).

However a number of shortcomings in this evaluative randomised controlled trial have been noted throughout the preceding text and of these the earliest to occur was the researcher bias introduced by the nurse members of the research team who had formulated elements of the research study before the academic members (including the author of this thesis) were involved. An example of bias arising at that time was the fact that patients with class 1 (NYHA) heart failure were excluded from the study. The clinical members making that decision were probably not aware at that time of the differing opinions that exist with regard to the usefulness of monitoring those patients, as the information only arose during the later interview process with other clinicians. A second form of bias was the interference with the randomisation process by the nurses who “cherry picked” patients must also have contributed to a distortion of the data. This bias probably also contributed to the low level of patient recruitment, which was clearly a major limitation preventing any statistically significant comparisons to be drawn in terms of monetary or clinical benefit. Furthermore those two factors together made it impossible to adopt any form of stratification to balance the randomisation process and also made the experimental and control groups too small to assume compensation for differences between individuals.

Clearly “blinding” was not possible for patients, they either received the telemedicine scales or they did not. For the researchers, firstly the recruitment process was carried out by the nurses who were members of the research team and secondly because the more remote researcher was the one who carried out the interviews. Even though robust techniques of analysing the data were employed (described in chapter 7) the chance of observer bias cannot be ruled out completely. The small number of participants exacerbated the potential of bias to exist, as individuals were easily recognised from small amounts of data. Researcher/observer bias was evident from the nurse members of the research team, as illustrated by the "cherry picking" behaviour previously noted, however observer bias on the part of the remote researcher carrying out the interviews was probably much less evident due, paradoxically, to the fact that the researcher had minimal knowledge about chronic heart failure. That suggestion is explored further in section 9.2 on page 255, which provides a reflection from the perspective of the researcher. Disadvantages caused by a lack of blinding related to analysis of the spoken word is in any case counteracted by the advantage of the analyst being able to interpret gestures, actions or other clues revealed by the participant at the time.

There were a number of participants lost to the study part-way through, thereby reducing the opportunity to assess "before and after" comparisons such as changes in anxiety or quality of life measure. In addition although all participants in the control group were offered the opportunity to experience the telemedicine system none accepted the invitation, therefore neither the complementary perspective nor the comparative quantitative data could be obtained. Discrepancies in the time intervals between interviews were unavoidable, as the researcher was based several hundred miles distant from the participants and so limitations in time and funding resources necessitated pragmatic decisions in delaying or advancing the timing of the interviews.

Other elements of missing data meant that some issues identified as potentially important could not be cross-checked. For example no participant entered anything in the diaries provided therefore reflective comment could not be supported by evidence recorded at the time of the relevant event, and the refusal of GP practices to allow access to medical records in many cases meant that objective data were unavailable.

Overall therefore, no measures such as mean differences in outcomes under any specified condition could be elicited from the data and therefore the study did not provide sufficient evidence on which to base any changes at the present time with regard to clinical practice or policy issues either for individuals or for the wider community. The value of the study is not lost however. In reviewing the hierarchy of evidence as it applies to nursing practice, Mantzoukas stresses the need to "consciously and explicitly choose the best treatment option for individual patients" and "the individual practitioner ... remains the most important element for achieving best practice..." **(Mantzoukas, 2008 p 221).** He went on to write,

> *"... the hierarchy of evidence with RCTs as the most valid form of evidence is not only in many ways flawed, but most importantly unsuitable for health practitioners... abandoning of the hierarchy of evidence will enable practitioners to practice in a reflective manner and, therefore, base their practice on conscious, justifiable and explicit evidences... The hierarchy of evidence that has promoted randomised control trials as the most valid form of evidence may actually impede the use of most effective treatment because of practical, political/ideological and epistemological contradictions and limitations ... Therefore, to enable the implementation of best evidence in practice, the hierarchy of evidence might need to be abandoned and reflection to become a core component of the evidence-based practice movement."* (Mantzoukas, ibid.)

This study has provided explicit evidence of issues relevant to individuals, each within a specific circumstance. Now that we are in a better position to understand what those issues are, we are in a much better position to construct a meaningful multicentre randomised controlled trail based around them.

9.2 Personal reflection on the research process. The emotional challenges experienced throughout the research process, at least that part of it that involved interaction with patient participants, came as something of a shock. I had considered myself to be very well prepared and awake to the potential emotional risks that many authors describe (Gilbert, 2001, Rosenblatt, 2001, Grover, 2002), having already conducted a number of qualitative research studies in the fields of health care and education.

As a health care professional with over thirty years clinical experience I had become adept at maintaining the professional detachment needed to be able to perform effectively in distressing situations, and had professional experience of the worst of them, from multiple casualties of war to victims of child abuse. "Mere heart failure", I though, was an insignificance compared with those. Furthermore I (wrongly) predicted that setting and maintaining boundaries would present no problem. As a lecturer with experience of conducting and supervising educational research I had often wrestled theoretically with the dichotomy between the need to set clear boundaries between researcher and participant and the need to immerse oneself in the situation to the extent that those boundaries inevitably become blurred. I have never had too much success in reconciling the two opposing requirements satisfactorily in practice, more often than not becoming impatient with the struggle and settling for the pragmatic course of action. This time however I predicted that boundary setting would present no problem. My knowledge and experience of heart failure was minimal, as was my experience of geriatric medicine. The participants lived several hundred miles distant from my place of work therefore I had no connection with hospitals, clinics, or clinicians in that location. In any event for the purposes of this research study I was based in a university setting and so presented myself as an academic and not a clinician, therefore the participants would not be aware that I had any connection with the professions allied to medicine. This, I judged, would also lessen the risk of participants having expectations that I could in some way effect a cure or improvement in their circumstance.

There were, as far as I could envisage, no commonalities that may cause emotional distress to me, as I had not even known my grandparents or other elderly relative, and neither parent had suffered from heart disease (as far as I knew). Furthermore I could identify no commonality which may encourage any level of self-disclosure, apart from the fact that I had spent my formative years in a remote part of the same county as many of the participants. That I saw as a potential advantage which may help to enhance the relationship between myself and the participants at the outset, as advocated by Scopelliti and colleagues (Scopelliti, Judd, Grigg, Hodgins et al., 2004), whilst maintaining a safe emotional distance as I had left the area over thirty years previously and therefore could contribute little to a dialogue about local issues relevant to the day.

It transpired that in all those beliefs I was remarkably naive. On meeting the patient participants for the first time I was struck by the level of delight they invariably expressed on hearing my northern accent. This seemed to give them confidence to begin chatting straight away, although once or twice they did check my comprehension.

"*You know what I mean by 'liggin' on' don't you love*?" (Yes I did.)

However, much greater than the surprise were the feelings of anger and powerlessness when confronted with the stories some participants shared with me. When an old man, clearly a force to be reckoned with in his day but now a vulnerable and frail gent with tears in his eyes, told me that a consultant had called him a "stupid old man," I was incensed. In recounting that story now I find that I revisit that anger and as I write want to add almost as many exclamation marks to the sentence as I did that evening when I wrote in my research diary,

"Why does this woman think she can do this to patients?!!!!!!"

In retrospect the research diary was probably the most effective method I had at the time of expelling those emotions. When working in the clinical arena it was common practice for workers to retire to the pub or restaurant after a particularly upsetting scenario in the workplace. As a group we had all experienced such distressing moments and could share our emotions with each other, sometimes with tears, confident that our emotion would not be belittled or revisited at a future time. The process was familiar and usually descended into black humour, which was the sign that the therapeutic process was complete. In the research situation however, because I was several hundred miles away from friends and colleagues, the research diary was often the only release I had and in reading it much later I am struck by the fact that the content is almost always anger at the vulnerability of these participants.

With the anger of course came a degree of pity, which I was able to recognise at the time as being counterproductive, using logic to argue (to myself) that it would be arrogant to feel that anything but a dispassionate approach would yield the impartial evidence which may ultimately assist in the care of persons with chronic heart failure. Recognising the phenomenon did not however remove the temptation to "befriend" the participants, a phenomenon remarked and warned against by a number of authors (Gair, 2002, Johnson and Clarke, 2003), but recognition did make it possible to avoid it to a great extent. (I qualify the statement by adding "to a great extent" because I did feel a degree of sorrow and loss at the death of two participants during the study, and sent letters of condolence to their partners.) If I am absolutely honest however, I am not sure that I would have completely resisted the temptation to befriend participants, particularly once the research study had finished, had I lived in the vicinity instead of hundreds of miles away.

Quite apart from the issues discussed above, there are two lessons learned from this experience that will remain with me. The first is that what I had assumed to be a major disadvantage, i.e. my lack of experience of chronic heart failure, turned out to be a substantial advantage, insofar as I did not have the pre-existing opinions or assumptions about the condition and how to treat it, such as at what point weight monitoring should begin. Had I already had those assumptions I may not have recognised the conflicting opinions that were merely mentioned "in passing," as the interviewees did not emphasise those points at all, they too assuming that no other opinion existed. I therefore now value the quality of "ignorance" in a researcher, which stems from an ***acknowledged*** position of "knowing" nothing as much as I value the quality of expertise. The second lesson is the frustration of "small print" not completely thought through. In this case it was the wording of the ethics submission which referred to gaining access to "medical records related to their heart failure." The argument from the GP practices was that they could not separate the medical information related to heart failure from that relating to other conditions, and therefore access could not be permitted. I must confess to a very high degree of frustration and indignation over this refusal, as it was initiated by a secretary, who is not a member of a professional body, whereas I am a member of the Health Professions Council. However the lesson has been learned and the "small print" will be flawless in future.

Summary conclusions and recommendations. There are insufficient data to provide robust conclusions on which to base decisions about practice or management. However the study has demonstrated that;

- From a strictly technological viewpoint, the remote automated weight monitoring system evaluated can be effective in the early recognition of weight gain in patients with chronic heart failure.

- The number of patients who experienced a weight gain during the period of the study (1) was not sufficient to conclude whether the system would be equally effective for the majority of patients.

- Initial resistance and pre-determined assumptions on the part of clinical staff acted to limit the effectiveness of the telemedicine monitoring system, both in terms of the opportunity to use it at all and in terms of the effective utilisation of the call centre service for those who did have the opportunity to try it. In the latter case 6 months “hands-on” experience of the system lowered that resistance and nurses were in favour of continuing to use the service and also willing to transfer greater responsibility to the call centre.

- Resistance on the part of patients and carers also limited the effectiveness of the telemedicine system. Three main causes of resistance were identified;
  a) the non-appreciation of the medical value of continuing to monitor weight consistently, for the rest of life, even when weight does not fluctuate.
  b) the perception that the telemedicine system was in place of nursing care, not an adjunct to it.
  c) A few minor practical or technical problems were encountered which were easily overcome by the nurses or call centre staff, but insurmountable for some patients and carers.

- The procedures imposed by the research process on patients, carers and clinician inhibited the recruitment of participants in all groups.

The recommendations are therefore that the lessons learned from this study should be used to inform the development of further research into this topic in the following ways;

- Clinicians should be closely involved in the research process, so as to make recruitment much less arduous for the participants and data collection much less prone to delay and obstruction than may be the case for an outside party (although data analysis can be conducted by other parties, as required).

- Clinicians who are able and willing to trial this service should pay particular attention to the introduction of the concept of remote monitoring to patients and carers in the first instance, emphasising a close association between their care and the monitoring of the weight data. Consideration of family members' involvement may be appropriate at this time, possibly in negotiation with the patient.

- Before beginning a research study consideration should be given to methods of "trouble-shooting" the minor practical and technical problems identified in the preceding report (and similar potential problems). Consideration of who carries out the remedial task, how quickly it could be done and who pays for it is a necessary prerequisite if patients are not to be deterred from using the system. In this context "practical problems" includes administrative procedures such as dealing with identified weight gain if the patient's own nurse is absent.

- In the early stages clinicians should be permitted to utilise the service for whom and in whichever fashion they feel most appropriate, to allow them to become familiar with the system. Once a degree of familiarity has been attained then stricter rules of randomised controlled trials can be more easily adhered to and more meaningful research studies developed, according to the clinicians' experiences and interests.

- Finally it is recommended that policy makers in disparate administrative regions of the health service engage in dialogue to explore the potential of sharing clinicians' expertise with regard to this technology, with the intention of sharing the duties of data monitoring to cover for periods of absence, or to permit access to patients who currently have no specialist heart failure nurse provision.

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PART 3

ECG monitoring by patients in the home, using a fixed land-line telephone connection to transfer data and communicate with a central call centre.

Introduction to Part Three.

This section of the thesis describes the evaluation of a 12-lead ECG monitor, used by patients in the home to diagnose and monitor episodes of cardiac arrhythmia by the transmission of the recorded ECG data to a call centre. With a few minutes of receiving the ECG data cardiac nurses or cardiologists at the call centre provide medical feedback and advice based on the ECG transmission and on the patient's medical history which is held in the data bank at the call centre.

The evaluation comprises five chapters as follows;

- **Chapter 10** provides an overview of previous studies related to the use of ECG equipment in telemedicine initiatives.
- **Chapter 11** describes the experiences of the patients and their spouses involved with the telemedicine facility, as recounted in interviews. There is also some contribution from some of the health professionals associated with their care.
- **Chapter 12** provides a detailed account of one patient's history of a lifetime of arrhythmic episodes and her experience of obtaining the necessary evidence of her medical problem via the remote ECG device. Comments from her spouse and clinician are included.
- **Chapter 13** describes a small study which investigated the potential to use the telemedicine ECG monitor and central call centre to diagnose or monitor paediatric patients. At the time of writing this equipment was not verified for use with paediatric patients. In this study comparisons are drawn between 12-lead ECG recordings made by experienced cardiac technicians according to normal practice in a large London hospital, and those made using the remote ECG telemedicine service, on the same patients during the same clinic visit. The telemedicine ECG recordings were made by a novice layperson, by a parent, or on occasion by the young patients themselves.
- **Chapter 14** reviews the limitations of the study and provides a personal reflection of the research process, conclusions and recommendations.

A summary discussion, which considers the studies in entirety, concludes this thesis in chapter 15.

CHAPTER 10: The case for ECG monitoring of arrhythmia in the home: a literature review.

The work of Scalvini and colleagues in the fields of chronic obstructive pulmonary disease and cardiac rehabilitation has been well documented since the early 1990's. (Scalvini, Marangoni, Volterrani, Schena et al., 1992). In 1998 this expertise was applied to a telemedicine initiative in Italy entitled the "Boario Home-care Project," in which 178 general practitioners were provided with a portable 12-lead ECG machine which could transmit the data via either a fixed or mobile telephone connection, to a central call centre where a cardiologist was available at all times for a teleconsultation (Scalvini, Zanelli, Domenighini, Massarelli et al., 1999). During the period of that study a total of 2,800 12-lead ECG traces were recorded and transferred to the call centre. The patients had a range of cardiovascular conditions, including chest pain, dyspnoea, palpitation, dizziness or faintness, and asthenia. Although 546 of these cases were excluded from the study due to incompleteness of requested data, the authors concluded from the patient outcomes that this telemedicine facility provided a useful support to general practitioners in the management, in real time, of patients with cardiovascular conditions, and possibly contributes to optimisation of health care costs in terms of appropriateness of hospital admissions and diagnostic tests.

A few years earlier another author with experience of ECG monitoring in the home by homecare nurses had reported that one home care agency found that 26.9% of their cardiac patients presenting with arrhythmias required intervention (Frantz, 1995). Although much of that work related to post surgical patients, later reports stated that the authors had found that cardiac patients present with a variety of conditions, including life-threatening arrhythmias, which require immediate medical intervention (Frantz and Lynn, 1999). The value of arrhythmia detection for the home care patient, the authors suggested, was that the early detection of arrhythmias may prevent more costly acute care interventions later.

When further analysing data from their 1999 study, Scalvini and colleagues reported that the telecardiology service showed a diagnostic accuracy of 92.5% when evaluating whether or not there was a need for the patient to attend the Emergency Department for admission (Scalvini, Zanelli, Gritti, Pollina et al., 2000). When further analyzed to provide an estimation of cost benefits of this system, the cost analysis showed a reduction varying between 22,760,000 and 140,060,000 Italian Lire (the approximate equivalent of £8250- £51,000) for 891 calls (Scalvini, Zanelli, Volterrani, Castorina et al., 2001). In addition it was noted in that study that in 36.4% of patients there was no evidence of previous cardiac disease.

The authors further claimed that there were advantages in terms of the interaction between primary and secondary care for individual patients, as well as educational gains for general practitioners which may possibly enable them to handle more advanced medical problems. In that study economic savings were seen as the force driving the development of the telemedicine system, although the cost savings were not yet fully established. However the findings were not exclusively propitious. In a paper the following year it appeared that some of the difficulties in establishing such a telemedicine system had been recognised, when the authors commented on the need for significant service reorganisation and provision of logistic support, without which the system was unlikely to operate efficiently (Scalvini, Giordano and Glisenti, 2002). Perhaps more interesting was the comment that the selection of patients was also a factor in its success or failure. It suggests that perhaps a number of patients were excluded from such evaluations, in a similar manner to that described in the previous section of this thesis, in which some patients were excluded from participating in automated weight monitoring studies.

Difficulties notwithstanding, by 2003 the Boario Home-care Project had evolved, providing services to general practitioners, to hospitals, to chronic patients managing their conditions at home, and to patients experiencing intermittent palpitations (Scalvini, Volterrani, Giordano and Glisenti, 2003). The authors considered that the contribution of the telemedicine ECG facility to healthcare was considered valuable, if not completely proven, and following on from earlier successes Scalvini and colleagues assessed a home-based telecardiology system for patients with chronic heart failure (Scalvini, Zanelli, Volterrani, Martinelli et al., 2004). This encompassed single-lead ECG monitoring, which the patients transferred via a telephone line to the call centre where a nurse was available for teleconsultation. This was shown not only to reduce hospitalisations but it also resulted in beneficial changes to treatment in some cases, thus indicating that the programme was both feasible and useful. In the same year the same authors compared 24 hour Holter monitoring to single-event 1 lead-ECG monitoring and telephonic transfer to the call centre, demonstrating an increase in efficacy of 29% for the transtelephonic event recorder over the Holter monitor and a reduction in costs of over 50% (Scalvini, Zanelli, Martinelli, Marchina et al., 2004). In that publication a clear diagnosis was shown to be received much more quickly with the event monitor and telecardiology service in patients with palpitations. The preference of a cardiac event monitor and supporting call centre services, in contrast to a Holter monitor for the diagnosis or monitoring of infrequent episodes of arrhythmia, was further supported in a book published the following year (Wootton, 2006) in which Scalvini and colleagues contributed a chapter entitled "Home-based cardiology." In this the authors commented that although a 24-hour Holter monitor was usually the instrument employed, the utility of the instrument was low in patients whose symptoms occurred infrequently.

Similar benefits for the tele-cardiology service were found in patients suffering from chronic atrial fibrillation (AF) and the service was deemed not only to provide a useful tool in the home management of chronic AF but also in the detection of new cases (Scalvini, Piepoli, Zanelli, Volterrani et al., 2005). In terms of advantages for patients with chronic heart failure Scalvini and colleagues also reported not only a significant reduction in rehospitalisations, but also an increased quality of life score for patients having access to the telecardiology resources (Scalvini, Capomolla, Zanelli, Benigno et al., 2005) and the telemedicine facility was further considered to provide valuable support for home nursing in cardiac care (Scalvini, Martinelli, Baratti, Domenighini et al., 2005).

Hjelm however, in commenting on the benefits and drawbacks of telemedicine (Hjelm, 2005) appeared to highlight some concerns regarding the adoption of telemedicine strategies, when he said;

> "…it (telemedicine) also has some disadvantages. The main ones that can be envisaged are: a breakdown in the relationship between health professionals; issues concerning the quality of health information; and organisational and bureaucratic difficulties" (Hjelm 2005 p66).

Thus he expressed reservations about the potential benefit of nurses accessing expert support, suggesting that it may result in an entirely opposed outcome, and concurred with the comments made by Scalvini and colleagues quoted above, regarding the organisational and bureaucratic difficulties. Those difficulties acknowledged, the reported outcomes indicated that the telemedicine system was of benefit to cardiology patients with a range of medical conditions, including episodes of arrhythmia. To quote Scalvini and Glisenti "Telecardiology has yet to reach maturity, but the evidence to date indicates that it has made a good start" (Scalvini and Glisenti, 2005) and Hjelm, who commented, "On balance, the benefits of telemedicine are substantial, assuming that more research will reduce or eliminate the obvious drawbacks" (Hjelm, 2005 p60).

That point of a requirement for further research to reduce or eliminate the drawbacks is precisely what the following studies are intended to address.

CHAPTER 11: Evaluation of a remote ECG monitoring system used by patients with a long-term history of undiagnosed arrhythmia.

11.1 Introduction. This chapter describes the study intended to evaluate a remote patient-operated 12-lead ECG recording system used in conjunction with a central call centre staffed by specialist cardiac nurses. Previous studies have provided promising indications of benefits to patient care as well as to reduced costs, however they have been undertaken in very different circumstances than the one described here. In those circumstances the administrative system was different, the ECG often being performed by nurses or general practitioners who used the telemedicine facility as expert support. In addition the telemedicine facilities described often incorporated other aspects, such as a scheduled consultation between patient and health care professional, during which a range of diagnostic or therapeutic encounters could occur. Thus the patient fulfilled only the role of patient and a healthcare professional occupied a position between the patient and the telemedicine service.

In the studies described in the following chapters not only is a different telemedicine company call centre used, but in this case the patient stands virtually alone, having to decide when to record the ECG data, then negotiating with the call centre in order to make a decision about the most appropriate action following the feedback received. Participants, with advice from call centre staff, had to decide for example whether to present at hospital as an emergency admission or whether to refer the diagnostic data to their GP for subsequent review and possible referral to a cardiologist. It was the responsibility of the patient to deliver the ECG data and medical report to the GP and to arrange an appointment for consultation. Thus in the circumstances reported here the patient role also incorporated aspects of motivator, decision-maker and diagnostician. The benefits and drawbacks of patient-operated remote ECG recording had not previously been explored under these circumstances therefore no administrative adjustments were made to the system. It was in the totality of that patient role, in relation to the telemedicine facility ***as it existed at that time*** that the study sought to identify drawbacks and benefits in order to inform future decision making.

11.1.1 Aims.

- To evaluate one system of remote 12-lead ECG monitoring in patients with a history of arrhythmia, from the points of view of the patients, their spouse or carer, and the healthcare professionals involved in their care.
- To expose any incidences of interaction between the participants and the telemedicine system in which change may be required in order to yield better outcomes from use of the equipment in the future.

11.1.2 Study Design. The position of these studies within the overarching design of the thesis has been discussed in chapter 2, and will not be repeated here. At the outset the evaluation of a remote 12-lead ECG monitoring device, in conjunction with a call centre staffed by specialist cardiac nurses was designed as a randomised controlled trial, incorporating a mixture of research methods including interview, state/trait anxiety questionnaire, quality of life questionnaire, a diary of events for patient and carer participants and a comparison of patient outcomes from medical records. The advantages of employing a mixture of methods to enhance validity and reliability were introduced in chapter 2 on page 39 and the reader is directed to that section of the thesis for further information. However in this case due to a paucity of participants and obstruction of data collection from patients' medical records (described later on page 299) the study design was, of necessity, amended. No diaries were returned and only six patients and four spouses returned a second questionnaire, therefore no attempt has been made to analyse those data. No patient outcomes apart from those described verbally by patients and clinicians were able to be included in the evidence therefore the evaluation rests solely on the interview data elicited.

As mentioned in part two of this thesis, definitions of the term "evaluation" usually include mention of "systematic assessment" of the "worth or merit" of some object (Shadish, Cook and Leviton, 1991, Scriven, 1998, Rossi, Lipsey and Freeman, 2004). In many of the previously reviewed studies the worth has been judged in terms of diagnoses achieved and an assessment of cost savings, either demonstrated or potential, however since the current chapter refers only to the interview data acquired it is thus an exploratory evaluative study intended to describe and explain both the broad scope of events resulting from the use of the remote ECG monitoring system and also the individual, possibly unique, experiences of participants as they interacted with it.

11.1.3 Data collection, interview and analysis techniques. The strengths and limitations of interview material as robust research data were discussed previously and the reader is directed to pages 170-172 of this thesis for a detailed description of those issues. The only difference in technique was that the majority of interviews with participants in the ECG study were conducted by telephone. They were not therefore able to benefit from the strengths attributed to face-to-face interviews as described on page 173 however recruitment was so intermittent that funding and time resources did not permit such frequent travel as would be necessary to interview each participant face-to-face.

The arguments proposed as supporting evidence for the choice of thematic analysis of the interview content, as discussed previously on pages 174-175, were as relevant in this case as in the interviews in the heart failure study, and the reader is directed to those pages for a review of those arguments. The recordings were transcribed verbatim and content analysis conducted using NVivo software to identify themes, assign codes to the themes and subsequently to group those themes into categories. The recordings were analysed independently by two researchers. The codes and categories developed by the researchers were compared, concepts defined and labels of codes agreed. Since so few particpants were recruited the coding of each interview was compared between the researchers. The interview schedules devised for the participants in this study and the coding schemes emerging from the analysis are reproduced in appendices 12 and 13 respectively.

11.1.4 Participants. Fifteen patients between 39 and 51 years of age in the care of GP practices in Lancashire or Cumbria accepted the invitation to participate in the study. All patients in this study were under investigation for arrhythmia and had already undergone 24 hour Holter monitoring or, in some cases had a loop recorder fitted. The telemedicine equipment was an addition to their care and did not replace medical investigation or care. Patients and carers and were given the consent form to sign and return. Three participants returned the consent form unsigned, indicating that on reflection they did not wish to participate in the study. Of these only one gave a reason, citing “my husband works away a lot and he doesn't want me to take part." A further three returned the signed consent form but withdrew almost immediately, one because he had undergone a pacemaker insertion in the interim, one because she was moving home and wanted her medical care transferred elsewhere and one citing "personal reasons".

Nine patients therefore agreed to participate in this study, two males and seven females. Six participants had spouses who agreed to participate. Three of those did not contribute a final interview, either because they declined (n=2) or because they could not be contacted (n=1). All participants were local to the area, having spent their lives in the North West of England and all had a history of arrhythmia of between two and thirty-one years duration. One patient had other medical problems relating to either renal or liver disease, but that was not known about at the time of recruitment and was in fact detected by nurses at the call centre during a consultation following receipt of the ECG data from the patient. Other participants had no comorbidities, only complaining of associated symptoms which occurred during the arrhythmic attacks, such as fainting, dizziness and shortage of breath. Contributions from some staff members who had had direct medical involvement in the care of these patients are also included.

11.1.5 Ethical considerations. The research was funded by the Diagnostic Futures Programme of the Department of Health. The clinical research lead was working as a GP in the North West of England at that time and held the post of Medical Advisor of Primary Care to the Strategic Health Authority. The academic input was provided by two members of the TeleHealth Research Group at Buckinghamshire New University, one of whom is the author of this thesis and who was responsible for all data collection, analysis and interpretation of the results. The research proposal was the result of collaboration between all members of the team in consultation with a number of cardiologists, and received the approval of the ethics committee on 20th April 2006, REC reference number 06/Q1309/1 (appendix 14).

Given the successes claimed by the authors of previous studies, there was no doubt that if those successes could be applied to the patients in North West Lancashire then the patients would benefit from achieving a diagnosis which had hitherto eluded them. Following lengthy discussions with the research clinical lead and also with cardiologists and administrative heads working in the strategic health authority to which the research grant related, the consensus was that patients with arrhythmia were the most likely to remain undiagnosed, despite frequent admission to hospital, due to the intermittent nature of the arrhythmic episodes. Thus not only did the patient continue to suffer from a debilitating condition, but in doing so consumed a significant portion of the annual healthcare budget. An effective solution to obtaining a diagnosis under these difficult conditions would therefore not only yield benefit to the patient but could usefully inform economic strategy for the healthcare system as a whole. However it was specified in the ethics application that it was unlikely that any statistically significant differences between groups would be identified, due to the limited supply of equipment (25 units). The overriding principle of any medical care is "Do no harm" and in this case every participant had the opportunity to access the telemedicine service, which was provided in additional to normal care and did not replace any part of it.

Due to the long-standing nature of the condition most patients were keen to grasp the opportunity of using the telemedicine equipment as their only remaining chance of obtaining a diagnosis and subsequent treatment. Great care was taken therefore to explain the exploratory nature of the study and that a successful outcome could not even be suggested, let alone assured. Nevertheless the patients were, without exception, desperate to obtain the equipment. For that reason it was decided to supply the equipment on a "first come first served" basis, partly because having experienced low recruitment with the heart failure patients it was thought that patients should not needlessly be prevented from experiencing the use of the telemedicine system if sufficient equipment were available for all, and partly because it was thought that outcomes from this cohort of participants could be compared with existing data gained retrospectively. Thus participants joining the study later could, following a period of contribution as a member of the control group, benefit from using the equipment that previous patients had finished with and also benefit from any adjustments made as a result of findings from earlier participants. Therefore the absence of a randomised controlled trial at this stage would not disadvantage any future patient group.

11.1.6 The remote patient-operated ECG recording system. The patient-operated ECG equipment comprises three electrodes fixed to the body by sticky pads, shown as yellow red and green in fig 11-1, and a hand held device which is placed in contact with the body in three sequential positions. The device is also shown in the figure, situated on the chest in the first of the recording positions. The two subsequent positions are labelled 2 and 3 on the diagram.

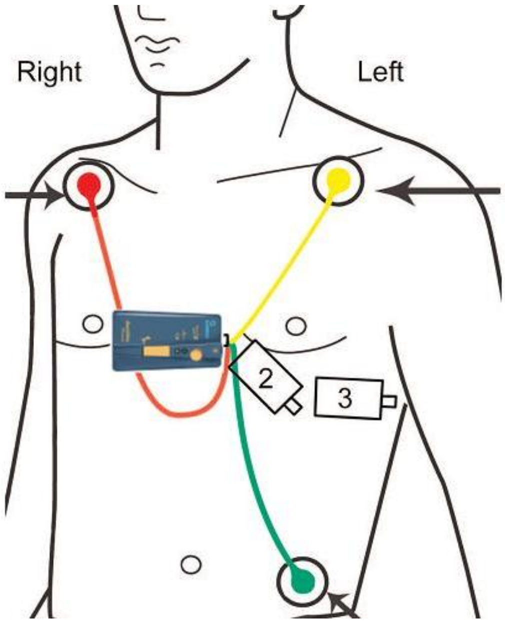

Fig 11-1 Diagram of position of electrodes for telemedicine ECG device

Recording is initiated in each position when the patient presses the large yellow button on the device. The data are transmitted via a landline telephone to a central call centre where they are processed and a composite ECG trace displayed. The trace and a report from either a cardiologist or specialist cardiology nurse is available within a few minutes and can be relayed to the required destination, such as a GP, hospital, or to the patient themselves, as required. The call centre is operational 24 hours a day, 365 days per year. After recording the ECG data and transferring it to the call centre, the patients are able to discuss their results with the staff and receive advice as to whether urgent action is required, such as an unplanned presentation at the A&E department of a hospital.

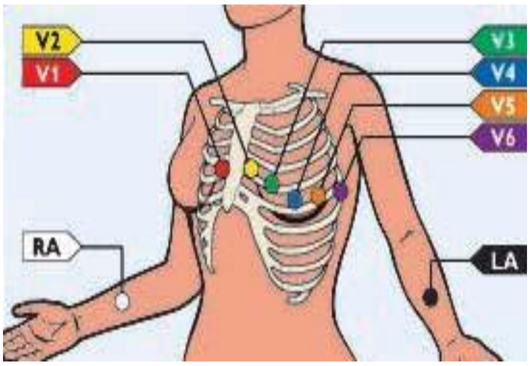

Fig 11-2 Diagram of electrodes in conventional ECG recording

In a conventional 12-lead ECG the patient has a large number of electrodes fixed onto the chest as shown in figure 11-2, in addition to wrist and limb leads. In the case of the telemedicine device only three electrodes are fixed to the body, as was shown in figure 11-1. The other electrodes are provided by the four electrodes which protrude from the under surface of the hand-held device (figure 11-3). These four electrodes make contact directly with the body to create the circuits needed to acquire the ECG data, replacing the electrodes labelled V1 – V6 in figure 11-2.

Fig. 11-3 Under surface of telemedicine ECG device showing additional electrodes

Each ECG recording device was supplied to the participants together with an explanatory leaflet in which diagrams (similar to the one shown in figure 11-1) are used to explain the positioning of the electrodes and hand-held recording device, together with instructions on communicating with the call centre.

11.1.7 Procedure. The cardiac nurse lead for research and development interrogated the medical database in order to identify patients with long-standing episodes of arrhythmia, and who had at least one unplanned visit to the emergency services during the preceding six months. Patients were to be excluded if they;

- had no landline telephone
- had dementia
- were non–English speakers (since the call centre currently only supported English speaking patients.)
- were not able to use the ECG machine, even with the help of a carer.
- were under 18 years of age
- were not residents of the Fylde health economy
- were not able to give informed consent.
- had low life expectancy due to other causes.

This resulted in zero recruitment and some reasons are offered in section 11.2.4 “ancillary findings” on page 295. GPs in practice within the region were therefore invited to participate in the study by means of a letter sent from the clinical lead of the research team (shown in appendix 10). Those who agreed to participate received a pack containing information sheets for patients and carers (appendices 15 and 16), consent forms for patients and carers (appendices 17 and 18) and a supply of stamped envelopes addressed to the researcher. The GPs undertook to provide the explanation of the study and obtain informed consent. Patients were free to consider the information and contact the researcher for further discussion if required. Consent was taken to be obtained if the researcher received a correctly completed and signed consent form from the prospective participant. On receipt of the signed consent form the researcher contacted each patient by telephone and explained the procedure of receiving the equipment and making contact with the call centre staff. Patients were advised that on receipt of the equipment they should practice using it a few times to familiarise themselves with the procedure before needing to use it during an arrhythmic event. Participants were also advised about the research requirements and that they would be interviewed as soon as the equipment arrived, to elicit accounts of their experiences related to their arrhythmia prior to that time, and also to assist with any problems that had arisen in using the telemedicine equipment.

Having experienced the difficulties of recruitment with the group of patients the decision was taken to provide the equipment on a “first come first served” basis, with the control group being the later participants to be identified. (In the event, so few participants were identified that no control group was possible.) The patients received the equipment together with an explanatory brochure, through the postal system, as was the normal practice for the call centre.

Telephone interviews were conducted with the patients as soon as possible after receipt of the telemedicine equipment, in order to elicit participant’s views of their condition and medical history to that point, and also to resolve any initial difficulties with the telemedicine equipment. The patient’s carer or partner, if any, was also interviewed at this time, in order to ascertain how they were affected by the patient’s condition, but also to cross-check the patient’s version of past events. Follow-up telephone interviews were conducted after 3 months use of the telemedicine equipment or as soon after that as possible. Later follow-up interviews were scheduled (after 6 months) although most patients had withdrawn from the study at that time or reported not using the equipment at all. As mentioned previously, the interview schedules and themes identified are presented in appendices 12 and 13.

Participants were contacted approximately monthly to enquire about progress and review any problems or events of note, then after a period of six months the final questionnaire was administered and interview conducted. The findings described in the next section relate to eight patients and five partners. The experiences of the remaining patient and her partner are presented in greater detail in chapter 12.

11.2 Results and discussion. The results discussed here relate only to the data arising directly from the patients, their spouses and the health care professionals involved in their medical care. Other observations, noted at the time, are described in section 11.2.4 on pages 295-299.

11.2.1 Patients' experiences. None of the patients referred to here were diagnosed with a cardiac abnormality requiring treatment from a heart specialist, although in one case the call centre staff reported an appearance that might be suggestive of a renal or liver problem. The patient later reported that this had in fact turned out to be a correct diagnosis. Four patients had arrhythmias diagnosed as ectopic beats, one was normal and two patients did not record any diagnostic ECG data at all as no arrhythmia occurred during the study period. All patients reported very similar experiences concerning their use of the equipment. When asked about their experiences they chose to address very similar issues and frequently returned to the same topics, focussing on;

- their interaction with call centre staff compared with other health care professionals
- the reassurance gained from having the equipment and call-centre resource available
- the practical advantages and disadvantages of having the telemedicine equipment
- the practicalities of using the equipment

Taking these in turn, it was clear that all participants valued the service provided by the call centre and in particular the interaction with staff. They valued the call centre staff as being both helpful and caring, citing particular examples such as being invited to call back in an hour or so;

> "to see how you are going on" and the fact that "…they ask you about all sorts of symptoms that you get …and they also give you … advice about what to do."

This outcome was frequently compared to contacting the GP, one participant saying;

> "If you ring your normal GP you can't get hold of them, or it's, they call you back and it's like an hour and a half wait, and even then they don't quite know what to suggest to you and then they tell you 'oh I'd better see you' and for me I've got to trek probably about half an hour away from where I live."

One participant compared the perceived approach of the call centre staff with that of her heart specialist, saying,

> "She (the heart specialist) didn't seem to want to know … at all … I just felt as though I had wasted her time. You know 'oh it's another one of these older women with' … you know ... I wasn't happy. I wasn't impressed."

Only one participant reported feeling that she had received sympathetic treatment from a healthcare professional other than call-centre staff, that being from her cardiac nurse.

In terms of reassurance gained from having the equipment on hand, most patients offered examples and the reassurance they valued appeared to address two main circumstances. The first circumstance was the simple knowledge that ***if*** an arrhythmic episode were to occur, the facility was there just in the case it was not harmless ***on this occasion***. One patient falling into this category had experienced no palpitations since receiving the equipment and believed that they would not occur in future, as they had begun when she was prescribed a new medicine and her medication had since been changed. However despite her belief that she was unlikely to experience further palpitations she commented;

> "But I'll hang on to the machine if it's alright with you and then if I do get any palpitations I'll plug myself in …"

A second patient had received a diagnosis and an explanation of her ectopic beats and was content that they represented no danger, nevertheless she asked;

> "Well, I wondered if I could carry on with it for a few more months, just because when it is occurring, if I do put it on, and send it down the line, I'm more, you know settled to know well it isn't, I'm not having a heart attack."

This situation was particularly interesting as she had been offered a 2-week loop recorder by her doctor, "to put her mind at rest," but she declined the offer in favour of keeping the telemedicine equipment for a little longer. A third patient reported that;

> "It's comforting to know that it's there and to know that when it… a couple of times when I have felt rough and used it to know that there's nothing overly … bad.. you know.. to worry about."

In this situation the telemedicine system did have the potential to affect normal care, the ECG data and report being forwarded to the GP who, being a cardiologist himself, was pleased to have his diagnosis confirmed and avoid an unnecessary procedure. However the attraction for the patients of retaining the telemedicine equipment was the fact that "someone medical" would continue to confirm that each episode experienced was not a life-threatening heart attack. Although the arrhythmic episodes captured had been confirmed as ectopic beats, patients were nevertheless in fear that future episodes would not be harmless and that one of them may indeed be a heart attack, despite the fact that they had never in fact had a heart attack in the first place.

Whether the reassurance afforded by the telemedicine equipment would reduce the number of unplanned attendances to hospital cannot be assessed by virtue of reports from so few participants however the instantaneous communication with a health care professional appeared to be the important issue for patients, particularly during the night. Neither the loop recorder nor the Holter monitor provides such instantaneous communication and diagnosis from a healthcare professional. Whilst NHS Direct is available for advice at all hours it does not offer specialist diagnostics or advice. At the time of writing the cost of one unplanned attendance at hospital which required ambulance transportation was estimated to be approximately equal to the cost of the telemedicine equipment, including unlimited calls to the call centre for one year. Since it is reasonable to speculate that in the coming years the cost of emergency care will escalate and the cost of technology decrease, on the grounds of cost alone it would therefore appear to be worthy of further investigation.

The second situation in which patients recognised the potential value of the telemedicine facility related to the fear of arrhythmic episodes occurring when they were away from home. Two patients had experienced palpitations when away from home, one when abroad on holiday and one when staying at a hotel in the UK in connection with their work. Both patients reported that they had felt quite ill on these occasions but had not taken their telemedicine equipment with them. In one case that was reported to be because there was no landline telephone available apart from in the main reception area of the hotel which in any event was not available at night. In the second case it was because the patient did not know how to telephone from abroad. Neither scenario appear to be particularly problematic and if arrhythmia is not to be perceived as an illness which prohibits people from living a normal and useful life then the relatively minor drawbacks should be explored.

One patient reported having his mobile phone and would have liked the facility to use this to transfer data and communicate with the call centre however the use of mobile telephones is not ratified by the telemedicine company at the present time. This is because there is an assumption that the mobile communication may not always be received without delay and without the data being compromised by compression of the signal. The rebuttal of this assumption by one mobile communications specialist was explained in the introductory section of this thesis, in which the company in question explained that the issue of data compression could easily be overcome in special circumstances such as an emergency health requirement. Some authors have already described the successful implementation of remote ECG devices using wireless networks (Dhruva, Abdelhadi, Anis, Gluckman et al., 2007, Sillesen, Sejersten, Strange, Nielsen et al., 2008). Although wireless communication has not yet been tested with this specific system, the facility to access the call centre via a mobile communications service may provide patients whose employment involves a degree of travel with the medical support they need to be able to continue in their job. Alternatively it presumably would not be difficult to arrange for access to a landline telephone in most hotels.

It appeared from the patients' comments that they valued not only the diagnosis and advice supplied by the call centre but were perhaps looking for logistical support in unfamiliar surroundings. In the words of one of the patients;

> "It's worrying even if in same country, you don't know where hospital is and so on."

The "and so on" to which the patient referred may encompass a range of variables quite outside the norm for most people, when considering travel abroad. Difficulties with the language, with knowing how to contact a doctor or the emergency services, and the possibility of incurring costs relating to emergency care may add to the burden of illness. It may be that in those circumstances the patients were anticipating being able to transfer the onus of taking the necessary action onto the call centre staff. Whilst the call centre staff have on occasion taken action such as contacting the emergency services in the UK, it is not likely that that service could be extended to cover such services abroad, at least in the near future. However the call centre is able to offer reassurance either that no emergency action is necessary, as in the case of no abnormality being detected, or the reassurance that emergency action is indeed necessary and this reassurance appeared to be an important contribution from the patients' point of view.

The latter circumstance is perhaps a different view of "reassurance" than is usually assumed to be the case and related to the frequently mentioned "bothering people" and "wasting their time." Two of the patients interviewed expressed the particular concern with not causing distress or inconvenience to others, either to friends and relatives or to people encountered in a professional capacity, such as hotel staff or medical services. However their concern appeared to stem from the potential embarrassment to themselves of causing an unnecessary disturbance. With the support of a diagnosis and advice from the call centre staff that concern would be removed because the uncertainty would have been removed. Either the patient would be reassured that they were in no danger, or they would be reassured that there was ample justification for "bothering people."   The role played by the call centre in removing the concern of "bothering people" may be a major factor in the reported success of the telemedicine service and is particularly cogent when considered in the light of patients' comments contrasting their experiences of the helpfulness of call centre staff with their experiences of interactions with GP services or heart specialists. One patient however did extend the worry of "bothering people" to the staff at the call centre as well, saying;

> "She (specialist nurse at the call centre) did say that perhaps I should have used it more to test in between but I sort of get it in my mind that… you don't want to waste their time, do you know what I mean?"

This perhaps suggests that greater attention needs to be paid to the psycho-social perceptions of patients in order to ensure they are all able and willing to access the care which is, theoretically at least, available to them.

The third aspect of the telemedicine system that patients valued was that they did not have to travel to access medical support. Whilst some patients mentioned the distances involved, the focus of the comments was most often the time, and not the distance, that the travel involved. This was sometimes related to the patient's fear that they were in danger of imminent death from heart attack, having a history of;

> "Feeling like having some sort of heart attack" or "(it) feels as though my heart is coming out of my ribcage."

However it was more often expressed as frustration that by the time the patient had travelled to hospital or to the GP practice, the arrhythmic episode was over and therefore could not be diagnosed. In the words of one patient;

> "Hospital says I could go there anytime but you can guarantee it would have stopped. With this (the telemedicine ECG recorder) I could just go straight away and hook it up and do it and I have this clear reading which shows exactly what I've got. Until then they thought it was that, but no one had been really sure. I had a 24-hr Holter (monitor) and not shown anything."

Another patient remarked;

> "First time it happened I woke up in the middle of the night with heart going like a steam hammer, and called NHS direct and they sent an ambulance but as it turned up it all calmed down, never found anything."

The clinical value of the immediacy of an ECG recording to participants in this study was highlighted by the fact that three of the seven patients had previously had a Holter monitor which had provided no diagnosis, and who had subsequently received a diagnosis from the telemedicine ECG equipment, even though the diagnosis of ectopic beats did not necessarily provide permanent reassurance.

Other authors have similarly found that there are clinical and health economic gains to be achieved by using telemetric equipment for patients with possible cardiac related events (Kouidi, Farmakiotis, Kouidis and Deligiannis, 2006, Katalinic, Waldmann, Schwaab, Richardt et al., 2008, Sillesen, Sejersten, Strange, Nielsen et al., 2008). More recently in the UK it has been shown that benefits should be obtained with regard to patient care and the local health economy by the use of this specific telemedicine facility to support patients and staff in the community (Weatherburn, Ward, Johnston and Chisholm, 2009). However whilst it has been shown that most patients prefer to receive care closer to home, for example as indicated in the evaluation of 'Closer to Home demonstration sites' (Leese, Bohan, Gemmell, Hinder et al., 2007) the contributions offered by the participants in this study perhaps suggest that "care closer to ***me***" is a more appropriate term than "care closer to ***home.***" It is not, for example, simply a matter of elderly or infirm patients who by necessity spend the majority of their time at home who may potentially benefit from remote care. It is just as likely to be otherwise independent persons, perhaps those who enjoy travel or who are in employment which requires travel, who would appreciate the ability to access familiar and empathic care. It may be prudent therefore to explore in greater depth the circumstances surrounding all patients' needs, in order to provide the most appropriate care for all.

The fourth and final issue raised by patients was related to the practicalities of using the telemedicine equipment. Three patients had no difficulty in using the equipment, even in the first attempt. Four of the eight reported initial difficulty in positioning the electrodes to correspond with the positioning on the explanatory diagram provided, and also in positioning the hand-held recording device in the position required to obtain the best recording. However in each case this was described by participants as only an initial difficulty which was eliminated by practise;

> "You need to do two or three practice runs"
>
> "After three or four goes I got a good reading"
>
> "The first three times I kept getting the little electrode things in the wrong place"
>
> "Staff explained where to put the patches."

(The telemedicine company emphasise initial "test runs" as being an important first step in using the equipment and encourage patients to record and send data frequently, even when not experiencing a palpitation, in order that they retain their competency.)

Two patients reported thinking that the diagram was incorrect, but in fact they had found difficulty in transposing the diagram into the corresponding position on their own body, thus they had confused "right" with "left" sides. However patients did not indicate that this detracted from the usefulness of the equipment, but instead took the opportunity to suggest possible improvements to the equipment to make it more user-friendly, for example labelling the sticky pads and leads with relevant anatomical indicators such as 'groin' and "left shoulder." Two patients reported that they left the unit with the colour-coded leads already connected to the electrodes;

> "… with all the wires attached ready to go so all I've got to do is strip off the sticky covers otherwise it takes a while to sort out what's what."

In a similar spirit of wanting to improve the equipment, one participant suggested reducing the noise the equipment makes during the recording phase, as he was concerned it may disturb sleeping children in the house, although he did acknowledge that patients with hearing difficulties may not be able to hear the audible cues which indicate recording is complete. Another suggested that the battery life of the equipment may need attention as he had found it to be flat on one occasion when wanting to use it.

11.2.2 Partners' experiences. Since only three partners contributed their views via interview following experience of using the equipment no generalisations can be attempted. However although all three spouses reported favourable perceptions of the telemedicine equipment it was interesting that their comments reflected benefits to themselves in terms of practical issues, not psychological or emotional aspects of concern for their loved one. This was particularly noticeable because it was seen in contrast to the responses of the spouses of patients suffering from chronic heart failure. In that scenario the issues raised related more often to concerns about the impact of the illness on their spouses, rather than to the everyday practicalities of their own lives. However in the case of the ECG study, the spouses appeared to have found it onerous having to drive their partners to hospital during arrhythmic episodes for example, and expressed satisfaction that the telemedicine facility had eliminated that need to a great extent. They appeared to be less emotionally involved with the physiological aspects of their spouse's medical problem than had the heart failure patients. The reasons for that difference were not identified, although it may be due to the fact that all spouses of ECG participants were in full time employment whereas the heart failure participants were all retired and therefore closely involved in the day-to-day minutiae of their spouses' lives.

It is interesting that in terms of the reassurance provided by the telemedicine equipment one spouse said, "If it ***pacifies*** (wife's name) … if it gives her peace of mind, then it's a good thing." Whilst this may appear somewhat callous, it is worth considering that a patient's illness does impose a burden to some degree on their spouse and that this may have a deleterious effect upon a busy working life. In this case the telemedicine facility may have advantages which have not hitherto been recognised. Unless they attain recognition they will remain unquantified and thus not be considered in an evaluation of cost effectiveness, which is by necessity a large part of evaluation in today's health service.

11.2.3 Health care professionals' experiences. The health care professionals involved with the recruitment and care of patients with palpitations included specialist cardiac nurses, GPs and consultant cardiologists. In one practice it was the remit of specialist cardiac nurses to care for the long-term patients on a regular basis and thus they attempted to recruit patients who fell into this category. However patients who had had a recent unplanned attendance at hospital due to arrhythmic episodes attended an appointment with their GP once the discharge letter from the hospital had been received, therefore it was the

GPs who recruited from that group of patients. It transpired that in that practice the cardiac nurses were unable to recruit a single patient, despite one nurse saying,

> "I have given out at least … ten … (information leaflets and consent forms) and obviously there's been no take-up, no take-up at all."

The GPs in the same practice recruited five patients (although one did not return the signed consent form) and it is debatable whether this was simply coincidence or whether there was an influential factor acting on the patient's decision of whether or not to participate. For example it may be that patients feel less able to refuse a request from a doctor than from a nurse, or it may be that the patients who consulted the doctor were those who had recently had the frightening experience of having to make an emergency journey to hospital, and they may therefore have been more receptive to the idea of the telemedicine support than those who had not experienced a recent acute episode.

The nurses however suggested an alternative theory to explain the lack of participation among their patients. They thought that had they been able to demonstrate the equipment to their patients they would have been more successful in recruitment.

> "I think if we'd had the equipment and said look, we've got the equipment here you put this into your phone line, you've got palpitations at two o'clock in the morning you can whack it on (nods of agreement and murmurs of assent from other nurses here) I think you'd get better take up… all the form filling and all the actual ringing and sending forms off - and then just being left with the piece of equipment … I think that's a lot to do with it. The gap between the participants and the carers is too remote I think – that's my feeling."

The GPs contributing to a focus group in that practice reported that they had found the diagnoses yielded by the telemedicine equipment very useful, as they had confirmed suspicions that the patients were experiencing ectopic beats rather than life-threatening abnormalities. They offered examples of specific patients for whom they would otherwise have had to arrange in-patient stays for tests. These included one patient in whose case they had suspected that the palpitations were ectopic beats precipitated by excess alcohol and caffeine, but for whom they had been unable to confirm that they were in fact normal arrhythmia. In the case of another patient, previous arrhythmic episodes had been of such short duration that they had not been able to confirm their provisional diagnosis despite a number of unplanned attendances to A&E. In both cases the telemetric equipment captured an event and confirmed their suspected diagnosis. After some discussion about the difficulty of capturing arrhythmic events the GPs expressed specific interest in the single-lead event monitors which are also offered by the telemedicine company. The reasons they offered were based on their opinion that;

- patients have to have a degree of dexterity to operate the 12-lead unit.
- patients have to be at home when the palpitations occur, as “you are not going to be slapping your leads on in Morrisons”.

When questioned about the usefulness of information yielded by the single-lead event monitor compared to the 12-lead ECG recorder, the GPs appeared to think that the single lead would provide enough diagnostic data for their purposes, but did not explain exactly what the differences would be and nor did they give examples. The suggestion that the single lead event monitor would be equally useful was particularly interesting in the light of two interviews which occurred later. One interview was conducted with a paediatric cardiologist and his comments are explored further in chapter 13, however he expressed the opinion that although the 12-lead ECG trace may be useful he would have preferred to see a longer “rhythm strip” such as is produced by the single-lead event monitor and that in most cases that would be sufficient for his purposes. In contrast to that, an interview with a consultant electro-physiology cardiologist showed that she was extremely excited about the facility for patients to record a 12-lead ECG trace in contrast to a single-lead rhythm strip outside the hospital setting. This consultant was very keen to pursue a research trial which unfortunately did not materialise in time to be included in this thesis. Whether this reflects a difference in knowledge and expertise or a difference in diagnostic approach was not explored, but may indicate that the choice and appropriateness of the telemedicine equipment employed may be characteristic of the healthcare professional’s experience as much as it is a characteristic of the disease under investigation.

11.2.4 Ancillary findings. The very few participants who experienced the telemedicine equipment all reported that they had found the service valuable, even if they did not actually use that service for its intended purpose. Instances of clinical benefit, such as the confirmation of the benign nature of some arrhythmia (due to ectopic beats) have also been demonstrated which may reasonably be taken to indicate the potential of cost savings to the NHS, although with such few numbers it cannot be considered to be proven. Some of the most important discoveries however were not able to be reported within the normal confines of the research study, as the events unfolded prior to the commencement of the study proper, during the design stage. They will therefore be considered here.

In the early stages of designing the study, meetings were held with a number of cardiologists and other staff members to identify the clinical scenario most appropriate to the investigation of the telemedicine facility. A number of suggestions were put forward, chest pain and post-operative monitoring among them, both of which were rejected in favour of arrhythmia. The reasons for rejecting both were essentially the same. That is that the existing systems in place for monitoring both groups of patient did not allow for the potential for the patient to monitor him or herself from home. In the case of chest pain, one leading cardiologist in a large hospital said;

> "We don't do it like that. Patients come to the clinic and have their ECG here – so I don't see it would be any use to us."

It may of course be that the cause of the pain is known to the cardiologist and that diagnosis and monitoring are redundant in the strict clinical sense, the clinic visit being targeted towards pain management. In that case it is entirely possible that the telemedicine system would be of no benefit to ***the cardiologist*** in terms of his care of the patient. It does not necessarily follow however that it would be of no benefit to the ***patient***. Given the evidence presented in the preceding sections it is possible that the patients may find it beneficial, if only from the point of view of the reassurance provided. As previously suggested, if that reassurance prevented one unplanned visit to the emergency department it would have paid for the telemedicine equipment for a year, thus there is a strong argument for cost implications. To put a value on patients' psychological or emotional ease is an impossible task, but nevertheless they are factors which should not be ignored.

In the case of post-operative monitoring, the clinicians were in complete agreement with the cardiologist who said;

> "We tell patients if they have pain, any pain at all, they should get straight to hospital, don't hang about."

All other cardiologists present at that meeting demonstrated their strong agreement that in those circumstances the remote ECG device would be of no value at all, and may waste valuable time when a patient with post-operative pain should be on the way to hospital. However, some weeks later, when the study was underway, a chance meeting between the researcher and someone who had undergone heart surgery some months before provided a very different perspective. This person was the spouse of a patient on the arrhythmia study and was interviewed as a spousal participant in that study. During his interview this person remarked that he would have liked the opportunity to use the telemedicine equipment during the weeks following his surgery, because;

> "they tell you to come straight back if you get any pain, but ... it isn't pain you know, it's just... you feel ***funny***, it isn't ***right*** somehow and you don't know."

Perhaps therefore the instructions which seem so clear to the clinicians caring for patients are not so clear to the patients. Once again it appears that there may be a role for the telemedicine equipment of which the clinicians are quite unaware. There were however strong positive reasons for selecting arrhythmia as medical condition most appropriate to the investigation into the use of the telemedicine equipment. Almost all the opinion offered from cardiologists, GPs, nurses and managers centred on the "hundreds" of patients whom they "***knew***" were frequent presenters at the emergency department, consuming a large proportion of the health budget. One manager said;

> "I see them coming through (the accountancy and audit database) and there's literally dozens every month."

This manager was confident that a search of the data base for the previous twelve months would identify a large number of patients who had a history of two or more unplanned visits to the emergency department due to undiagnosed arrhythmic events, and whom she would invite to participate in the study. The search was carried out, but after several weeks of trawling the database, and even after extending the search period to include the previous five years and also widening the search criteria to include patients who had only one reported instance or arrhythmia, only 34 potential participants had been identified. None were recruited however as all patients had either had a pacemaker inserted or were about to receive one. The process of interrogating the database highlighted to the manager for the first time the promptness with which patients in that region were fitted with pacemakers after experiencing even a single episode of palpitations. It was thought to be an unusual situation, possibly due to the proximity of a major specialist cardiac centre in the locality. Whatever the reason it became apparent that the cardiologists, GPs, nurses and managers had been mistaken in their perception of “hundreds” of patients attending the emergency department on a frequent basis. It appeared that members of the medical and administrative staff in the cardiology departments were no less immune to the power of false belief than those in any of the other examples already cited in this thesis.

The next stage in recruitment was to include the ECG study in the letter of invitation, which had already been drafted in relation to the chronic heart failure study, to the GP practices in the region,. The reasons for declining to participate in the study on the grounds of time or pressure of work may be taken to apply equally to the ECG initiative as to the heart failure study therefore will not be revisited here, but only three GP practices agreed to participate in the study. One GP however, on receipt of the letter, contacted the researcher with a request to trial just one of the remote ECG monitoring devices, for use by that doctor’s spouse who had apparent arrhythmic episodes. On receiving the explanation about the requirement for data collection and randomisation of the participants, this GP chose to obtain a cardiac event monitor from elsewhere and did not contemplate enrolling any patients to participate in the study. Thus although the GP clearly envisaged deriving some benefit from the equipment in the diagnosis or monitoring of arrhythmia, she was discouraged by some aspect of the research process. Unfortunately, because the GP had refused consent to be involved in the study the researcher was unable to explore their reasons for the reluctance to extend that potential benefit to patients.

To some extent the inability to appreciate the potential of a system which can only operate under circumstances which exist outside current working practice, such as was the case with the patients attending the cardiology clinic, can be understood. Similarly the apparent inability of a cardiologist to appreciate the patient's dilemma in differentiating between pain and "just feeling funny" can be understood, as can the GP's desire to use the ECG monitor without the associated research formalities. These deficiencies should not be ignored, lest a potentially useful device is never given the opportunity to demonstrate its worth, but entrenched assumptions such as the ones described are understandable given that the focus of medical concern is clear cut, at least from the health professional's point of view. The problem appears to be that the framework of the research design is similarly clear cut and closely regulated. Had the clinicians initially consulted regarding the research design been given the freedom to use one or two of the telemedicine units as they saw fit prior to discussing the research design, it is possible that they may have agreed upon a different study and a greater number of participants recruited. As suggested in the heart failure study, perhaps the key to overcoming the barriers to research in these situations lies in refraining from imposing such strict control as is generally considered to be the benchmark of good research design, and instead allow practices to evolve before attempting to measure them.

Finally, the issue of strict control as it relates to the access of researchers to medical records was even more problematic in this study than it was in the chronic heart failure study (as reported on page 258). Once again the "small print" of the ethics submission inhibited access to medical records as it specified, in this case, patients' medical records "relevant to their arrhythmia". In one practice, which recruited a large proportion of the participants, the practice manager felt access was inappropriate as she could not separate that information from other medical details relevant to other conditions and was concerned about possible repercussions of permitting the researcher to have access to those other medical details. That difficulty was compounded by the fact that the clinical lead of the research studies had communicated the participation of that practice to some, but not all, of the GPs in that practice. This caused a number of difficulties which were exacerbated by the clinical research lead leaving his post in that practice. This meant in essence that the practice had withdrawn its participation and therefore medical records were unavailable.

11.3 Summary of findings. The limited data in this study supported the findings of other authors that clinical benefits may arise from the use of a remote patient-operated ECG telemetric system and that those benefits may have the potential to provide economic benefits to the health services. Unfortunately there are too few robust data to provide detailed conclusions regarding how effective the equipment would be on a wider scale or how beneficial (or otherwise) the reassurance factor may be however the following findings should be noted;

- patients were able to operate the telemedicine equipment after a short practice period.
- the remote 12-lead ECG telemonitoring system provided a diagnosis in cases where arrhythmic attacks had been recorded.
- patients reported being reassured by the presence of the telemonitoring equipment.
- some minor adjustments to the telemedicine equipment and/or accompanying literature were proposed by some participants, to enable those factors to be used more easily.
- some patients preferred the interaction with the call centre staff to that they experienced with their GP or consultant.
- there were some circumstances described in which patients were unable to access the telemedicine resources, and which, if resolved, may contribute not only to the patient's immediate wellbeing but also to the wider employment economy.
- Some healthcare professionals held assumptions and/or perceptions which were not necessarily correct but which had the potential to affect adversely both the conduct of research and the care of patients.

A summary of conclusions and recommendations arising from the three contributing sources of data in chapters 11, 12 and 13 are presented in chapter 14 at the end of part 3 of this thesis. Also presented in that chapter is the appraisal of the limitations of the evaluation study and a reflection on the research process.

CHAPTER 12: Elaine's story. A vignette of one patient's experience of receiving a diagnosis via a remote ECG monitoring system.

12.1 Introduction. The events described here relate to one patient who was one of those recruited from GP practices in the North West of England. The data arising from this patient's use of the remote ECG monitoring system were originally intended to inform the findings described in the previous chapter and therefore the aims, study design, data collection and analysis techniques and ethical considerations are those described in the previous chapter and will not be repeated here.. However the patient's account of her progress from initial diagnosis via the telemedicine equipment to eventual treatment was so dramatic as to be thought worthy of more detailed description. It is presented in two parts. Section 12.2 comprises the diary of the events which occurred, as recounted by the participants, from shortly before the participants were recruited onto the study to the point at which the patient received treatment. Extracts from the patients' and spouses' own words are used to emphasise both the positive and the negative feelings that were engendered by those events. The sequence of events over the relevant time period is summarised in figure 12-1 on page 310. Section 12.2.1 contains additional comment from the patient, the spouse and the consultant, relating to the use of the telemedicine equipment, but which are not anchored within the time frame described in section 12.2.

12.1.1 Participants. The patient, who shall be called Elaine here (real name withheld) was a 47 years old lady, married and in full time employment as a hea d teacher. Her husband was also a participant in his role as spouse. Elaine first experienced palpitations at the age of about sixteen years and they had been occurring intermittently for over thirty years at the time of participating in the research. The palpitations had been increasing in frequency and severity over the previous ten years. There was no associated chest pain but some slight shortness of breath. The patient had attended her GP practice on many occasions in regard to the palpitations, although the exact number of attendances could not be determined due to the refusal of permission by the GP practice to view this patient's records. She had also presented as an unplanned attendance at the emergency department on a number of occasions, but on each occasion by the time the patient arrived at casualty the heart was once again in normal rhythm, therefore members of staff were unable to capture evidence of the arrhythmia in order to inform diagnosis. A typical record in one portion of the patient's medical notes, which were later made available by the consultant cardiologist, reported;

> "Patient returned with two symptomatic episodes reported. 12- lead ECG shows Sinus Rhythm at a rate of 72 BPM. Normal QRS & PR intervals."

The cardiologist responsible for the specialist medical care of Elaine was not recruited as a participant in this study but retrospectively contributed his views and experiences relating to this patient.

12.1.2 Procedure. In common with other participants in this study the patient was invited to participate in the study by a GP in the medical practice she attended. Following receipt of informed consent Elaine and her husband completed the quality of life and state/trait anxiety questionnaires after which the ECG monitoring device was supplied to her. The evidence offered in this chapter is based on material taken from the interviews conducted with the patient and her spouse and also from an interview held with the consultant cardiologist who was treating the patient at the time a diagnosis was finally achieved. The first round of interviews with the patient and spouse were conducted in the early stages of the patient's involvement in the study, shortly after receipt of the telemedicine equipment, in order to elicit her medical history and early experiences of using the telemedicine machine. Two later interviews were conducted face-to-face, the first after a period of just over three months, and the final interview six months later, as the interim discussions had revealed that events relevant to the use of the telemedicine equipment were still on-going. The final interviews with the patient and her spouse were captured on video.

The evidence is presented as a chronological account of events in the life of this patient and therefore is to some extent reminiscent of a case study. It is not the author's intention to claim it as such however, since it was not designed at the outset to reflect a case study approach. Rather, it is an account from the perspectives of the patient and her spouse, much of which was reported retrospectively and which has been coloured by subsequent events. Some of the issues may therefore have been reported with less vehemence than they engendered at the time.

The ethical considerations relating to this group of patients have been discussed previously on pages 280-281 and will not be revisited here.

12.2 Report and discussion on events experienced by one patient and her spouse.

Following a number of visits to her GP complaining of episodes of palpitations which she described as debilitating, Elaine was referred to a cardiologist. Neither a 24-hour Holter monitor nor a 3-day loop recorder captured an arrhythmic event and as the events increased in severity they began to impact on her working life.

> "… with my career it has become obviously quite difficult because I could have a palpitation in the middle of a meeting or a presentation … which again isn't very pleasant when I have to carry on regardless and my jumper is you know (makes jumping signs with hand on chest) flying around and I'm getting all … er and it's the after effects of that as well."

Both the patient and her spouse had discussed the clinical features of her palpitations with her GP on a number of occasions, but as the frequency and severity of attacks increased both reported feeling frustrated that she was not believed by the healthcare professionals;

> "… because I couldn't actually show that I was having symptoms there and then it was very difficult ... for them to actually visualise what 180 (beats per minute) actually meant … I was then having people saying well it was probably stress, or they did look into thyroid problems … but they went down those avenues rather than saying well there must be something causing the palpitations … it just felt as though it wasn't important."

This acted to discourage the patient from seeking medical help when the palpitations occurred;

> "(I was) frustrated and I stopped going to the GPs because there was no point ... because all I was being told was .. 'perhaps you're imagining it' (but) if I was in the car and went over a bumpy hill it would start then and that wasn't me imagining it."

Matters continued in this vein for some time, the patient continuing to experience debilitating palpitations which she self-managed by following advice which she had accessed from the internet, employing such tactics as lying on the floor with her feet raised or applying pressure to the pulse in her stomach. Although the episodes were distressing and sometimes inconvenient the patient was satisfied by assurances given to her by the GP that they were not life-threatening. Nevertheless she tended to avoid travel "in case it happened."

Matters came to a head when she experienced one palpitation of extreme severity and duration whilst on a cross-channel ferry. On this occasion the arrhythmic episode lasted some hours and she reported being very frightened because she was unable to alleviate the symptoms and the familiar forms of medical support such as calling out her GP or summoning an ambulance were not available to her. Her spouse reported;

> "It's the worry … just the worry that - I know (Elaine) says it wasn't life threatening but when you see somebody having palpitations like she had … It's a bit like a car … you can drive a car fast but if you really drive it and drive it, it gets tireder and tireder and I was thinking that's her heart - she was having too many miles put on her heart … I thought in the long run it's cutting her life short. I could measure the heart by her pulse, it was going about 190."

Both the patient and her spouse confessed to having been very frightened by this particular occurrence, but because the patient felt she had been disbelieved and somewhat dismissed by their GP neither saw any point in seeking help from that source unless they could provide clinical evidence. Having discussed the problem they decided to purchase a small commercially available heart rate monitor, and attempt to record the patient's heart rate during a palpitation, which they did successfully. The monitor recorded a heart rate of 210 beats per minute.

Having successfully recorded a raised heart rate during one arrhythmic episode, the patient scheduled an appointment with her GP to present the evidence. Her spouse accompanied her but again they felt that the GP was uninterested. On showing the recorded heart rate of 210 beats per minute, according to the patient's spouse;

> "… she took notice. Why? We had this little machine what told us – Why didn't they have a little machine ... or just have the courtesy to say yes, there is something wrong. She never did. We had to provide the evidence."

The patient's spouse was particularly bitter that the evidence had not been sought in the first instance by the healthcare professionals, despite the length of time the patient had been ill.

> "… there was no urgency with anybody to get this done and we made it our main point of urgency to get this sorted out because over the past 5 years we've been trying to catch this with various methods."

Following that meeting the GP made an appointment for the patient at the cardiology department of the local hospital, but the consultation did not go well. It appears that the patient was examined by the registrar and both the patient and her spouse reported that;

> **Patient:** "She sort of said to me "oh I can get my heart to 160 – 180" and I said well fine so can I when I'm running or exercising but I've just been sitting down … that was when I sort of felt ... is there any point in this?"
>
> **Spouse:** "she was very dismissive of Elaine's complaint … she had the readings (of the exercise heart-rate monitor) ... so we lost confidence in that consultant, coming out with a statement like that. I don't know how long they looked at the notes ... but coming out with comments like that when ... just by reading the notes would look like there is something wrong with the heart condition and it's not just running to bring it up to that figure."

As a result of that exchange the participants returned to the GP practice with the intention of demanding a change of consultants, telling the GP;

> "We need to get this sorted out, we need to have proper tests."

On this occasion as a matter of expediency they accepted an appointment with a different GP in the practice. This GP was, by coincidence, the clinical lead for the research trial and therefore the patient and her spouse were invited to participate in the study, which they readily agreed to do. At the same time the GP requested that a treadmill test and tilt test be performed on an out-patient basis and also requested a follow-up appointment with a different cardiologist.

Whilst waiting for those appointments the patient received the telemedicine ECG unit and began her first attempts at recording her ECG trace. In common with a number of participants she experienced some initial problems in positioning the sticky pads on her torso and enlisted her husband's help, because;

> "… you are looking at a picture and doing it upside down because you're actually having to fit the prongs here (pointing on own chest) whereas you're looking at the picture - and it is… whether you've got them in the right place."

However the main problem was in obtaining complete data due to the patient's body shape. (See explanatory footnote for details.) [10] Nevertheless, within a few days the patient had captured an arrhythmic episode and within a few minutes of capturing the event she had transmitted it to the call centre and received support from the staff, and also a copy of the ECG trace and report via email. When asked how she felt about that moment of capturing the palpitation, the patient said;

> "I think it was that … I was able to record it and I was able to go with it (to the GP) - and because it's a 12 point ECG and to be able to show exactly from a medical point of view what the symptom was and for them to believe me - because it was that belief or disbelief to be saying how severe it was."

[10] The four electrodes on the under surface of the hand-held device must all be in contact with the patient's body. This patient's thoracic cage had bony protrusions which made it all but impossible to get all four electrodes in contact with the body surface at the same time, thus some of the necessary electrical pathways were not recorded. This patient was the only one in whom this particular problem occurred.

This should have been the end of the process. In an ideal situation the telemedicine data would have provided the basis for informed decisions and the patient would have been treated without delay. This was not the case however and the following events demonstrate clearly where administrative failings acted to inhibit an otherwise successful system.

On the day following her successful communication with the staff at the telemedicine call centre, the patient received a telephone call from them, explaining that they had been unable to forward the data to her GP practice either via the internet or by fax as the receptionist had refused to provide details of either method of contact. They were happy to send a copy by post, but if the patient wanted a quicker service she would have to forward them herself. The patient, being concerned that the information might be mislaid in the post, chose to forward the information herself, but found that she too was refused access to her GPs email address. She printed the copy that had been emailed to her the night before and took them to the GP practice herself. There, in her own words,

> “The receptionist wasn’t obviously expecting the ECG ... didn’t know what to do with them - so I was left in the dilemma of saying well I’ve got these readings I’d been told by Manchester to give them into my GP … for a GP to look at them and to decide what to do and the receptionist didn’t know what to do… I then offered the telephone number of the call centre and then thought well actually this isn’t my job this… I was getting more and more involved in having to sort it out… I mean I wasn’t wanting to email a personal GP it was just to get this in to somebody to flag it up quickly.”

The only option given to the patient was for her to make an appointment and give the ECG report to the GP herself. She felt very strongly that an appointment was not necessary and would waste not only her own time, but that of the GP as well, and;

> “I knew if I felt quite ill I could have gone straight to A&E with them, that wasn’t a concern, but it was the fact that I was still meeting barriers … it was “well you can come and see a doctor in a few days and I’m thinking ‘Well I’ve got the readings now, I need … just to pass them on…’ I didn’t really need to

take a GP's appointment to go and give them the readings because then I was fine and … that all sort of started to fall down…"

There was a delay of several days before she could see a GP and this time it was her own GP, not the one who had enrolled her on the telemedicine study. The patient was dismayed to find that her own GP knew nothing about the study, was not able to comment on the ECG trace and appeared deeply suspicious of the source of the data;

"also it was the skills of the actual GP's ... in being able to read it, because when I took it in ... she (the GP) was questioning the skills of the people in Manchester (the call centre) … she was asking me 'well are they technicians? are they doctors? are they nurses?' … and so … my confidence then was well… I've got this … this evidence but now you're sort of questioning … not the results but the skills of the people involved. … that was when I sort of felt … is there any point in this?"

The GP did however agree to forward the data to the consultant from whom the patient had received an appointment to attend clinic. That appointment was for two months hence and the patient hoped that the additional telemedicine evidence would cause her appointment to be brought forward;

"…because I thought maybe they would have wanted to see me a little bit earlier to bring my appointment forward ... they didn't."

It later transpired that the consultant had not seen the telemedicine ECG data until the time of consultation with the patient, as it had been inserted into the patient's medical notes by a nurse in the clinic, but the lack of action reinforced the patient's feelings of neglect;

"… that's how I feel, it wasn't sort of so important … it wasn't important."

On the day of appointment at the cardiology clinic, the tilt test arranged by the GP who enrolled Elaine onto the telemedicine study was scheduled to be performed just before the consultant appointment. As the patient was being prepared for the investigation and the ECG electrodes being fitted to her chest, she experienced a palpitation. This was captured via the ECG recording and also witnessed by the doctors and cardiac technicians present. In her husbands' words;

> "The technician was worried, everybody was worried. Doctors were coming flying in and out. I was out in another room and they asked me in and when I came into the room Elaine started to relax and suddenly it just flipped and everybody saw it flip from 210 to 160 and the technician saw it and then they realised that her heart was going back as normal again and from that time onwards they took it very very seriously … things started to happen more or less straight away … people started to listen …"

The patient did not complete any of the scheduled investigations as she was taken directly to intensive care, but she demanded to be released after a few hours as the palpitation had been no different to those she had been managing for over thirty years. The ECG data captured at that time informed the diagnosis and the patient attended hospital for a successful ablation procedure about one month later. However when interviewed about the events, and in particular about the potential contribution of the telemedicine ECG and report to achieving a diagnosis, the consultant reported that despite the base-line artefact present (due to the difficulty already explained in getting body contact with all four electrodes on the hand-held device in this particular case),

> "… you could make a clear diagnosis of it's an arrhythmic ECG on the basis of this particular recording … I probably, on the basis of the fairly clear symptoms that were suggestive of an arrhythmia, I would probably have sent her off for EPS (Electro-physiological studies) on the basis of this ECG."

Thus, if the ECG had been brought to the attention of either the cardiologist or a GP who was able to interpret it the patient could have been diagnosed and treated months earlier, without the need for additional investigation or consultation.

Time		Events
For 31 yrs	→	Patient had palpitations. Many visits to GP and emergency attendances at A&E with no diagnosis. Consultant appointments, receiving Holter monitor & loop recorder – no diagnosis.
For last 5 yrs	→	Feels disbelieved by GP and consultant, so reduces visits to GP. Continues to manage palpitations alone.
Suddenly	→	One very severe episode. Patient and spouse are afraid for her life. Still feel they will not be believed by GP, so obtain a small heart rate monitor as is used by athletes, and record the heart rate during one episode.
3 weeks later	→	Take recording to the GP, who is sceptical, but arranges another consultation with a cardiologist, **2 months** hence.
At consultant	→	Patient and spouse feel cardiologist has not listened to them or read the medical notes. They return to GP practice to demand a change of consultant. They see a different GP, who enrols them on telemedicine study and also requests treadmill and tilt tests.
In 1 week	→	Patient captures arrhythmic event. **ECG trace and specialist nurse report now available, BUT** GP practice receptionist refuses to provide an email address or fax number for the purpose of receiving the data.
A couple of days later…	→	Patient takes her own copy of ECG trace and report to the GP practice, but receptionist refuses to take delivery. Patient has to make an appointment to see the GP to deliver telemedicine data. In the meantime the patient received an appointment to have the tilt tests and see a new cardiologist in two months time.
2 weeks later	→	Patient attends GP appointment, but sees her own GP, i.e. not the one who had enrolled her onto the telemedicine study. The GP knows nothing about the study and questions the source of the data and the skills of the healthcare professionals involved, however GP agrees to send the data to the consultant with whom the patient has an appointment in six weeks time. Patient now feels very insecure about telemedicine.
6 weeks later	→	Patient attends cardiology appointment. As she prepares for tilt test she experiences a typical palpitation which is witnessed by the doctors present and recorded on ECG. She is sent to intensive care but demands to be released when the palpitation has passed, as this episode was no different to those she had been experiencing for over thirty years.
1 month later	→	Consultant had explained the diagnosis and referred the patient for ablation, which has improved the patient's condition. The consultant later reported that he would have been able to reach the correct diagnosis from the telemedicine ECG, had he seen it earlier. He is interested in conducting further studies using the equipment.
Conclusions:-	→	A minimum of 3 months delay and resource-intensive tests could have been avoided if the telemedicine data had been seen by the cardiologist when first available. Several **years** delay and economic cost to the NHS could have been avoided if the patient had had access to the telemedicine equipment when it was first available to the public.

Fig 12-1 Diary of one patient's experience of the telemedicine device.

12.2.1 Criticism and approbation - additional comment by both participants. The patient's spouse was particularly bitter that the evidence required for a diagnosis had not been sought in the first instance by the healthcare professionals;

> "… you need some kind of evidence … your machine gives that kind of evidence … but we had to do it – we had to change consultants – again it's this barrier where we had to force the issue … where the consultant would react to that and he did … the other consultant didn't and that's how people work and I know it's their views but we weren't convinced and that's why we changed consultants"

Both participants felt that a diagnosis would not have been achieved had it not been for their own considerable efforts in breaking down those barriers, and that they had been forced into a position of having to direct the medical care. In addition they had also hd to act as facilitator in order to get the evidence to the GP in the first place;

> "…it is that link between me, the call centre and the admin … whether someone at the surgery … one of the receptionists who needs to be aware that this person is part of the research having these readings, if this happens then you must … accept them (the ECG data) straight away."

It is not surprising therefore that the participants were critical of that part of the administrative pathway which should exist between the call centre and eventual treatment. The problems identified by this patient's experience appear to permeate every step of the process, causing great distress;

> "At the end of the day I think all this is to do with time and it's dragged on so long. Even with your method (telemedicine unit) it's dragged on … somebody has to make a decision and say we've found a condition or there's something there we don't know what it is, let's sort it out, not just sit on it and have the patient trying to push it along."

Conversely the patient had only high praise for the call centre staff;

> "…he was super … gave me a lot of reassurance asking me obviously how did I feel now… did I feel I needed any medical attention … if I wanted to take another

reading at any time or wanted to take another reading now that was fine, and then also they said if I had any other symptoms to ring them immediately … because they're on call 24 hours a day … it is reassuring. I think that's …. really what people do need … someone who is immediately available because you don't know … in the middle of the night whether its important or not and for someone to be saying well yes your reading has shown this then see … if it's still happening, if it happens again do you want me to call an ambulance? … do you need any medical assistance? … or just to ring to talk to them and I think that's the good bit – that's what's helped. Maybe somebody ... at the beginning of treatment or the beginning of having symptoms like this then they do need some reassurance immediately."

The process of capturing the data was not without some drawbacks. The initial difficulty of positioning the electrodes and the problems of getting good contact with the body has already been mentioned. In addition this patient found that it was not always convenient to remove clothing and put the sticky pads on and therefore some opportunities to record a palpitation were lost. On one occasion the battery was flat and both participants thought that patients would benefit if the equipment could be made more "mobile" in some way, although they could not suggest how that might be attained. However despite the logistical problems the device itself was thought to be of particular use to this patient, because;

"…someone eventually looked at it (the telemedicine ECG recording) and said 'yes there is a problem here…'"

and this patient had been waiting to hear that for thirty-one years.

12.3 Summary discussion. It is clear from the experiences reported by the participants in this study that insufficient attention had been paid to the lines of communication between patient, the telemedicine company, the GP and the cardiologist. With hindsight it must be acknowledged that to some extent the blame may be laid at the door of the researcher, as it had been assumed that because the clinical lead for the research had agreed that his practice would recruit patients for the study, all partners in that practice would be similarly involved, or at least informed. This clearly had not been the case and nor had that decision been communicated to ancillary staff, therefore there was no system in place for the practice to receive information from the call centre. In any event even if it had it may not have reached the appropriate doctor. "Appropriate" in this context means any doctor who had knowledge of the source, purpose or nature of the ECG information. In this example the GP involved in the research knew the background and expertise of the telemedicine service and also had a specialist interest in cardiology, therefore had some expertise in the evaluation of the ECG trace. However the GP who eventually received the information had no knowledge of the telemedicine service. This should perhaps have been foreseen as it is common for patients of any large practice to see whichever GP may be available for an early appointment. The scepticism demonstrated by this GP was therefore perhaps reasonable and the decision to pass the ECG data to the cardiologist the correct one.

The receipt of the ECG data at the cardiology clinic was another missed opportunity to expedite the patient's treatment. Although intended for the cardiologist's attention it was not flagged as urgent by the GP and the administrative system in place resulted in the data being placed in the patients' medical notes, which are not usually reviewed until the patient attends the next clinic appointment. Had those medical notes been reviewed before the patient was scheduled to receive the additional investigations of treadmill and tilt tests, it is possible that both would have been negated, and it is interesting that after viewing the telemedicine ECG data the cardiologist remarked;

> "I think its (the ECG unit) role really is for GP's screening … patients who are having intermittent but significant episodes … that's probably where this lies … having said that they probably would be beneficial, they'd probably stop us doing implants with loop recorders – perhaps it is something we could look at – they'd be cheaper than implants with loop recorders – they're around a thousand pounds."

It is a testament to the quality and potential value of the telemedicine ECG data that this consultant is keen to contribute to further studies with this device, although his bias is towards healthcare professionals in the practice setting using the equipment, rather than the patients. Given that he assessed the patient-recorded ECG data as perfectly diagnostic it is difficult to resolve any logic from that standpoint. Nevertheless, despite having less enthusiasm for the patient-operated approach he is open to the suggestion that it may be useful in certain circumstances, such as those Elaine found herself in, and that further study is warranted. The scenario described in Elaine's case does however indicate that the existing administrative working practices and communication pathways between patients, staff and call centre should be evaluated before commencing any such study. Furthermore, in common with suggestions made throughout this thesis, any evaluation should not be concluded before those involved in the use of such equipment have allowed their working practices to evolve to accommodate necessary changes.

12.4 Summary of the findings:- The data collected and presented in this part of the study have demonstrated that;

- The data captured by the patient via the telemedicine equipment were confirmed as accurate by the ECG data subsequently captured by chance in the cardiology clinic. Thus even an inexperienced patient can capture an accurate recording and such a recording can yield an accurate diagnosis.

- The data captured by the telemedicine equipment were available several months before those captured in the cardiology clinic, thus providing evidence of its value in early diagnosis.

- The communication of the information from the call centre to the health care professional best placed to utilise that information was obstructed in this study by the administrative systems currently in place. Thus the nature of the administrative underpinning of each practice or clinic may be a significant factor in the success or failure of the telemedicine facility.

- Similar obstructions may have impacted upon the research process.

As with the previous chapter, the conclusions and recommendations arising from this chapter will be presented together with those from chapters 11 and 13 at the end of part 3 of this thesis. Also presented in that chapter is the appraisal of the limitations of the evaluation study and a reflection on the research process.

CHAPTER 13: Evaluation of a 12-lead telemedicine ECG device used by laypersons on paediatric patients.

13.1 Introduction. The telemedicine ECG device described in the previous chapters of this section has not been ratified for use on paediatric patients. However the previous chapter explained the difficulty experienced by an adult patient in achieving body contact with all four electrodes at the same time, and this was thought to be due to the exceptional body shape of the patient's thoracic cage. Since many paediatric patients, particularly those in adolescence, may equal or even exceed the size of many adults, the distinction between adult and paediatric patient was felt to be somewhat artificial in this circumstance, as it appeared that body size or shape may be the limiting factors rather than the age of the patient.

This chapter describes a small study in which the 12-lead ECG data from paediatric patients, captured by untrained persons using the telemedicine device, are compared with those captured by experienced cardiac technicians or paediatric nurses using hospital equipment. Additional comment which was volunteered by the paediatric cardiologist and by some parents is included, as is comment on notes made at the time by the researcher.

13.1.1 Aim. To explore the feasibility of using the telemedicine ECG device in the home, for the diagnosis and monitoring of heart disease in children.

13.1.2 Study design. Having learned the lessons from the findings of the preceding studies, it was understood that existing working practices may undermine an unbiased evaluation of the telemedicine device. The preparatory work required to put the necessary administrative processes in place would be a huge undertaking, particularly in view of the fact that the equipment had not been shown capable of capturing ECG data in children. It was decided therefore that a large randomised controlled trial of telemonitoring was not appropriate at this stage and that a pilot study should be conducted in order to explore whether or not it may be possible to capture useful ECG data of children in the home environment. That exploration was based around two main questions;

a) Is the telemedicine ECG device technically capable of capturing ECG data on children? and,

b) Are there obstacles, inherent in the procedure of capturing ECG data on children by a layperson, that have not been identified in the studies relating to adults and which may obstruct the process?

A simple exploratory study was therefore designed to compare the quality of ECG data obtained by laypersons using the telemedicine device with the quality of ECG data obtained by healthcare professionals using normal hospital equipment, on the same children at the same clinic visit. Field notes would identify any particular difficulties or factors which may have affected the quality of the resultant data from either method.

13.1.3 Participants. 63 patients attending the paediatric cardiology clinic of a large London hospital agreed to undergo the telemedicine ECG procedure, although due to time constraints and their concern about the journey home, only 52 actually did so. The patients were aged between three months and seventeen years and the ECG data was collected over a period of eight days, the clinic occupying approximately four hours on each of those days. Of the 52 ECG studies, 21 were performed by the patient, 29 by the researcher and 2 by a parent.

13.1.4 Ethical considerations. During exploratory meetings with a consultant paediatric cardiologist and an electrophysiologist, both specialists stressed the excitement they felt at the potential uses for a 12-lead ECG unit which could be used in the home. There was, they felt, a great need for this facility and the examples they gave indicated clear clinical and medical benefits, such as;

- the frequent close monitoring of children, which would provide an early alert to a deteriorating condition, or perhaps allow less frequent clinic attendance in the absence of adverse clinical findings,
- the possibility of achieving a diagnosis which had thus far eluded them, due to the absence of symptoms during the very brief clinic consultations.

They also mentioned that, being a specialist centre, their caseload included many patients whose parents had to bring them hundreds of miles on a regular basis simply to attend the clinic, placing a burden on both parent and child. Thus the benefits they envisaged applied to patient, carer and the NHS economy. Single lead event monitors were available to patients and their parents but both specialists stressed that the additional information yielded by a 12-lead ECG would prove valuable, and therefore patients were recruited from their specialist paediatric cardiology clinic as part of a service audit initiative that was being carried out at the time.

Due to the age of the patients, it was the parents who first received an explanation of the nature and purpose of telemedicine and the procedure involved in acquiring the ECG data. At the same time the exploratory nature of the study was stressed, taking care to emphasise that it was unlikely that this equipment would be made available to them as a diagnostic tool, at least in the near future. If parents consented to the additional ECG procedure then those children of an age where they were able to converse also received an explanation, although the explanation was made age-appropriate. The telemedicine device was demonstrated and the child given the choice of participating or not. Those who agreed to participate, and the babies whose parents had agreed to participation, had the ECG which was performed by hospital staff on hospital equipment as the first examination and the telemedicine ECG afterwards. This permitted either parent or child to change their minds if they had found the first ECG difficult or distressing, or if there were time constraints.

13.1.5 Procedure. All patients who were deemed to require a 12-lead ECG by the consultant cardiologist prior to their consultation were considered eligible for the study and those agreeing to participate had the ECG procedure conducted in the normal way by a paediatric nurse, according to hospital policy. The paediatric nurse responsible for acquiring the first ECG produced a second copy of the trace from the ECG apparatus and made it available to the researcher, who then took the patient into a separate room for the telemedicine procedure. Children who were considered able to manipulate the hand-held device (with help where necessary) and also the parents of younger children were asked if they would like to perform the ECG procedure themselves. Those who declined had the ECG recording performed for them by the researcher, who had no experience whatsoever in the technique and who followed the printed instructions which were normally provided by the telemedicine company to new patients. The telemedicine data were transmitted via a landline telephone to the telemedicine company in the normal fashion and a copy of the ECG trace emailed to the researcher for retrieval and printing later. A report was not provided in this case as the intention was to compare the quality of the ECG traces free from confounding evidence. Both copies of each patient's ECG data were anonymised and placed in a folder for subsequent review.

During the telemedicine ECG procedure written notes were made by the researcher to record;

- All comments made by the patients and by parents,
- All observations of difficulties or events which occurred during the procedure which may have affected the performance of acquiring the data.
- All comment on the quality and/or request to repeat the ECG which came from the staff at the call centre.

The two sets of ECG data were scanned and printed and a copy was passed to a paediatric cardiologist from another hospital for comparison. His comments were recorded using a digital voice recorder. The folder of ECG traces was then passed to the electrophysiologist in the hospital where they had been recorded, for a similar comparison.

13.2 Results and discussion. 52 patients attending the paediatric cardiology clinic of a large London hospital had both the hospital-based ECG and the telemedicine ECG performed within a few minutes of each other. Of the 52 ECG studies, 21 were performed by the patient, 29 by the researcher and 2 by a parent. One patient had dextracardia and therefore all the leads were reversed but this did not appear to have a detrimental effect on the ECG trace.

Four patients had the telemedicine ECG recording repeated on the advice of staff at the telemedicine call centre. Of these one was due to movement (the patient was 3 months old) two were due to extraneous interference (more detail in the next paragraph) and one was due to poor contact of the electrodes on the hand-held device. This last patient was of very small and very slight build and the problem appeared to reflect that of the patient "Elaine" in the previous chapter.

The interference mentioned above resulted from electrical equipment which was in close proximity to the patient and the ECG device during recording and transmission. Unfortunately there was no consulting room free for recording the telemedicine ECG and it had to be conducted in a small cubicle used for the housing of large banks of transformers and air conditioning equipment. This was very noisy, certainly much noisier than the average domestic kitchen and suffered from intermittent electrical hum as air conditioning switched on and off. On one occasion the patient's mobile phone rang during the ECG recording. The mobile phone was in her shirt pocket and it is not known whether it was this or the adjacent electrical equipment which caused the interference.

13.2.1 Cardiologists' testimony. When comparing the telemedicine ECG traces with those performed by the paediatric nurse, the paediatric cardiologist made a number of interesting observations. The first was that the quality of information generated by the telemedicine ECG device was comparable to that generated by the hospital equipment;

> "In terms of concordance between what's there and there (comparing telemedicine and hospital ECG's) that seems fine."

This was despite the difficulties of adverse conditions;

> "My impression is that that's good (the telemedicine ECG trace) and yes you're going to get artefact as children move and so on … I mean that's a perfect one, that's a baby. You've tried on all sorts of adverse things and you've got a very good recording … despite the fact that it's obviously kicking."

However it was his second observation which provided great surprise. In his opinion the additional data provided by a 12-lead device over and above that provided by "a one or two lead device" was not essential;

> "We don't really need it in that sense but it's quite useful to have as an additional thing. If it's quick to do, there's no harm in having it. It can be

useful. But what we're really looking for is if we're going to be asking parents to take these home is … what the rhythm strip is doing."

The respondent repeated that opinion frequently during the interview as he compared the sets of ECG traces, but this was in direct conflict with the impression given by the electrophysiologist during the initial exploratory meetings. She was so enthused by the facility provided by the 12-lead device compared to that provided by a single lead event monitor that she requested the loan of one for an acquaintance who was experiencing arrhythmia.

The paediatric cardiologist went on to support his view, saying that;

"V4 (one of the chest leads seen in figure 11-2 on page 282) doesn't matter at all."

This was a general comment, not related to one specific patient and is particularly interesting because it is this lead that both "Elaine" and the one paediatric patient, already mentioned at the bottom of page 306, had found difficulty with, in trying to establish satisfactory contact with the body. Selecting one telemedicine ECG as an example, the cardiologist explained;

"That wasn't one held exactly … in the right place, but you would also pick up a voltage on that if it (arrhythmia) was happening at the time. So it's happening there (pointing to one section of the ECG trace.) It's the rhythm, it's the overall heart rhythm whether it's too fast, too slow, long pauses whatever we shall be needing. The 12 lead isn't so important."

However he later appeared partially to contradict himself by saying;

"… a 12 lead ECG, that's more useful for children because they have more dominant right side forces and it's useful to have that extra lead but you don't need it for just looking at the rhythm."

It was initially tempting to assume that a fundamental difference of opinion existed between the two specialists and that the differences may have been the result of additional specialist knowledge and expertise held by the electrophysiologist in the interpretation of the electrical data revealed by the 12-lead ECG. However a later comment by the cardiologist indicated that perhaps his view, and therefore presumably that of the electrophysiologist were coloured by their respective working practices when he remarked;

> "If they're referring a patient in from another hospital then a 12 lead … we would need that. But on the other hand they can just do a normal ECG within their department anyway and just fax it through, that's what they usually do, so … it probably doesn't have a place in that sense. It's different if you (the patient) were going home."

This appears to reflect the cardiologist's current working practice in which his patients are usually referred from other centres for specialist treatment, usually surgery. Thus he is rarely privy either to the often long and painstaking process of establishing a diagnosis, or the lengthy follow-up process of monitoring recovery. During the time his patients are under his care he has recourse to a wide variety of sophisticated medical equipment, thus a remote diagnostic tool of this kind may not be the ideal in this particular circumstance. The electrophysiologist on the other hand, perhaps because of the nature of her expertise in diagnosis from ECG data, is involved with the often prolonged diagnosis and monitoring procedures for patients who are, in the meantime, normally living at home. These patients are often domiciled hundreds of miles from her clinic and were cited as coming from regions such as the far north of Scotland and from Germany.

13.2.2 Researcher's observations. During the data collection period a number of observations were made by the researcher and noted at the time. The first was that patients as young as 8 years old were able to record the ECG data themselves, with a little assistance in the positioning. They had not had the opportunity to look at the instruction diagram, they were merely shown where to hold the device for each of the three recording positions and it is quite likely that they would be able to repeat the procedure unaided after a little practice. One very young patient (4 years old) made a good attempt but the record button on the device has to be depressed by the forefinger whilst the other fingers hold the device on the chest wall. That manoeuvre proved too difficult for this patient, mainly because of the pressure required to depress the button. A number of patients declined the invitation to attempt self-recording, although they may have been persuaded once they had witnessed it a few times.

The second observation was that the telemedicine ECG had to be performed in extreme haste due to the rapid throughput of patients at the clinic. Many patients had travelled long distances and it was the aim of all consultants and registrars to see them very quickly so that they could travel home. The normal course of action was for patients to register at reception, have the normal ECG then proceed to the consulting room of whichever cardiologist was free. Therefore the telemedicine ECG had to be performed in the very short time between the normal hospital ECG and the next vacancy to see a cardiologist, and this may have resulted in a poorer quality ECG trace than would have otherwise been possible. On a number of occasions there was no time to do the telemedicine ECG and a number of potential participants were lost to the study.

Thirdly, all patients were startled by the noise made by the recording device. The sound is not entirely dissimilar to that made whilst transmitting a facsimile via a landline. This is a deliberate feature of the equipment and is present so that the patient knows when the device has finished collecting data in the first position, after which they move the device to the second position and record again, the same sound being heard during that recording. The noise caused some patients to jump slightly, but most laughed or giggled at the sound, particularly the younger patients and this may have had an adverse effect on the quality of the ECG recording, causing movement artefact. With hindsight a “practice run” before the recording of ECG may have eliminated that particular problem however it would rarely have been possible due to the very limited time available as explained above. A further source of movement artefact was in young children looking round to see their parents, or where the parents spoke to the child and the child replied or nodded. In one case, where the father operated the device, the father proceeded to bounce the baby on his knee throughout the whole process. This however produced the ECG trace which the cardiologist in the previous section had pronounced “a perfect one.”

Most parents witnessed that part of the procedure in which the data were transferred during a normal telephone call and were aware that the staff member receiving that call was able to view it almost immediately and comment on the quality of the ECG trace. A number of parents volunteered favourable comment on the idea of the telemedicine device and its application to their own circumstances. In particular, one parent was keen to know much more about the telemedicine system and after her consultation with the cardiologist she returned to seek more information. The email attachment comprising the telemedicine ECG trace of her own child was shown to her on the computer, at which point she volunteered the comment that;

> "This would have been a Godsend… not now, we know what it is and we come to the clinic, but all that time he was a baby and we were – we didn't know – this would have been a Godsend…"

13.2.3 Electrophysiologist's testimony. Despite many telephone requests and four personal visits to the hospital department, during which time the electrophysiologist claimed to have "looked at over half but not finished yet" it has not been possible to retrieve either the folder of ECG traces or the results of the comparisons. Nevertheless at the time of writing the electrophysiologist reported that the ones she had seen "look very good" and she remains keen to obtain a number of the telemedicine devices for use with her patients. Therefore it must be deduced that she envisaged some useful application for the device and that perhaps it was the burden of rigorous research procedures which proved onerous. The ECG device she used to pass to her friend with arrhythmia has not been returned.

13.3 Summary discussion. In addition to demonstrating the feasibility of acquiring good quality ECG traces on children with this telemedicine equipment, this study also provided the strongest indication of all the studies that it is the individual the senior position as healthcare professional who is in a position to choose either to obstruct or to further the course of research into new telemedicine technologies. It also helped to clarify the dual nature of the origins of obstruction.

For example one healthcare professional, the electrophysiologist, was very keen to use the equipment and saw clear application to practice. Existing working practices in this case were no obstruction, as this person was in a position simply to dictate that results were to be emailed to her. It is possible that the equipment would only be deployed in circumstances in which a benefit was assumed and the potential to apply it to other patients would not be realised, however the equipment would be utilised in the first instance. It was the requirement to perform the steps of research which obstructed the evaluation in that instance, and as already suggested, in the absence of evidence regarding cost-effectiveness the financial resources required to provide the equipment are unlikely to materialise.

The second health care professional, a consultant paediatric cardiologist, gave considerable time and attention to evaluating the quality of the ECGs provided. He had extensive research experience, which may account for his unquestioning acceptance that this stage was necessary. In this case however, although he did acknowledge that the telemedicine device would give more information for children, he did not see a benefit to his immediate practice, due to discrete characteristics of his working practice. The interesting point is that he had already arrived at that conclusion before the study commenced, but nevertheless still gave his time and expertise to the evaluation. It appears therefore that in order to carry out a large randomised trial in order to evaluate the use of this equipment for children at home, it would first be necessary to identify those healthcare professionals who are keen to use the equipment, and subsequently from that number identify those who appreciate the need to evaluate it in an unbiased and robust manner. Finally, from that dwindling number it would be necessary to identify those who could contribute the time and expertise to the evaluation.

13.4 Summary of the findings. The ECG data yielded by the 12-lead telemedicine ECG device, even when operated by a complete novice, has been shown to be comparable in most cases to that obtained from a clinic-based 12-lead ECG device operated by an experienced paediatric nurse when used on paediatric cardiac patients.

In cases where the telemedicine data were inferior to the data from the clinic-based machine, the loss of quality was judged to be due to electrical interference from the proximity of equipment which would not normally be found in the home. The clinic-based machine was not sited near that electrical equipment and therefore it is not known if it would cause similar interference to the hospital equipment.

The discrimination between adult and paediatric patient is not in itself a reliable distinction when considering the appropriateness of the telemedicine device, although size and shape of the thorax may be.

The perceived usefulness of the device by health care professionals may depend less on the age or precise medical condition of the patient than on the stage of diagnosis or treatment upon which current medical attention is focussed for the individual patient. For example the home-based telemedicine ECG device may be valuable in the early stages of investigation, providing evidence to contribute to a diagnosis.

The acquisition of robust research evidence may be hindered by the demands on resources, in particular the time of patients, clinicians and researchers that the research process requires. However, the results arising from this small exploratory study indicate that further research into the use of the telemedicine ECG device is worthy of consideration.

As with the previous studies, a summary of the conclusions and recommendations arising from this study is presented in the following chapter, which also offers an appraisal of the limitations of the evaluation studies and a reflection on the research process.

CHAPTER 14: Limitations of the study, a personal reflection of the research process, conclusions and recommendations.

14.1 Limitations of the evaluation study. As with the studies on automated weight monitoring, the loss of the features characteristic of a randomised controlled trial meant that virtually no robust evidence in terms of demonstrating statistical significance can be claimed. There was no control group and even in the experimental group the numbers were so small that no such conclusions relating to the efficacy of the telemonitoring system on a wide scale can be reliably derived from the events described.

Bias on the part of clinicians was evident on a number of occasions, for example those who refused to trial the equipment on patients for post-operative monitoring of chest pain because “We don’t do it like that” (page 296). Without that bias it is possible that that group of patients would have provided more data from which to draw conclusions, particularly as the “post-operative” period is very well defined, i.e. every patient recruited would have had an operation very recently. The problem with intermittent arrhythmia as a medical condition of research interest is that it is, by definition, intermittent. A number of the participants in this study who were given a telemedicine ECG unit did not have an arrhythmic attack in the six months following receipt of the equipment. To obtain any truly comparative data on this group of patients data collection would have had to continue until each participant had experienced at least one such attack. Then comparisons of unplanned hospital admissions could be made. Time and funding constraints did not permit this.

As with the chronic heart failure study “blinding” was not possible, for patients, researchers or clinicians. Even in the study to compare the ECG traces on paediatric patients, although all identification marks were removed, the traces from the two sources (hospital clinic and call centre) had a very different appearance. It cannot be claimed with certainty that the consultant cardiologist comparing them would not be familiar with the appearance of traces acquired in the hospital clinic.

A lack of cross referencing data from other sources, such as patients' medical records, diaries or quality of life and anxiety questionnaires meant that self-reported incidents or occurrences could not be cross-checked and nor could "before and after intervention" comparisons be made. The very small numbers, together with the lack of triangulation of sources meant that neither validity nor reliability can be claimed for any findings reported as a result of the interviews with participants. Furthermore, pragmatic reasons related to time and funding resources meant that many interviews were conducted only over the telephone, therefore the researcher did not have the same opportunity to create the conversational approach needed to elicit confidences which may otherwise have yielded valuable information. This was felt to be a major limitation as the richness of contribution provided by the heart failure patients was not generally made available by participants interviewed in this study.

Whilst the comparative study of paediatric ECG traces incorporated 52 patients, there was no formal assessment method carried out by the consultant cardiologist who performed the comparison. The cardiologist compared the traces visually, but did not conform to counterbalancing procedures in terms of the order of viewing, due to time constraints. This was not thought be to be a problem at the time because comparisons performed by the cardiologist and the electrophysiocardiologist could have been repeated subsequently by any number of clinicians. However as reported in section 13.2.3 on page 323 the results of that evaluation by the electrophysiocardiologist, if conducted, have never been communicated to the researcher and nor has the file of ECG traces been returned.

Overall therefore, no measures such as mean differences in outcomes under any specified condition could be elicited from the data. There is not sufficient evidence on which to base any changes at the present time with regard to clinical practice or policy issues either for individuals or for the wider community. However, again in comparison with the heart failure study;

> *"The hierarchy of evidence that has promoted randomised control trials as the most valid form of evidence may actually impede the use of most effective treatment because of practical, political/ideological and epistemological*

> *contradictions and limitations ... Therefore, to enable the implementation of best evidence in practice, the hierarchy of evidence might need to be abandoned and reflection to become a core component of the evidence-based practice movement."* (Mantzoukas, 2008)

Therefore although the study has not provided an exhaustive evaluation of the use of the remote ECG unit in patients with intermittent arrhythmia in terms of the manner conventionally demanded by fund holders, it has fulfilled the purpose of a descriptive study in that it has exposed many of the shortcomings, as well as the benefits, of a national healthcare system which has a telemedicine element incorporated within it. As Green and Wajed note, "…statistical significance does not necessarily mean clinical importance. 'A difference is only a difference if it makes a difference'"(Green and Wajed, 1998) .

The obstruction to evaluation caused by the legal, ethical and administrative demands of the research process were demonstrated in the study on chronic heart failure and will not be repeated here, although these studies were equally affected. A number of other shortcomings and benefits which have been identified by participants in this study do not appear to have been appreciated previously and therefore new information has been uncovered. The extent to which the administrative processes in the health service debilitate an otherwise effective resolution to a problematic diagnosis has arguably never been so clearly demonstrated as in the case of "Elaine" described in this study. Similarly, clinicians' ignorance of some patients' confusion over the concept of "chest pain" (and the role the ECG unit could play in that confusion) appears not to have been previously recognised. In the same vein, those treating patients with intermittent arrhythmia may have to consider the fact that patients are not necessarily reassured by obtaining a benign diagnosis of the cause of their arrhythmic attack on one single occasion. Thus the research has highlighted a number of issues which must be addressed before further evaluative studies would be able to quantify the benefits in the manner conventionally demanded by fund holders.

14.2 Personal reflection on the research process. Issues surrounding boundary setting and preparation for emotional challenges were very similar to those described for the heart failure study in section 9.2 on pages 255-256. I had no personal experience of heart disease in family members and once again my clinical knowledge of the medical condition or its treatment was minimal. A very different emotional response was elicited by the participants interviewed for this study compared with that relating to chronic heart failure however. This may have been due in part to the enforced distance between me and the majority of participants, as I was unable to conduct face-to-face interviews with most.

The interviews were in the main very brief and it appeared that the participants did not want long telephone conversations. Even though I had made specific appointments to phone at a time convenient for them, they were invariably engrossed in something else, either making lunch or watching a programme on television and they were keen to curtail conversation. Had I had the facility to meet the participants in person the advantages of being a “local” may have afforded the opportunity to enhance the relationship and thus educe more personal reflection from them. The relationship with most participants therefore remained extremely remote. That, together with the fact that they were not generally either particularly elderly or particularly vulnerable, created what felt like a vacuum in terms of emotional connection. I did not experience pity, as I had with participants in the heart failure study, and none of them reported any incidents which caused me to feel anger on their behalf. Even when reporting that a diagnosis had been achieved with the telemedicine equipment the participants did not appear to be particularly moved and none wanted to give up the telemedicine unit. It was almost as though they did not believe that the ectopic beats demonstrated were the real cause of their arrhythmia and they appeared to be waiting for a different outcome. Thus the research diary did not contain much emotional content related to these participants.

It was however a different matter with “Elaine” and with the paediatric patients in the hospital clinic. Again that may be partially the result of a face-to-face interaction with the participants, but on this occasion the emotion elicited was euphoria. On interviewing “Elaine” and her husband for the final time she had already undergone treatment with a successful outcome. Therefore the frustration and anger she had felt at the delays and obstructions to her diagnosis were reported from the point of view of delight that she was now well. Had I interviewed her prior to the accidental diagnosis achieved in hospital, during the period when she was trying to get the results of her telemedicine ECG recording to the attention of a doctor, her feelings (and mine) may well have been very different. As it was, when I first received the news that she had achieved a diagnosis within just a week of having the telemedicine equipment, I wrote in the research diary;

"Wow – we've got one!"

The fact that we only "got" one other diagnosis which required treatment did nothing to reduce that euphoria.

The paediatric patients too were also at the point of having achieved a diagnosis and were receiving treatment for their condition from a consultant cardiologist. Therefore uncertainty and fear which some parents reported having experienced in the early stages of their child's illness were largely overcome by the time I met them and so neither pity nor anger were stimulated. In this case the euphoria arose from my successful attempt to produce an ECG trace on a patient for the first time. Even though I had read the documentation and been assured it was easy, I was still astounded that it worked and I got a good ECG trace. In retrospect patients receiving the equipment for the first time must be equally sceptical and probably equally excited when they have a successful transmission confirmed by staff at the call centre. After the first time a child performed her own ECG trace (almost) without help, I remember being struck by great excitement and for the first time thinking that this equipment should be out there in the community now, available to everyone who may benefit from it without a single moment's delay. I felt a great deal of frustration that, due to the limitations of the study it probably would not achieve the recognition it deserved at that time and that further, larger studies would be required in order to verify the efficacy of this little "gadget" before it found a place in mainstream care. I was, and still am, extremely proud to have demonstrated its capability and also to have pointed the way to ensuring that in future studies the major obstructions can be avoided.

Summary conclusions and recommendations. There are insufficient data to provide robust conclusions on which to base more widely generalised decisions about the use of the patient-operated telemedicine ECG recorder. However the study has shown that;

- diagnostic ECG traces were successfully acquired by all patients who attempted the self-operated procedure, and in the case of paediatric patients, by an inexperienced lay person using the telemedicine equipment.

- there may be some elements, related to the design of the equipment, to the siting of the equipment or to the patient’s body-shape which exert a negative impact on the quality of the ECG trace acquired from some people.

- difficulties in the administrative and communication pathways between the persons holding the diagnostic data and those whose responsibility it was to treat the patient exerted a negative impact on the perceived success of the telemedicine facility.

- the necessity of a landline telephone posed an obstruction to patients in a few cases.

- patients reported being reassured by the presence of the telemonitoring equipment and by the interaction with call centre staff.

- some healthcare professionals were unable to envisage the potential benefit of the telemedicine equipment because their perceptions of some circumstances were not necessarily correct (such as the extent of the resource budget consumed by patients with arrhythmia or a patients’ problems in deciding upon a course of action when faced with a medical dilemma such as chest “pain”.) This exerted an impact upon the nature and design of the research, in particular the patient group targeted for the study.

The recommendation is therefore that clinicians should be encouraged to engage with further research into the use of the patient-operated ECG equipment, across a wide range of medical contexts, in order that larger randomised controlled trials may be conducted. Practical ways to foster engagement may include;

- Disseminating the information arising from the studies described in this part of the thesis, i.e. that the equipment appears to be technologically capable of yielding high quality ECG traces and a rapid report, regardless of age of patient or experience of the operator, and that it may assist in attaining a diagnosis in patients where other attempts have failed. It must be particularly emphasised, with regard to the use of the equipment for paediatric patients, that the telemedicine should not be used ***in place of*** other tried and tested methods however.

- Educating clinicians in the patients' position of indecision regarding the concept of "chest pain" when faced with the dilemma of whether or not to call an ambulance.

- Removing the necessary but arduous tasks inherent in research study from the clinicians as far as possible.

- Identifying and removing potential "bottle necks" in the communication pathways between data and clinician.

- Identifying and exploiting any particular enthusiasm held by clinicians which may act to promote research opportunities. "Enthusiasms" may be clinical scenarios such as a particular patient group, or may be related to a specific technological interest, such as mobile phones.

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CHAPTER 15: Summation.

The provision of equipment (or otherwise) in the NHS is often the remit of managers, who require evidence on which to base their decisions. The intention at the outset of this work was to provide that evidence by the evaluation of a number of telemedicine devices, and a large part of that evaluation comprised an exploration of the reality of their use in specific clinical scenarios in the UK health system from the perspectives of the users. It was evident from the studies described in this thesis and from the literature reviewed that all the telemedicine applications under evaluation have the ability to be of clinical benefit, and furthermore some have demonstrated instances of clear benefit in individual cases. However the application of those benefits to the wider audience was often obscured, either by the inability of existing working practices to make effective use of the applications or by barriers imposed by the research process which acted to discourage a comprehensive evaluation.

The evidence arising from these studies does however also indicate that in order to achieve an effective evaluation there first needs to be an environment in which both the telemedicine applications and the evaluation are permitted to thrive. Moreover, the indications are that such an environment was often degraded by an absence of three particular features, those being;

a) freedom of use of the equipment under evaluation,

b) administrative systems and working practices able to accommodate the necessary communication pathways, and;

c) people who are effective in their role and are willing to embrace the technology whilst at the same time willing to conform to the requirements of research.

These three requirements are described diagrammatically in figure 15-1, which illustrates the fact that the evidence on which decisions are based relies on the best performance from each if the evaluation is to be accurate. However the three are interdependent and so cannot be considered in isolation. For example constraints are placed on people by their working practices with associated administrative systems and also by the limitations imposed on their ability to utilise the equipment as and when they would like. Conversely, it is people who have evolved those working practices and administrative pathways, many of which obstruct the free operation of the telemedicine systems under evaluation. If individuals lack either the desire or the ability to be proactive in evolving those practices to accommodate the telemedicine systems under evaluation, then the evaluation will suffer.

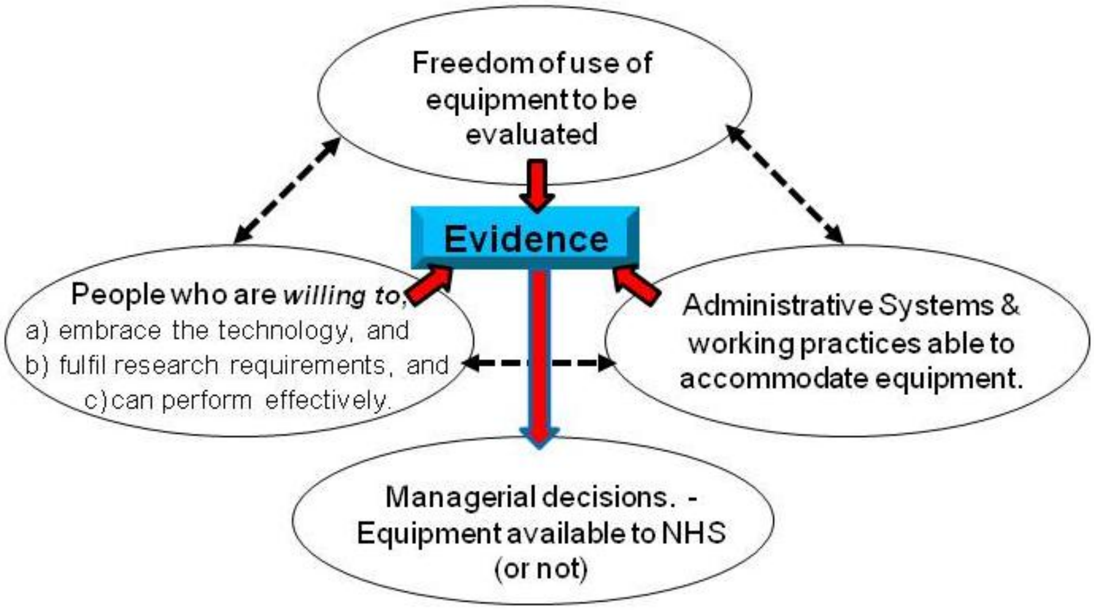

Fig 15-1 The requirements of a successful telemedicine evaluation environment.

The opportunity to use the equipment in the chronic heart failure and arrhythmia studies described in this thesis was provided within the strict confines of a research study, as is often demanded by the managers whose responsibility it is to justify expenditure. That responsibility may result in a dichotomous situation in which managers feel that the justification of expenditure on new technology requires robust evidence, but unfortunately the gathering of robust evidence has associated with it all the rules, regulations, protocols and paraphernalia which surround the research process. Thus the evidence, if it is gathered at all, does not reflect what would happen if the equipment were freely available over a sustained period of time, but only what happens when its use is distorted by all manner of unnatural demands. That in effect is what happened in some of the studies.

For example, although a few weeks' experience of using the weighing scales caused nurses to change their minds about excluding patients with class 1 NYHA heart failure, this could not happen due to the strict protocols laid down by the research process. In another example the delay in obtaining the necessary ethical permission from the relevant hospital authority meant that one nurse was unable to have access to the automated weighing scales and thus she and her patients were not able to experience them. Even the imposition of the strictly controlled parameters of a randomised controlled trial meant that the equipment was not freely available to all patients. Thus there was willingness to provide the equipment to certain specific patients, but the strict parameters of the research requirements obstructed the ability to do so.

In addition to denigrating the outcomes of that evaluation, such obstructions may discourage potential participants from contributing their time and efforts in the future. Whilst strict attention must be paid to ethical matters in medicine, the same situation does not appear to apply to the use of mobile phones in teledermatology. In those situations the equipment is already freely available to all and is usually the private property of the clinician or patient taking the photograph. Thus "availability" is not the remit of managers and the need for robust evidence arising from randomised controlled trials is not strictly applied. Perhaps that is one reason why the use of mobile phone images continues to proliferate whilst other initiatives such as the use of automated weighing scales for patients with chronic heart failure do not. The paradox is of course that the studies described in the early part of this thesis suggest that the use of mobile phone images may be more in need of stringently controlled trials than the other items of equipment evaluated.

The administrative systems in place, within which the telemedicine chain of care was attempting to exist, require an unobstructed line of communication between the patient recording the relevant clinical data via the telemedicine equipment and the clinician responsible for initiating treatment. That line of communication encompasses a chain of any number of individuals, each of whom have a role in the pathway of care. For example it may include family, local nurses, receptionists, a number of GPs within a practice, specialist consultants, or any number of staff at the telemedicine company. All of these may in turn have ancillary administrative staff members associated with their role. It only requires one of these people to be ineffective in their role to present a potential threat to the patency of that line of care and therefore to the process of evaluation.

The impact of an unprepared administrative system on an otherwise successful telemedicine strategy could not have been more clearly demonstrated than in the case of "Elaine," who made such strenuous attempts to negotiate the route between telemedicine diagnosis and her consultant cardiologist. Obstructions occurred at every administrative level in that example, from the receptionists and doctors in the GP practice, to the receptionist and nurse in the cardiology clinic and finally to the consultant cardiologist who was not made aware of the ECG data which was already to hand.

It is freely acknowledged that there was an assumption on the part of this researcher that the clinical research lead, being a member of that practice and active in recruiting participants, would undertake to ensure that he received the telemedicine data. This did not happen and resulted in the initial obstruction in the communication of the telemedicine data. It is however not easy to comprehend the refusal of the receptionist to accept medical data over the counter. Presumably post addressed to the doctors arrives frequently and is not refused, therefore had Elaine posted the documents the same receptionist would have accepted them without question. Whether a more proactive individual would have taken a more flexible approach to the existing working practices and passed the data to the GP is debatable, but the same circumstance arose in the cardiology clinic, where normal working practices resulted in those data being placed in the medical notes and not brought to the attention of the cardiologist. Thus the patency of the communication pathway was closely associated with some working practices which were embedded in policy, however the result was that the individuals involved were unable to perform effectively as part of that communication pathway, thus they had a negative impact on the evaluation of the telemedicine system. A further example of working practice inhibiting the evaluation process was afforded by the nurse working in a heart failure clinic, who could not access patient notes at the appropriate time to complete the medical questionnaire required by the telemedicine company. Fortunately this nurse was proactive in developing an administrative system in which the evaluation could flourish, but not all clinicians felt able to do this.

Although deficiencies in the administrative pathways and limitations caused by the constraints imposed on the use of the telemedicine devices did impact negatively on the evaluation process, it was found to be the individuals involved who had the greatest influence on the outcomes. There appeared to be three main attributes that individuals needed in order to engage successfully with the evaluation, those being the willingness to embrace the technology, the willingness to conform to the research requirements and the ability to perform effectively within their role in respect of the telemedicine system under evaluation. Unfortunately very few individuals encountered in this study were able to fulfil all three. Even Elaine, whose eagerness to embrace the technology was paramount and who gave generously of her time and efforts to conform to every detail of the research requirements, was not permitted to perform effectively because the system within which she was trying to operate let her down.

In general terms the dermatologists have demonstrated a willingness to embrace the technology but less enthusiasm to conform to the rigours of research protocol. Even though in this thesis the equipment has been shown to have some defects in colour and shape replication and a review of the literature has commented on problems of variation in photographic skills with an associated threat to accurate diagnosis, on the whole the literature has also shown, by virtue of its volume and the often generous conclusions reached, that many clinicians are prepared to overlook those shortcomings in their desire to embrace the technology in pursuit of their goals. That eagerness to embrace the technology may have been at least partially responsible for the absence of obstruction from the working systems in place, thus they are generally effective in their role of telemedicine practitioners. In most situations described in the literature the dermatologists were leading the initiative and requesting the images. It cannot be assumed that if a patient had of their own volition simply sent some images addressed to the doctor at the clinic, that those images would not have ended up in the patients notes, only to be found when the patient turned up for a consultation, as happened with the ECG equipment.

There was no lack of willingness to embrace the technology in the other two telemedicine applications either, at least by the healthcare professionals. Examples include the specialist nurse who wanted the weighing scales for specific patients because they were “brittle”, the GP who wanted the ECG unit for her husband, the electrophysiologist who wanted the ECG unit for her friend who had arrhythmia, and the several GPs who expressed an interest in contributing to both ECG and weight monitoring studies. It was the strict requirements of research practice which deterred them in each of these examples.

The patients’ performances in the three criteria specified were very varied. In general the patients in the arrhythmia study were keen to embrace the technology, although there was the occasional exception. There is no evidence as to the effectiveness of their performance in their role as telemedicine patients, as none but Elaine had a positive diagnosis to communicate, however a number withdrew or refused to participate due to the requirement to complete the questionnaire, although a number of those were happy to be interviewed. Patients on the heart failure study, on the other hand, were often irritated by the technology and expressed delight when the study finished and the equipment removed. On the other hand a few of those, such as “Arnold”, once the initial “teething problems” of the system were solved, embraced the technology as a normal part of his daily life. Although his methods were somewhat unexpected, he became a very effective performer within his own idiosyncratic telemedicine system.

The disparity in the findings, which have arisen from the individuality of the people involved and their relationship with the research process, has raised some interesting issues about the recommendations which would normally follow such an evaluation process. Shortcomings in equipment performance have already been clearly demonstrated in the arena of image capture and display, and to a lesser extent in the problems with batteries, the siting of the weighing scales and the audible signal of the ECG unit, but it is unlikely that manufacturers would make available specialised items of equipment (for example a mobile phone that which does not have software colour enhancement) in the absence of clear evidence that there was a market for such a device.

It would of course be negligent in the extreme to advocate a policy which denied a telemedicine application simply because the evaluative evidence had been based on poor photographic techniques or shortcomings in the equipment which meant it was difficult for the elderly or infirm to use it. Conversely however it would be dangerous to construct a single universal policy to cover every situation based on evidence derived from a specific scenario, because each scenario is characteristic of the individuals within it and of the environment within which they exist. For example, a dermatologist with a busy practice in a large hospital would probably find that his photographic equipment and viewing monitors were maintained at optimum performance level because the necessary equipment, technical expertise and maintenance procedures would already be in place. They form a necessary part of the work of radiographers, medical photographers and medical physicists in large hospitals. On the other hand a single-handed dermatologist or dermatology nurse in a small outlying clinic would be unlikely to have either equipment or expertise readily available and would therefore incur much greater cost in ensuring the quality of the viewed image, if indeed they considered it at all.

The comparison of differing working practices in dermatology may be developed further. For example sub-optimal images received from an inexpert photographer could be corrected for colour and distortion with minimal time and effort in the large department where such expertise was commonplace, but again a clinical colleague in a small establishment may need to possess the ability to accomplish that image manipulation himself. In either scenario the comparison effectively indicates that either teledermatology is a safer procedure when carried out from a large hospital department (all other aspects being equal) than when it is carried out from a small clinic, or alternatively that the lone worker in a small establishment needs to possess a greater range of ability than his counterpart.

The photographer, too, is a variable in this evaluation. It is unreasonable to expect every nurse, every GP, every patient or every family member who is ever likely to want to photograph a patient's skin lesion to undergo a photography course before they can access remote assistance. I would suggest that, whilst in an ideal world an evaluation of teledermatology would address every type of lesion on every variant of skin colour, in every clinical scenario and with every possible variation of ability of people and equipment, that this is clearly unrealistic. Even if such an evaluation were possible then policy issues could not be derived from evidence which has already clearly demonstrated variation between individuals. Can one realistically legislate that one specific mobile cameraphone must be used in every case, or that one nurse may not use photographs when seeking assistance because they less adept at photography than another? If nothing else, time dictates that these aspects are not practical bases for policy construction. The speed of technological development, of staff turnover and even the speed of change in expertise through education, mean that today's policy may not be relevant tomorrow. With the development of "smart vests" which can capture physiological data this applies as much to the telemonitoring of heart diseases as it does to teledermatology.

Similarly, automated weighing scales cannot be hailed as a cure-all for every elderly person with chronic heart failure even if they are otherwise fit and able to use the equipment effectively, because many elderly persons live in the type of accommodation which precludes the siting of additional equipment. Additionally, whilst a nurse based largely within the community may be able to assist with siting and setting up equipment, or teaching the patient how to position ECG electrodes to the best advantage, a clinic-based nurse may not. The important point is that what may be an effective clinical tool in one situation may not necessarily be so effective in another.

Policy therefore needs to be based upon and to relate to, evidence from small idiosyncratic scenarios. Unfortunately as previously suggested the dictates of policy related to evaluation research in small idiosyncratic scenarios has left us in a "chicken and egg" situation whereby the research itself demands such time and effort of already over-stretched individuals that the research often falters before it is even begun, as happened to a number of proposed clinical studies developed for inclusion in this thesis. Even if begun, there is so often a mismatch between what the demanded protocol dictates and what the individuals would prefer to do, that much of the time an evaluation suffers from imposing on people practices they find unpalatable, which in turn results in a negative outcome. If each practice had been permitted to evolve or to be adapted to the individual then the evaluations may have had very different outcomes. Examples are found within the experiences reported in this text, such as;

- the doctor who wanted to use the ECG machine for her husband but did not want to fulfil all the obligations dictated by the research policy.
- the nurses who would have liked to use the automated weighing scales for certain patients whom they felt may have benefited but could not, due to the randomisation procedures in place.
- the many GP practices who were interested in the telemedicine facilities but felt they could not further burden themselves with the administrative requirements of the research.
- the case of a dermatology nurse who wanted to conduct a small evaluation based on the use of images as an ongoing record of patient's condition within her own clinic. Sadly the members of the Research and Development department of the hospital could not decide whether the evaluation described fulfilled the role of research or audit, and even after receiving confirmation from the national bodies that full research ethical approval was not required, another three months passed before permission was granted. This was too late for the study to be included in this work and now may not be conducted at all as both the researcher and the dermatology nurse have moved on to other employment.

Differing levels of willingness and ability in individuals have been seen to exist throughout the studies addressed here. In the case of the automated weighing scales it was the patients who were, in the main, unwilling and/or unable to use them effectively. Even those patients who could have derived some clinical benefit from the fact that their deteriorating condition had been recognised chose not to use the system effectively. Whether this would be overcome by introducing a different administrative procedure in relation to the staff at the call centre, or by the implementation of a different relationship with the healthcare professional caring from them is not clear. It was clear however that these patients valued the relationship with a person, in terms of their healthcare, above all else, so it could be argued that adjustments may have to be made to the administrative system involved in providing and monitoring the weighing scales, and possibly even to the weighing scales themselves, to provide a more "user-friendly" interaction. Staff too exhibited different levels of willingness in using the automated weighing scales. In their case the differences appeared to depend in some instances on their relationship with the individual patient or in other instances on their own entrenched working practices, or sometimes to the administrative burdens imposed by the requirements of research.

In all of the situations described above it is unrealistic to expect identical performance, theoretical stance or practical experience from the individuals concerned. Nor is it realistic to expect sweeping changes to occur rapidly in working practices and administrative systems which had been operating possibly for decades. Given that willingness appears to be the driving motivational force in pursuing the goal of achievement in telemedicine endeavour, such successes as may occur are likely to do so in small discrete sections of healthcare. Any successes are likely to be adopted on a wider scale somewhat gradually, and would probably continue to be adjusted according to the idiosyncrasies of the individuals and environments involved.

Is it not reasonable therefore to permit the evaluations which take place to include all those idiosyncrasies, and allow them to demonstrate success, rather than impose such restriction as forces them to fail? Furthermore, should the remit of the evaluation not be permitted to incorporate such idiosyncratic values as may be advanced by either patient or clinician? The value of objective evidence is not in doubt, but it cannot reasonably be hailed as the only valuable aspect of all evaluation to the exclusion of all other. I suggest that we are not in a position to define all the valuable concepts related to telemedicine, let alone measure them, and we will not be in a position to identify them until we permit them to exist within the scope of the evaluation. This is not to suggest that evaluation should be an unregulated free-for-all, but it is perhaps time to acknowledge the possibility that some healthcare professionals may have particular experience, knowledge or expertise which is not necessarily manifest to even the most highly qualified colleague but which enables a telemedicine initiative to succeed in one situation where it may fail in another.

I leave the (almost) final words to a quote taken from a book published in 1996[11] in which the authors suggested a framework for evaluating telemedicine applications.

[11] Telemedicine: a guide to assessing telecommunications in health care. Institute of Medicine (US) Committee on Evaluating Clinical Applications of Telemedicine; Edited by Marilyn J Field. Washington (DC): National Academies Press (US); 1996.

> "The framework highlights the importance of both delineating how technical, clinical, and administrative processes are intended to work and determining how they actually are implemented. This is crucial if evaluators who find disappointing or unexpected results are (a) to distinguish the failure of an application from the failure of an application to be implemented as intended and (b) to provide guidance to decision makers considering whether to adopt, substantially redesign, or discontinue telemedicine programmes."

Fifteen years on we appear to be no closer to achieving that evaluative goal in so very many promising telemedicine applications.

“Videophones ring the changes in healthcare” Appendix 1
Reference Gray http://www.scotsman.com/?id=1778702005
http://news.scotsman.com/health.cfm?id=1778702005

Copy of “Video phones ring the changes in health care”

10 NEWS

Video phones ring the changes in health care

Unhappy snap: but camera footage is saving doctors time by removing the need to decipher garbled descriptions of accidents.

Pictures speak louder than words for doctors faced with emergency cases

RICHARD GRAY
HEALTH CORRESPONDENT

VIDEO footage of accidents recorded on camera phones is helping doctors diagnose injuries quickly and save crucial time in emergency situations.

With more than 6 million video-capable mobile phones in the UK, the first instinct in an emergency is now to record what is going on.

GPs and casualty doctors can waste valuable time attempting to decipher jumbled descriptions of how accidents happened from patients and families.

But footage of accidents recorded on camera phones is now allowing them to see how injuries happened and also the first aid patients received.

Neurologists in Glasgow are even using video phones to help them with difficult-to-diagnose conditions such as epilepsy in children.

Mary O'Regan, a consultant paediatrician neurologist at Yorkhill Royal Hospital for Sick Children, asks parents to record their children as they go through a fit. She said: "It is difficult to diagnose epilepsy in a child without seeing what is going on during a fit. It is important as it might not be epilepsy causing the event.

"For patients who have episodes less than once a week, it is unlikely to ever happen while they are seeing a doctor.

"Taking a video of a fit is the next best thing, and video phones have really caught on. They can record quite long segments and I am seeing quite a few parents coming in with footage of their children on their phones."

But O'Regan admits reaching for a phone while children are having a fit or have injured themselves is not the easiest thing for parents to do.

"It can be a frightening experience, and recording what is going on is often not the first thing on their minds," she said.

Other doctors are also seeing a growth in the number of patients presenting them with mobile phone footage. GPs are beginning to find patients turning up at their practices with pictures of rashes, swelling, blisters and sores.

Charles Lam, an accident and emergency doctor who works for the British Medical Association, said camera phones were spreading into hospitals. He said: "A couple of days ago a young child was brought to us with a nasty laceration.

‘A phone showed me the shed my patient jumped off and the fence he landed on’

"When I asked what had happened, instead of getting the usual incomprehensible description, I was entertained with a mobile phone video, showing the garden shed he jumped off and the fence he landed on.

"I even got to see the first-aid response, which appeared to consist of his mother putting a used dishcloth over the wounds, before demanding that her partner do something useful instead of messing with 'that bloody mobile'."

Experts predict mobile phones will become commonplace in hospitals and aboard ambulances as the picture quality improves.

The emergence of the third generation (3G) network has seen the amount of information that can be sent soar.

Telemedicine experts claim mobile phones will replace landline video phones, allowing doctors to carry out consultations on the move.

Neurosurgeons at Hammersmith Hospital in London are already trialling the use of 3G mobile phones to assess brain scans of patients before going into surgery.

Staff send pictures of scans to surgeons' mobile phones, allowing them to examine the condition of a patient before his arrival at hospital.

Paramedics have started using video phones to send footage from accident scenes directly to doctors in emergency rooms. Telemedicine firm All New Video is installing screens in hospitals in Berkshire to allow staff to see patients' injuries before they arrive and prepare for them.

The Scottish Ambulance Service is considering adopting a similar system to link its staff to hospitals.

A spokesman said: "It is not something that is likely to happen in the near future, but we may be considering it in the more distant future."

Last month's terrorist attacks in London highlighted the value of mobile phone videos after passengers on trains recorded the immediate aftermath of the bombings.

Police appealed for footage as they attempted to track down the suspects behind the failed attacks of July 21.

All New Video is developing a system to allow members of the public to send in their own footage from the scenes of emergencies.

Patients will be able to dial an NHS 24-type number and their footage will be passed on to doctors and emergency staff.

Mobile phone firms are predicting that video phones will see a massive growth in telemedicine over the next couple of years.

A spokesman for Three Mobile said: "The picture quality of camera phones is improving and the ability of 3G handsets to handle high quantities of data means doctors are now looking at it as an additional clinical tool."

Interview schedules – Patients and carers (1st interview)

Required	Question	Must address / listen for
Early History	When did you (he/she) first know you (he/she) were ill?	Hospitalization? GP? (acute/chronic episode) Advice or follow up after diagnosis?
Post diagnosis	What happened after you were diagnosed? Any other medical problems?	Other tests / findings (medical) Sources of help/assistance Comorbidities Understanding/non understanding
Since CHF nurse Dr. or specialist	What does (nurse's name) ask you (your partner) to do now? How does (nurse's name) ask you (your partner) to look after yourself (himself). Do you see a doctor or a specialist?	Weight monitoring (advised / understood?) Clinic visit/ how often? Home visit Diet Self care / self examination (oedema/breathless etc.) Level of satisfaction with current care. Perception of care or role (Dr. V CHF nurse)
Health & social recent	How does it affect your life? What do you do for leisure now?	Physical/social/mental restrictions. • Hobbies & activities. • Holidays. • Anxieties / worries • Depression Any change in life/circumstance e.g. roles within relationship Physical activity – clues on reduction e.g. "not as much as I used to...." Mental activity Social interaction
Tele-medicine	Check: understanding / consent requirements of participation etc. Expectation of telemedicine for those in experimental group.	 Confusion / non understanding Burden of research not too onerous for participant.

Interview schedules continued – Patients and carers (2nd & subsequent interviews)

Required	Question	Must address / listen for
Life Experiences	How have you been keeping?	Changes in health / circumstances general Changes related to CHF or associated conditions. Issues important to the participant but which appear (at the moment) to be unrelated to the topic of interest.
Weight monitoring	Have you been weighing yourself (telemed or conventional)? How have you found that – any changes in weight?	Routine / ability Identified or unidentified – to compare with log of weights from medical notes.
Telemedicine	Has it been any good to you / have you found it any use?	Positive or negative experiences Seek information on costs.

Interview schedules continued – Clinicians (1st interview)

Required	Question	Must address / listen for
First patient contact	How diagnosed? How & when referred?	Dr / specialist role & transfer to nurse's care
Nurse's role	What does care comprise?	Examples of care "categories"? e.g. drug administration / prescription self-care / life advice other family members or just patient?
Weight monitoring	Can you tell me about weight monitoring in CHF? Do you recommend to all patients? Do all patients comply? What are the problems with weight monitoring as a strategy? Are there any problems specific to individual patients in terms of weight monitoring.	Regimen - general Individual or common to all patients? Exceptions? Cases where helpful / unhelpful to patients. As a care strategy Reasons for non-effectiveness in specific cases.
Tele-medicine	Expectations? Problems?	Of improvement or scepticism For care in CHF (or NHS) For patient For self Practical / administrative For care For patient For self.

Interview schedules continued – Clinicians (2nd interview)

Required	Question	Must address / listen for
Telemedicine	What has been your experience of the telemedicine scales?	Overall impression favourable/poor? Specific points mentioned, noted for follow-up questions
Differences to staff	Can you describe any ways in which they have helped your practice? Can you describe any ways in which they have hindered practice or caused you a problem?	Plus points and/or negative points e.g. more or less interaction with patients?
Differences to patients	What do your patients think of it – has it made any difference to them?	Overall impression versus specific examples – check number of practical examples with strength of opinion. Cross check examples cited with patients. Extent of knowledge of individuals.
Specifics to follow up from first question.	Dependent upon points raised.	General impressions versus facts cited. Elicit examples where possible.

Coding:- Patient views

1. Weight monitoring
    - i) Self care behaviour
    - ii) Problems
    - iii) Perception of wt monitoring
    - iv) Assistance needed
    - v) Confusion
        - Contradictory advice
        - Weight gain with diet
        - Kilos and pounds

2. Signs physical
    - i) Symptoms recognized
    - ii) Symptoms not recognized
    - iii) Eating
    - iv) Specific symptoms causing concern
        - Tiredness
        - Discomfort
        - Collapse
        - Breathlessness
        - Agitation
        - Absence of pain
        - Activity:- social & physical

3. Signs psychological
    - i) Memory loss
    - ii) Loss of confidence
    - iii) Frustration
    - iv) Fear/anxiety/worry
    - v) Disorientation
    - vi) Depression
    - vii) Awareness and acceptance of cognitive dysfunction

4. Perceptions of healthcare
    - i) Satisfaction / dissatisfaction with healthcare
        - Consultants/doctors
        - Attending hospital
        - HF nurses
        - Emergency care
    - ii) Seeks knowledge
    - iii) Independence and decision making
    - iv) Coping

Cont. overleaf

Coding:- Patient views (cont.)

1. Scales
   - i) Usefulness
     - Reassurance
     - Contact/relationship with healthcare professional
     - Potential (not always realised in practice)
   - ii) Problems (technology/scales)
     - Confusion / uncertainties of weight monitoring
     - siting
     - costs
   - iii) Problems (healthcare system)
     - Dependence/empowerment
     - Potential not recognized

Coding:- Carers' views

1. Seek knowledge
2. Need for support
3. Coping mechanisms
4. Concern for patient
5. Involvement in care
6. Telemedicine scales
   - i) Supports patients (therefore self)
   - ii) Affect on own life (inconvenience)

Coding:- Health care professionals' views

1. Weight monitoring
    - i) Importance of weight monitoring
    - ii) Routine / schedule
    - iii) Problems of weight monitoring
    - iv) Additional benefits

2. Nurses role
    - i) Person most responsible
        - Comparison to doctors
    - ii) Reduce referral admissions & audit
    - iii) Optimise treatment & prolong life
    - iv) Frustrations
    - v) Advice & education to other healthcare professionals
    - vi) relationship with patient & family
        - Encouragement to comply, QoL & family support
        - Face-to-face contact

3. Telemedicine monitoring
    - i) Recruitment and participation
        - Reasons, problems & cherry picking
    - ii) Working practices
        - How, why, when to use scales
        - Workload (increase or reduction?)
        - Increased role
    - iii) Positive / negative aspects
        - Good for people who…?
        - Reassurance aspects
        - Other beneficial outcomes for nurses/patients.
        - Limitation & adverse outcomes
        - Technology
        - Research problems & opportunities
        - Patients perception of scales?

Letter of ethical approval - CHF Study.

Cumbria and Lancashire B
Lancashire & South Cumbria Agency
Room 1.08
3 Caxton Road
Fulwood
Preston
Lancashire
PR2 9ZZ

Telephone: 01772 221428
Facsimile: 01772 221435

20 April 2006

Dr Stephen T Ward
Medical Advisor, Primary Care
Cumbria & Lancashire Strategic Health Authority
Preston Business Centre
Watling Street Road
Preston
PR2 8DY

Dear Dr Ward

Full title of study: **The role of telemedicine in primary care for the care of patients with Heart Failure: a pilot study**

REC reference number: **06/Q1309/1**

Thank you for your letter of 30 March 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA. There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Application	5.0	14 February 2006
Investigator CV		
Protocol	1	14 February 2006
Covering Letter		
Summary/Synopsis		
Letter from Sponsor		20 July 2005
Statistician Comments		
Compensation Arrangements		09 December 2005
Interview Schedules/Topic Guides For patients	1	14 February 2006
Interview Schedules/Topic Guides for carers	1	14 February 2006
Interview Schedules/Topic Guides Staff interview schedule	1	14 February 2006
Questionnaire		
Questionnaire		
Sample Diary/Patient Card		
Letter of invitation to participant	1	14 February 2006
GP/Consultant Information Sheets	1	13 February 2006
Participant Information Sheet	2	28 March 2006
Participant Information Sheet	2	20 March 2006
Participant Consent Form	3	28 March 2006
Participant Consent Form	2	28 March 2006
Response to Request for Further Information		30 March 2006
Broomwell Healthwatch information		
Letter from Julia Miller, R&D		14 February 2006

Research governance approval

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1309/1 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr P A Wilkinson
Chair

Email: Davina.Halliday@lasca.nhs.uk

Enclosures: *Standard approval conditions*

Copy to: Dr Jeremy Nolan
Room 4N20
Quarry House
Leeds
LS2 7UE

Mr J Wardle, R&D Department

SF1 list of approved sites

Patient Information sheet – CHF Study

Cumbria and Lancashire NHS
Strategic Health Authority

EVALUATION OF HOME MONITORING EQUIPMENT FOR PATIENTS WITH CHRONIC HEART FAILURE

PATIENT INFORMATION LEAFLET

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1.

What is the purpose of the study?
Many people with a heart condition monitor their weight to help them control their fluid balance.
The purpose of this study is to find out if there is any benefit if people with a heart condition monitor their weight on a daily basis, or if it is better to have their weight monitored automatically, from home, by a specialist centre.

Why have I been chosen?
We will be asking about 100 people in your area who have a heart condition. You have been chosen because you have been investigated for a heart condition in the past and your doctor has recommended that your weight is monitored.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?
You will be put into one of two groups. Either you will be given a set of weighing scales which are linked to a special call centre, or you will not. In either case, you must follow your normal weight monitoring routine for yourself.
To make sure the people in each group are the same to start with, each patient is put into a group by chance (randomly.) There will be 50 people in each group, so you have an even chance of being in either group. The groups will be compared to see if there is any benefit to using the automated weighing scales.

All volunteers will be asked to fill out questionnaires and keep a diary. Some people from each group will also be interviewed. If you have a spouse, partner or carer, they will also be asked to fill out a questionnaire and some will be invited to be interviewed.
There should be no additional risk to you by taking part in this study. This is **in addition** to your normal care, **not instead** of it, so you should follow your normal regular weighing procedure, whether you do this yourself or whether your nurse does it when she visits.

What do I have to do?
We need you to;

- Keep a daily diary for 6 months. This would normally be only a couple of words, eg "Ok today" but if you have a concern or query about your weight, then we would like you to make a note of how you felt and what you did about it.
- Give us permission to read your medical records.

We need you **and your spouse/partner** to;

- Spend a few minutes on three separate occasions within 6 months, filling in a questionnaire.

We **may** need you **and your spouse/partner** to;

- Spend about half an hour on three separate occasions being interviewed. This may be recorded on tape

Expenses and payments:
Some interviews may be conducted on the telephone, but if we ask you to make a special journey to the hospital we will pay your travel expenses.

What are the possible benefits of taking part?
We cannot promise the study will help you, but the information we get might help improve the care of people with a heart conditions.

What happens when the research study stops?
If you have been given weighing scales, at the end of the study you must return them.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential. No names, addresses or other identifying details will be included in any reports. Further details are included in Part 2.

Contact Details:
If you have any questions or concerns about this study, or if would like further information, please telephone Glenis Johnston on 0779 1586334, leaving your name and phone number. I will call you back as soon as possible.
If you have any concerns about your health you should contact your GP or nurse in the normal way.

Thank you for taking the time to read Part 1 of the Information Sheet.
If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Patient Information sheet – CHF Study (cont.)

EVALUATION OF HOME MONITORING EQUIPMENT FOR PATIENTS WITH CHRONIC HEART FAILURE

PATIENT INFORMATION LEAFLET

Part 2

What happens if I choose to withdraw part way through the study?
We will keep the information you have already provided, for example your first interview or questionnaires. We may use the information in our report, but you will not be identified in any way.

What if there is a problem?
If there is a problem with the weighing scales, telephone Broomwell Healthwatch on 0161 2360141

Complaints:
If you have a concern about any aspect of this study, you should ask to speak with the researcher who will do her best to answer your questions. Phone Glenis Johnston on 0779 1586334. If you remain unhappy and wish to complain formally, you can do this through the complaints procedure of either; Chorley and South Ribble PCT, (Freephone 0800 0322424) or Preston PCT (Freephone 0800 0324222), depending on where you are a patient.

Harm:
It is very unlikely that you could be harmed by taking part in this study, but in the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. In the unlikely event that something happens, you should contact the Patient Advisory Liaison Service at your local PCT. This will be either. Chorley and South Ribble PCT, (Freephone 0800 0322424) or Preston PCT (Freephone 0800 0324222), depending on where you are a patient.

Will my taking part in this study be kept confidential?
Yes. You will be allocated a study number. All information about you will be stored anonymously under that number and kept in a locked filing cabinet. It will be seen only by the researchers. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research sites.
The procedures for handling, processing, storage and destruction of the information collected are compliant with the Data Protection Act 1998. You have the right to check the accuracy of data held about you and correct any errors. Your information will be kept until the study and all reports are completed. After that it will be destroyed securely.

Involvement of other Medical Practitioners
If you are loaned weighing scales, each time you use them your GP or the specialist nurse normally looking after you will be told the results.

What will happen to the results of the research study?
The results will be made available to the Strategic Health Authority and will be published in medical journals. On request the results will be made available to volunteers.
*NB You will not be identified in any report or publication.

Who is organising and funding the research?
The research is being led by Dr Stephen Ward and conducted by researchers from Buckinghamshire Chilterns University College on behalf of the Cumbria and Lancashire Strategic Health Authority. Funding is provided by the Department of Health.

Who has reviewed the study?
This study was given a favourable ethical opinion for conduct in the NHS by the Cumbria and Lancashire Research Ethics Committee. Reference number 05/Q13/09/49

If you would like to discuss this further or ask questions, contact Glenis Johnston on 0779 1586334

Thank you very much for considering taking part in this research. If you would like to take part, please write your name, address and telephone number on the attached sheet and return it to me, Glenis Johnston, in the postage paid envelope provided and I will contact you in the very near future.

Partner Information sheet – CHF Study

Cumbria and Lancashire NHS
Strategic Health Authority

EVALUATION OF HOME MONITORING EQUIPMENT FOR PATIENTS WITH CHRONIC HEART FAILURE

INFORMATION SHEET for PARTNERS of PATIENTS

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, please read the following information carefully. Make sure you understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear or if you would like more information. Our contact details are at the bottom of this sheet.

What is the research about?
We are asking patients who have had heart problems in the past to help us to test a new way of monitoring their condition, and we would like to find out how the patient's heart condition affects the people who care for them.

If I take part, what will I have to do?
a) Fill out questionnaires about your wellbeing. This will take a few minutes at the beginning, middle and end of the research study.
b) You may be asked to take part in an informal telephone interview. If you agree to this, the researcher, Glenis Johnston, will contact you to arrange a convenient time for her to phone you. You will not have to pay for this telephone call

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you decide not to take part this will not affect the standard of care to your partner.

Can I withdraw from the study part way through?
Yes. You may withdraw at any time and without giving a reason. If you withdraw, you can choose either to permit us to use any information we have already collected from you, or to have it destroyed. In either case you will not be identified in any way.

Expenses and payments:
There is no payment for taking part in this research. .

What are the possible benefits of taking part?
We cannot promise the study will help you or your family directly, but the information we get might help improve the care of people with heart conditions in the future.

What if there is a problem?
If you have any concerns about the way you have been dealt with during the study, you should phone the researcher, Glenis Johnston on 0779 1586334 and she will do her best to resolve matters. If you remain unhappy and wish to complain formally, you can do this through the Patient Advisory Liaison Service at Blackpool and Victoria Hospital. Details can be obtained from Margaret Cooper. Research & Development, Blackpool and Victoria hospital.

Will my taking part in the study be kept confidential?
Yes.
All identifying details will be removed from the documentation and it will be stored anonymously in a locked filing cabinet. It will be seen only by the researchers. No identifying details will appear in any reports. Your information will be kept until the study and all reports are completed. After that it will be destroyed securely. The procedures for handling, processing, storage and destruction of the information are compliant with the Data Protection Act 1998. You have the right to check the accuracy of data held about you and correct any errors.

What will happen to the results of the research study?
The results will be made available to the Strategic Health Authority and will be published in medical journals. On request the results will be made available to volunteers. *NB You will not be identified in any report or publication.

Who is organising and funding the research?
The research is being led by Dr Stephen Ward and conducted by researchers from Buckinghamshire Chilterns University College on behalf of the Cumbria and Lancashire Strategic Health Authority. Funding is provided by the Department of Health.

Who has reviewed the study?
This study was given a favourable ethical opinion for conduct in the NHS by the Cumbria and Lancashire Research Ethics Committee. Reference number 05/Q13/09/49

If you would like to discuss this further or ask questions, contact Glenis Johnston on 0779 1586334

Thank you very much for considering taking part in this research.

If you would like to take part, please write your name, address and telephone number on the attached sheet and return it to me, Glenis Johnston, in the postage paid envelope provided and I will contact you in the very near future.

If you do not want to take part in this study, it would be very helpful if you will tell us why. Please write your reasons on the attached sheet and send it to me in the prepaid envelope. Thank you

Patient Consent Form – CHF Study

Cumbria and Lancashire NHS
Strategic Health Authority

Patient Identification Number for this study:......................

CONSENT FORM for PATIENT

Title of Project:
EVALUATION OF HOME MONITORING EQUIPMENT FOR PATIENTS WITH CHRONIC HEART FAILURE
Name of Researchers: Dr Stephen T. Ward, Dr Gwyn Weatherburn, Dr David Shaw, Mrs Glenis Johnston and Ms Julie Hendry.

Please initial box

1. I confirm that I have read and understand the information sheet dated 28.03.06 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes relating to my heart condition, and data collected during the study, may be looked at by responsible individuals from Buckinghamshire Chilterns University College, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I understand and agree that if I am interviewed, my interview will normally be recorded on an audio machine.
5. I understand and agree that if I am interviewed, some of my words may be quoted, anonymously, in reports.
6. I agree to my GP, specialist, or nurse being informed of my participation in the study.
7. I agree to my GP, specialist or specialist cardiac nurse being consulted about my medical history.
8. I understand and agree that my spouse, partner or carer will complete similar questionnaires, and may be interviewed, about matters relating to my condition.
9. I agree to take part in the above study.

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Glenis Johnston Researcher	Date	Signature

Version 3 28.03.06

Partner Consent Form – CHF Study

Cumbria and Lancashire NHS
Strategic Health Authority

Patient Identification Number for this study:............................

CONSENT FORM for PARTNER of patient.

Title of Project: EVALUATION OF HOME MONITORING EQUIPMENT FOR PATIENTS WITH CHRONIC HEART FAILURE

Name of Researchers: Dr Stephen T. Ward, Dr Gwyn Weatherburn, Dr David Shaw, Mrs Glenis Johnston and Ms Julie Hendry.

	Please initial box
1. I confirm that I have read and understand the information sheet dated 20.03.06 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I understand and agree that if I am interviewed, my interview will normally be recorded on an audio machine.	
4. I understand and agree that if I am interviewed, some of my words may be quoted, anonymously in reports.	
5. I agree to take part in the above study.	

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Glenis Johnston Researcher	Date	Signature

GP information letter. – CHF Study

Cumbria and Lancashire NHS
Strategic Health Authority

Dear Colleague,

Re:- Telemedicine research for Chronic Heart Failure

You probably know that I am leading a research programme to investigate the potential benefits of telemedicine diagnostic equipment, in the management of cardio-vascular disease, on behalf of the Cumbria and Lancashire Strategic Health Authority.

One of the pieces of work will be based on the use of electronic scales to monitor patient's weight in chronic heart failure. Evaluation will be made by assessment of patient's healthcare for six months after joining the study.

I wish to inform you that your patient

Name

Date of Birth

Address

Has consented to take part in this research study.

I have enclosed an information sheet outlining the study for you to consider. Further guidance is available if required, from the researcher, Glenis Johnston. (Tel. 0779 1586334. e-mail gjohns01@bcuc.ac.uk)

This will **not** impose any additional workload on the practice. All patients will continue to receive their normal care and in addition some patients will have automated weighing scales and access to a staffed call centre. Your practice will not be asked to undertake any additional work.

Patients using the automated weighing scales will receive feedback about their weight monitoring. If you would also like to receive a copy of this feedback, please contact the researcher.

If you would like to receive a summary of findings at the end of the project please contact either myself or the researcher.

Thanking you for your help with this work,

Yours sincerely,

Dr. Stephen Ward.

Date 13th February 2006 Version 1

GP letter, invitation to participate in research studies.

NHS
North West

Preston Business Centre
Watling Street Road
Fulwood
Preston
PR2 8DY

Tel: 01772 647099

29th September 2006

Dear Colleague,

RE **Telemetric monitoring for cardiovascular disease**

I would like to ask for your help in recruiting patients to one or both of two pieces of research work that have gained approval of the local Research and Ethics Committees and are being carried out on the footprint of the former Cumbria and Lancashire SHA, now part of NHS North West. This work is based on the use of telemetric devices supplied by Broomwell Healthwatch and both are considering aspects of cardio-vascular monitoring. Health service researchers from Buckinghamshire Chilterns University College are overseeing this work on my behalf.

One piece of research involves providing patients who present with palpitations or arrhythmias with an ECG machine so that they can record their own ECG. This is then interpreted by the clinical staff at Broomwell Healthwatch who then advise as to whether there is a need for clinical intervention. The second piece of research involves monitoring patients with heart failure by providing them with electronic scales by which Broomwell Healthwatch tracks changes in weight and provides feed-back to allow early clinical intervention if significant changes occur. In both studies patients will be randomised to use the telemetric equipment or to continue with normal care.

I would appreciate your help with the recruitment of patients to the two groups. The time commitment from your perspective is minimal but the benefits the work will give to developments for patient care in the future is potentially considerable.

If you agree to be involved you will be required to identify suitable patients and ask your practice nurse to send out packs prepared by the researchers. The patients can then respond directly to the researcher who will establish contact and arrange consent and inclusion into the trial.

For your information my research colleague who will be in contact with the practice nurse is Glenis Johnston who can be contacted for further information on gjohns01@bcuc.ac.uk or on 0779 1586334.

I look forward to your help and support with the work, a copy of the final report will be sent to you on completion of the research.

Thank you for your continuing support of this work,

Yours sincerely

Dr Steve Ward
SHA Medical Advisor, Primary Care

Cc
Michael Rowe, Broomwell Healthwatch
Glenis Johnston, Researcher, Buckingham and Chilterns University College
Dr Gwyn Weatherburn, Reader in Telemedicine, Buckingham and Chilterns University College

Patient Questionnaires

Cumbria and Lancashire NHS
Strategic Health Authority

Buckinghamshire Chilterns
UNIVERSITY COLLEGE

Confidential

QUALITY OF LIFE QUESTIONNAIRE

For patients

Cumbria & Lancashire Strategic Health Authority
Buckinghamshire Chilterns University College

Heart Failure monitoring study.

We are conducting a survey of all patients who are taking part in this study to ask about their general level of health and their usual daily activities. All the information you provide will be treated in the strictest confidence.

Thank you very much for your help with this study.

Please return the completed questionnaire in the envelope provided to;
Glenis Johnston
Research Centre for Health Studies
Buckinghamshire Chilterns University College
Gorelands Lane
Chalfont St Giles
Bucks
HP8 4AD

MAC NEW
HEART DISEASE HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE

We would like to ask you some questions about how you have been feeling **DURING THE LAST 2 WEEKS.**

Please tick the box ☐ that matches your answer

1. In general, how much of the time during the last 2 weeks have you felt frustrated, impatient or angry?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

2. How often during the last 2 weeks have you felt worthless or inadequate?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

3. In the last 2 weeks, how much of the time did you feel very confident and sure that you could deal with your heart problem?

1 ☐ NONE OF THE TIME
2 ☐ A LITTLE OF THE TIME
3 ☐ SOME OF THE TIME
4 ☐ A GOOD BIT OF THE TIME
5 ☐ MOST OF THE TIME
6 ☐ ALMOST ALL OF THE TIME
7 ☐ ALL OF THE TIME

Patient Questionnaires cont.

4. In general, how much of the time did you feel discouraged or down in the dumps, during the last 2 weeks?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

5. How much of the time during the past 2 weeks did you feel relaxed and free of tension?

1 ☐ NONE OF THE TIME
2 ☐ A LITTLE OF THE TIME
3 ☐ SOME OF THE TIME
4 ☐ A GOOD BIT OF THE TIME
5 ☐ MOST OF THE TIME
6 ☐ ALMOST ALL OF THE TIME
7 ☐ ALL OF THE TIME

6. How often during the last 2 weeks have you felt worn out or low in energy?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

7. How happy, satisfied, or pleased have you been with your personal life during the last 2 weeks?

1 ☐ VERY DISSATISFIED, UNHAPPY MOST OF THE TIME
2 ☐ GENERALLY DISSATISFIED, UNHAPPY
3 ☐ SOMEWHAT DISSATISFIED, UNHAPPY
4 ☐ GENERALLY SATISFIED, PLEASED
5 ☐ HAPPY MOST OF THE TIME
6 ☐ VERY HAPPY MOST OF THE TIME
7 ☐ EXTREMELY HAPPY, COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED

(c) macnew.org

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8. In general, how often during the last 2 weeks have you felt restless, or as if you were having difficulty trying to calm down?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

9. How much shortness of breath have you experienced during the last 2 weeks while doing your day-to-day physical activities?

1 ☐ EXTREME SHORTNESS OF BREATH
2 ☐ VERY SHORT OF BREATH
3 ☐ QUITE A BIT OF SHORTNESS OF BREATH
4 ☐ MODERATE SHORTNESS OF BREATH
5 ☐ SOME SHORTNESS OF BREATH
6 ☐ A LITTLE SHORTNESS OF BREATH
7 ☐ NO SHORTNESS OF BREATH

10. How often during the last 2 weeks have you felt tearful, or like crying?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

11. How often during the last 2 weeks have you felt as if you are more dependent than you were before your heart problem?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

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Patient Questionnaires cont.

12 How often during the last 2 weeks have you felt you were unable to do your usual social activities, or social activities with your family?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

13. How often during the last 2 weeks have you felt as if others no longer have the same confidence in you as they did before your heart problem?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

14. How often during the last 2 weeks have you experienced chest pain while doing your day-to-day activities?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

15. How often during the last 2 weeks have you felt unsure of yourself or lacking in self-confidence?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

16- How often during the last 2 weeks have you been bothered by aching or tired legs?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

17- During the last 2 weeks, how much have you been limited in doing sports or exercise as a result of your heart problem?

1 ☐ EXTREMELY LIMITED
2 ☐ VERY LIMITED
3 ☐ LIMITED QUITE A BIT
4 ☐ MODERATELY LIMITED
5 ☐ SOMEWHAT LIMITED
6 ☐ LIMITED A LITTLE
7 ☐ NOT LIMITED AT ALL

18- How often during the last 2 weeks have you felt apprehensive or frightened?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

19- How often during the last 2 weeks have you felt dizzy or lightheaded?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

Patient Questionnaires cont.

20. In general during the 2 weeks, how much have you been restricted or limited as a result of your heart problem?

1 ☐ EXTREMELY LIMITED
2 ☐ VERY LIMITED
3 ☐ LIMITED QUITE A BIT
4 ☐ MODERATELY LIMITED
5 ☐ SOMEWHAT LIMITED
6 ☐ LIMITED A LITTLE
7 ☐ NOT LIMITED AT ALL

21. How often during ~ last 2 weeks have you felt unsure as to how much exercise or physical activity you should be doing?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

22. How often during ~ last 2 weeks have you felt as if your family is being over-protective toward you?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

23. How often during the past 2 weeks have you felt as if you were a burden on others?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

24. How often during the past 2 weeks have you felt excluded from doing things with other people because of your heart problem?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

25. How often during the past 2 weeks have you felt unable to socialize because of your heart problem?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME

26. In general, during the last 2 weeks how much have you been physically restricted or limited as a result of your heart problem?

1 ☐ EXTREMELY LIMITED
2 ☐ VERY LIMITED
3 ☐ LIMITED QUITE A BIT
4 ☐ MODERATELY LIMITED
5 ☐ SOMEWHAT LIMITED
6 ☐ LIMITED A LITTLE
7 ☐ NOT LIMITED AT ALL

27. How often during the past 2 weeks have you felt your heart problem limited or interfered with sexual intercourse?

1 ☐ ALL OF THE TIME
2 ☐ MOST OF THE TIME
3 ☐ A GOOD BIT OF THE TIME
4 ☐ SOME OF THE TIME
5 ☐ A LITTLE OF THE TIME
6 ☐ HARDLY ANY OF THE TIME
7 ☐ NONE OF THE TIME
8 ☐ NOT APPLICABLE

That's all for this section. Thank you very much for answering the questions. Would you now complete the next section please?

 (Version: November 2004)

Patient Questionnaires cont.

SELF-EVALUATION QUESTIONNAIRE

Developed by Charles D. Spielberger
in collaboration with
R.L. Gorsuch, R. Lushene, P.R. Vagg and G.A. Jacobs

STAI Form Y-1

Name ______________________ Date ____ S_____

Age ________ Sex: M ____ F ____ T ____

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you feel *right now*, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately so	Very much so
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

9

SELF-EVALUATION QUESTIONNAIRE

STAI Form Y-1

Name ______________________ Date ________

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Almost never	Sometimes	Often	Almost always
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am "calm, cool and collected	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that really doesn't matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

Thank you very much for taking the time to complete this questionnaire.

10

Partner Questionnaires.

Cumbria and Lancashire NHS
Strategic Health Authority

Buckinghamshire Chilterns
UNIVERSITY COLLEGE

Confidential

QUALITY OF LIFE QUESTIONNAIRE

For spouses, partners or carers

Cumbria & Lancashire Strategic Health Authority
Buckinghamshire Chilterns University College

Heart Failure monitoring study.

We are conducting a survey of ***the spouses or partners*** of all patients who are taking part in this study to ask about their general level of health and their usual daily activities. All the information you provide will be treated in the strictest confidence.

Thank you very much for your help with this study.

Please return the completed questionnaire in the envelope provided to;
Glenis Johnston
Research Centre for Health Studies
Buckinghamshire Chilterns University College
Gorelands Lane
Chalfont St Giles
Bucks
HP8 4AD

HEART DISEASE HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE FOR CARDIAC SPOUSES (QL-SP)

We would like to ask you some questions about how you have been feeling DURING THE LAST 2 WEEKS

Please tick the box ☐ that matches your answer.

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
1. How often during the past 2 weeks have you felt concerned or worried?	☐	☐	☐	☐	☐	☐	☐
2. How often during the past 2 weeks have you felt questioning or uninformed?	☐	☐	☐	☐	☐	☐	☐
3. How often during the past 2 weeks have you felt tense or upset?	☐	☐	☐	☐	☐	☐	☐
4. How often during the past 2 weeks have you felt sad or depressed?	☐	☐	☐	☐	☐	☐	☐
5. How often during the past 2 weeks have you devoted time to nutritional habits or concerns?	☐	☐	☐	☐	☐	☐	☐
6. How often during the past 2 weeks have you felt nervous or anxious?	☐	☐	☐	☐	☐	☐	☐
7. How often during the past 2 weeks have you had trouble getting a good night's sleep, or found yourself watching your spouse while he/she is sleeping?	☐	☐	☐	☐	☐	☐	☐
8. How often during the past 2 weeks have you felt disappointed or discouraged?	☐	☐	☐	☐	☐	☐	☐
9. How often during the past 2 weeks have you devoted time to changing exercise patterns?	☐	☐	☐	☐	☐	☐	☐
10. How often during the past 2 weeks have you felt frustrated or angry?	☐	☐	☐	☐	☐	☐	☐
11. How often during the past 2 weeks have you felt physically strained or low in energy?	☐	☐	☐	☐	☐	☐	☐
12. How often during the past 2 weeks have you been limited in travelling because of your partner's heart condition?	☐	☐	☐	☐	☐	☐	☐
13. How often during the past 2 weeks have you felt tearful or like crying?	☐	☐	☐	☐	☐	☐	☐

	Em	Ph	So	Gl
Σ SI				
Tota				

Partner Questionnaires cont.

Quality of Life Questionnaire for cardiac spouses cont….

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time
…n during the past 2 weeks have you … to being concerned about or changing …its?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …e or lonely?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …'s heart problem has limited or interfered …activity?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you … to being concerned about or changing …	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …strained?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you …self for things or felt guilty?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you …in your usual social activities?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …secure?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …ied or pleased with your personal life?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …e or frightened?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …limited because of your partner's heart	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …ve?	☐	☐	☐	☐	☐	☐	☐
…n during the past 2 weeks have you felt …ied or pleased with communication with …amily?	☐	☐	☐	☐	☐	☐	☐

	Em	Ph	So	G
Σ SI				
TOTAL				

…r this section. Thank you very much for answering the questions. Would you now complete the next section please?

3

SELF-EVALUATION QUESTIONNAIRE

Developed by Charles D. Spielberger
in collaboration with
R.L. Gorsuch, R. Lushene, P.R. Vagg and G.A. Jacobs

STAI Form Y-1

Name ______________________ Date _____ S_____

Age __________ Sex: M _____ F _____ T_____

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you feel *right now*, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Not at all	Somewhat	Moderately so	Very much so
1. I feel calm	①	②	③	④
2. I feel secure	①	②	③	④
3. I am tense	①	②	③	④
4. I feel strained	①	②	③	④
5. I feel at ease	①	②	③	④
6. I feel upset	①	②	③	④
7. I am presently worrying over possible misfortunes	①	②	③	④
8. I feel satisfied	①	②	③	④
9. I feel frightened	①	②	③	④
10. I feel comfortable	①	②	③	④
11. I feel self-confident	①	②	③	④
12. I feel nervous	①	②	③	④
13. I am jittery	①	②	③	④
14. I feel indecisive	①	②	③	④
15. I am relaxed	①	②	③	④
16. I feel content	①	②	③	④
17. I am worried	①	②	③	④
18. I feel confused	①	②	③	④
19. I feel steady	①	②	③	④
20. I feel pleasant	①	②	③	④

Partner Questionnaires cont.

SELF-EVALUATION QUESTIONNAIRE

STAI Form Y-1

Name ________________________________ Date ____________

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	Almost never	Sometimes	Often	Almost always
21. I feel pleasant	1	2	3	4
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30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

Thank you for taking the time to complete this questionnaire.

5

Interview schedules – Patients and carers (1st interview)

Required	Question	Must address / listen for
Receipt of equipment? Admin and contact details	Trial run of equipment? Any problems? Do you have my number?	Required action to facilitate use Repeat contact details Emphasise availability – any problems just call.
Medical history	Can you tell me about the beginnings of the illness? Did it affect daily life? In what ways? Were any tests undertaken?	Duration of arrhythmia. Age of onset. History of investigation Physical / psychosocial impact. Outcomes

Interview schedules – Patients and carers (2nd interviews)

Required	Question	Must address / listen for
Experience of ECG recording	How did you (he/she) get on with the equipment? Did you manage to catch one of the palpitations?	Number of occasions used. Problems with ECG recording Interaction with staff at call centre Success or failure to record / transmit.
Outcomes of ECG recording	What did the call centre say? What happened to the information? did the call centre send it to your doctor or have you got it? What has happened since / what's the next step?	Diagnostic information. Success / failure of outcomes. Results of diagnosis – treatment?
Changes to QoL?	Has it made any difference to you?	Pre & post intervention comparisons.

Interview schedules – Clinicians (Post use interviews)

Required	Question	Must address / listen for
Impressions of quality of ECG trace	Have you seen the telemedicine ECG? (Show a copy.) What do you think of the quality?	 Comparisons with previous ECGs
Impressions of usefulness	Does it yield a satisfactory diagnosis? Did you experience any problems with receiving the data? Do you see a role for this equipment in your practice in future?	Yes / versus shortcomings Obstructions / Any points which may encourage or discourage use of the equipment. Role related to • patient operation at home • superior diagnostic expertise of call centre • alternative clinical applications
Future intentions	Would you see any opportunities for investigating the potential of this equipment further? Would you be interested in trialling with any other patients or patient groups?	Interest in pursuing research Evidence of ability to incorporate research or previous experience of research.

Coding Scheme for patients, spouses and healthcare professionals.

Group	Categories	Sub -categories	Sub -categories
Patients	Perceived attitude of Health care staff	Call centre	Welcoming / caring / interested / have time Explains findings / suggests action
		Cardiologist	Disinterested / Wasting their time
		GP	Doesn't know what to do
	Practical interaction with healthcare	Hospital	Distance to travel / Time of travel. Delay = arrhythmic episode not witnessed
		GP	Unavailable / Long trek to surgery
	Impact of arrhythmia	Fear	Of heart attack (despite not having heart attack) Unable to get help away from home / at night
	Impact of telemdicine system	Reduces fear / reassures	Better than existing care even in working hours Available even if not likely to be needed. Emergency assistance available "out of hours"
		Provides support	Confirmation of no danger Advice/ confirmation of action necessary.
		Practical	Reduces time to access care Health care from any location (with landline)
	Shortcomings of telemedicine system		Cannot use mobile phone to transmit data. Assistance or demonstration required initially Practice required Printed material unclear for some Clearer labeling of electrodes would help Battery life problems Noise of equipment during recording stage
Spouses	Impact of telemdicine system	Practical	Reduces emergency journeys to hospital /GP etc
		Emotional	"pacifies spouse" / reduces stress
Health care Professionals	Benefits and shortcomings of telemdicine system	GPs & Cardiologists	Confirmed diagnosis in some cases Avoided in patient stays/ tests for some patients Operation requires dexterity. Single lead may provide sufficient diagnostic data
		Cardiac nurses	Practical demonstration required to encourage patient acceptability

Letter of ethical approval - ECG Study.

Cumbria and Lancashire B
Lancashire & South Cumbria Agency
Room 1.08
3 Caxton Road
Fulwood
Preston
Lancashire
PR2 9ZZ

Telephone: 01772 221428
Facsimile: 01772 221435

20 April 2006

Dr Stephen T Ward
Medical Advisor, Primary Care
Cumbria & Lancashire Strategic Health Authority
Preston Business Centre
Watling Street Road
Preston
PR2 8DY

Dear Dr Ward

Full title of study: **The role of telemedicine in primary care for the care of patients with Arrythmia: a pilot study**
REC reference number: **05/Q1309/49**

Thank you for your letter of 30 March 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA. There is no requirement for other Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Application	5.0	14 February 2006
Investigator CV		
Protocol	1	14 February 2006
Covering Letter		
Summary/Synopsis		
Letter from Sponsor		20 July 2005
Statistician Comments		14 February 2006
Compensation Arrangements		09 December 2005
Interview Schedules/Topic Guides	1	14 February 2006
Interview Schedules/Topic Guides	1	14 February 2006
Questionnaire		
Questionnaire		
Sample Diary/Patient Card	1	14 February 2006
Letter of invitation to participant	1	12 February 2006
GP/Consultant Information Sheets	1	13 February 2006
Participant Information Sheet	2	20 March 2006
Participant Information Sheet	2	20 March 2006
Participant Consent Form	2	20 March 2006
Participant Consent Form	2	28 March 2006
Response to Request for Further Information		30 March 2006
Letter from R&D		14 February 2006
Broomwell Health Watch		

05/Q1309/49 Page 2

Research governance approval

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/Q1309/49	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr P A Wilkinson
Chair

Email: Davina.Halliday@lasca.nhs.uk

Enclosures: *Standard approval conditions*

Copy to: Department of Health
Room 4N20
Quarry House
Leeds

John Wardle, R&D Department

Patient information sheet - ECG Study.

Cumbria and Lancashire NHS
Strategic Health Authority

EVALUATION OF A HOME ECG MONITORING SERVICE FOR PATIENTS WITH PALPITATIONS

PATIENT INFORMATION SHEET

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, please read the following information carefully. Make sure you understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear or if you would like more information. Our contact details are at the bottom of this sheet.

What is the research about?
We are asking patients who have had palpitations in the past to help us to test a new way of monitoring their condition. The research study will last for 6 months. During this time **either**…

a) You will receive, on loan, a small ECG machine to use at home (you will be taught how to use it) or …
b) You will be asked just to continue to go about your daily life as you normally do

We will then compare information from the two groups to see if there is any benefit to having the ECG machine at home. Whether or not you are one of the people who receive the ECG machine will be decided entirely by chance and the machines must be returned at the end of the study.

If I take part, what will I have to do?
1) If you are one of the people with an ECG machine, if you have a palpitation, you should record an ECG while you are having the palpitation., You will then send your ECG recording via your normal telephone line, to a specialist centre, where a specialist cardiac nurse will interpret your ECG recording and give advice. The specialist centre is staffed 24 hours a day, every day. You will have to pay the cost of the call yourself. The cost will depend on your telephone company, but will cost the same amount per minute as would any call from your house to Manchester. There is a direct line to the specialist centre and it normally takes less than 1 minute to transmit the ECG recording. The exact duration of each call will depend on how long you discuss your symptoms with the specialist cardiac nurse.

2) Everyone who volunteers will be asked to:-
a) Fill out questionnaires about their wellbeing. This will take a few minutes at the beginning, middle and end of the research study.
b) Keep a **brief** diary for the duration of the project. This would normally be only a couple of words, eg "Ok today" but if you have a palpitation we would like you to make a note of how you felt and what you did about it.
c) Give us permission to look at your medical records.

3) Your spouse, partner or carer, if you have one, will also be asked to fill out similar questionnaires.

4) Some people, and their spouses, partners or carers will be asked to take part in an informal telephone interview. These interviews will normally be recorded. If you are asked to take part, the

Version 2   20/03/2006
Page 1 of 3

researcher Glenis Johnston will arrange a time when it is convenient for her to phone you. You will not pay for the cost of these calls.

Is there any risk to me?
There should be no additional risk to you by taking part in this study. This is **in addition** to your normal care, **not instead** of it, so you should follow your normal procedure if you have a palpitation. In the unlikely event that something does go wrong and you are harmed during the research study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against Blackpool, Fylde or Wyre PCT's, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you, if appropriate.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you decide not to take part this will not affect the standard of care you receive.

Can I withdraw from the study part way through?
Yes. You may withdraw at any time and without giving a reason. If you withdraw, you can choose either to permit us to use any information we have already collected from you, or to have it destroyed. In either case you will not be identified in any way.

Expenses and payments:
There is no payment for taking part in this research unless we ask you to make a special journey to the hospital and then we will pay your travel expenses.

What are the possible benefits of taking part?
We cannot promise the study will help you directly, but the information we get might help improve the care of people with palpitations or other heart conditions.

What happens when the research study stops?
At the end of the study you must return the ECG machine if you have been given one. We cannot continue to provide you with the equipment, however it is available for private purchase from Broomwell Healthwatch.

What if there is a problem?
If you have a problem with the equipment, call the supplying company, Broomwell Healthwatch on 0161 2360141.
If you have any concerns about the way you have been dealt with during the study, you should phone the researcher, Glenis Johnston on 0779 1586334 and she will do her best to resolve matters. If you remain unhappy and wish to complain formally, you can do this through the Patient Advisory Liaison Service at Blackpool and Victoria Hospital. Details can be obtained from Margaret Cooper. Research & Development Department, Blackpool and Victoria Hospital.

Will my taking part in the study be kept confidential?
Your GP will be told that you have agreed to take part in a research study. If you are one of the people using the ECG machine, your doctor will be sent the results of your ECG each time you call the Specialist Centre. Apart from that, nothing that could reveal your identity will be disclosed outside the research sites. All identifying details will be removed from the documentation and it will be stored anonymously in a locked filing cabinet. It will be seen only by the researchers. No identifying details will appear in any reports. Your information will be kept until the study and all reports are completed. After that it will be destroyed securely. The procedures for handling, processing, storage and destruction of the information

Version 2   20/03/2006
Page 2 of 3

Patient information sheet ECG study Cont.

are compliant with the Data Protection Act 1998. You have the right to check the accuracy of data held about you and correct any errors.

What will happen to the results of the research study?
The results will be made available to the Strategic Health Authority and will be published in medical journals. On request the results will be made available to volunteers. *NB You will not be identified in any report or publication.

Who is organising and funding the research?
The research is being led by Dr Stephen Ward and conducted by researchers from Buckinghamshire Chilterns University College on behalf of the Cumbria and Lancashire Strategic Health Authority. Funding is provided by the Department of Health.

Who has reviewed the study?
This study was given a favourable ethical opinion for conduct in the NHS by the Cumbria and Lancashire Research Ethics Committee. Reference number 05/Q1309/49

If you would like to discuss this further or ask questions, contact Glenis Johnston on 0779 1586334

Thank you very much for considering taking part in this research.

If you would like to take part, please write your name, address and telephone number on the attached sheet and return it to me, Glenis Johnston, in the postage paid envelope provided and I will contact you in the very near future. Please keep this information sheet.

If you do not want to take part in this study, it would be very helpful if you will tell us why. Please write your reasons on the attached sheet and send it to me in the prepaid envelope. Thank you

Partner information sheet - ECG Study.

Cumbria and Lancashire NHS
Strategic Health Authority

EVALUATION OF A HOME ECG MONITORING SERVICE FOR PATIENTS WITH PALPITATIONS

INFORMATION SHEET for PARTNERS of PATIENTS

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, please read the following information carefully. Make sure you understand why the research is being done and what it will involve. Please ask us if there is anything that is not clear or if you would like more information. Our contact details are at the bottom of this sheet.

What is the research about?
We are asking patients who have had palpitations in the past to help us to test a new way of monitoring their condition, and we would like to find out how the patient's heart condition affects the people who care for them.

If I take part, what will I have to do?

a) Fill out questionnaires about your wellbeing. This will take a few minutes at the beginning, middle and end of the research study.
b) You may be asked to take part in an informal telephone interview. These interviews will normally be recorded. If you agree to this, the researcher, Glenis Johnston, will contact you to arrange a convenient time for her to phone you. You will not have to pay for this telephone call

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you decide not to take part this will not affect the standard of care to your partner.

Can I withdraw from the study part way through?
Yes. You may withdraw at any time and without giving a reason. If you withdraw, you can choose either to permit us to use any information we have already collected from you, or to have it destroyed. In either case you will not be identified in any way.

Expenses and payments:
There is no payment for taking part in this research.

What are the possible benefits of taking part?
We cannot promise the study will help you or your family directly, but the information we get might help improve the care of people with palpitations or other heart conditions in the future.

What if there is a problem?
If you have any concerns about the way you have been dealt with during the study, you should phone the researcher, Glenis Johnston on 0779 1586334 and she will do her best to resolve matters. If you remain unhappy and wish to complain formally, you can do this through the Patient Advisory Liaison Service at Blackpool and Victoria Hospital. Details can be obtained from Margaret Cooper. Research & Development, Blackpool and Victoria hospital.

Will my taking part in the study be kept confidential?
Yes.
All identifying details will be removed from the documentation and it will be stored anonymously in a locked filing cabinet. It will be seen only by the researchers. No identifying details will appear in any reports. Your information will be kept until the study and all reports are completed. After that it will be destroyed securely. The procedures for handling, processing, storage and destruction of the information are compliant with the Data Protection Act 1998. You have the right to check the accuracy of data held about you and correct any errors.

What will happen to the results of the research study?
The results will be made available to the Strategic Health Authority and will be published in medical journals. On request the results will be made available to volunteers. *NB You will not be identified in any report or publication.

Who is organising and funding the research?
The research is being led by Dr Stephen Ward and conducted by researchers from Buckinghamshire Chilterns University College on behalf of the Cumbria and Lancashire Strategic Health Authority. Funding is provided by the Department of Health.

Who has reviewed the study?
This study was given a favourable ethical opinion for conduct in the NHS by the Cumbria and Lancashire Research Ethics Committee. Reference number 05/Q13/09/49

If you would like to discuss this further or ask questions, contact Glenis Johnston on 0779 1586334

Thank you very much for considering taking part in this research.

If you would like to take part, please write your name, address and telephone number on the attached sheet and return it to me, Glenis Johnston, in the postage paid envelope provided and I will contact you in the very near future.

If you do not want to take part in this study, it would be very helpful if you will tell us why. Please write your reasons on the attached sheet and send it to me in the prepaid envelope. Thank you

Patient consent form - ECG Study.

CONSENT FORM for PATIENT

Title of Project: EVALUATION OF AN ECG HOME MONITORING SERVICE FOR PATIENTS WITH PALPITATIONS

Name of Researchers: Dr Stephen T. Ward, Dr Gwyn Weatherburn, Dr David Shaw, Mrs Glenis Johnston and Ms Julie Hendry.

Please initial box

1. I confirm that I have read and understand the information sheet dated 20.03.06 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes relating to my palpitations, and data collected during the study, may be looked at by responsible individuals from Buckinghamshire Chilterns University College, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
4. I understand and agree that, if I am interviewed, my interview will normally be recorded on an audio machine.
5. I understand and agree that if I am interviewed, some of my words may be quoted, anonymously, in reports.
6. I agree to my GP, specialist, or nurse being informed of my participation in the study.
7. I agree to my GP, specialist or specialist cardiac nurse being consulted about my medical history.
8. I understand and agree that my spouse, partner or carer will complete similar questionnaires, and may be interviewed, about matters relating to my condition.
9. I agree to take part in the above study.

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Glenis Johnston Researcher	Date	Signature

Version 2 23.03.06

Partner consent form - ECG Study.

Cumbria and Lancashire NHS
Strategic Health Authority

Patient Identification Number for this study:..................

CONSENT FORM for PARTNER of patient.

Title of Project: EVALUATION OF AN ECG HOME MONITORING SERVICE FOR PATIENTS WITH PALPITATIONS

Name of Researchers: Dr Stephen T. Ward, Dr Gwyn Weatherburn, Dr David Shaw, Mrs Glenis Johnston and Ms Julie Hendry.

	Please initial box
1. I confirm that I have read and understand the information sheet dated 20.03.06 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I understand and agree that if I am interviewed, my interview will normally be recorded on an audio machine.	
4. I understand and agree that if I am interviewed, some of my words may be quoted, anonymously, in reports.	
5. I agree to take part in the above study.	

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Glenis Johnston Researcher	Date	Signature

Publications and presentations

a) **Oral and poster presentation.** Johnston, G., Weatherburn, G. Bodie, D.A., and Shaw, D. 2005. "A comparison of 'Store and forward' technology equipment." Telemed and eHealth '05 - Meeting Healthcare Challenges. 2005. Royal Society of Medicine, London.

Abstract. (Poster on following page.)

TM05/RE34

A Comparison of Store and Forward Technology Equipment

G Johnston, G Weatherburn, D Brodie & D Shaw (UK)

Correspondence

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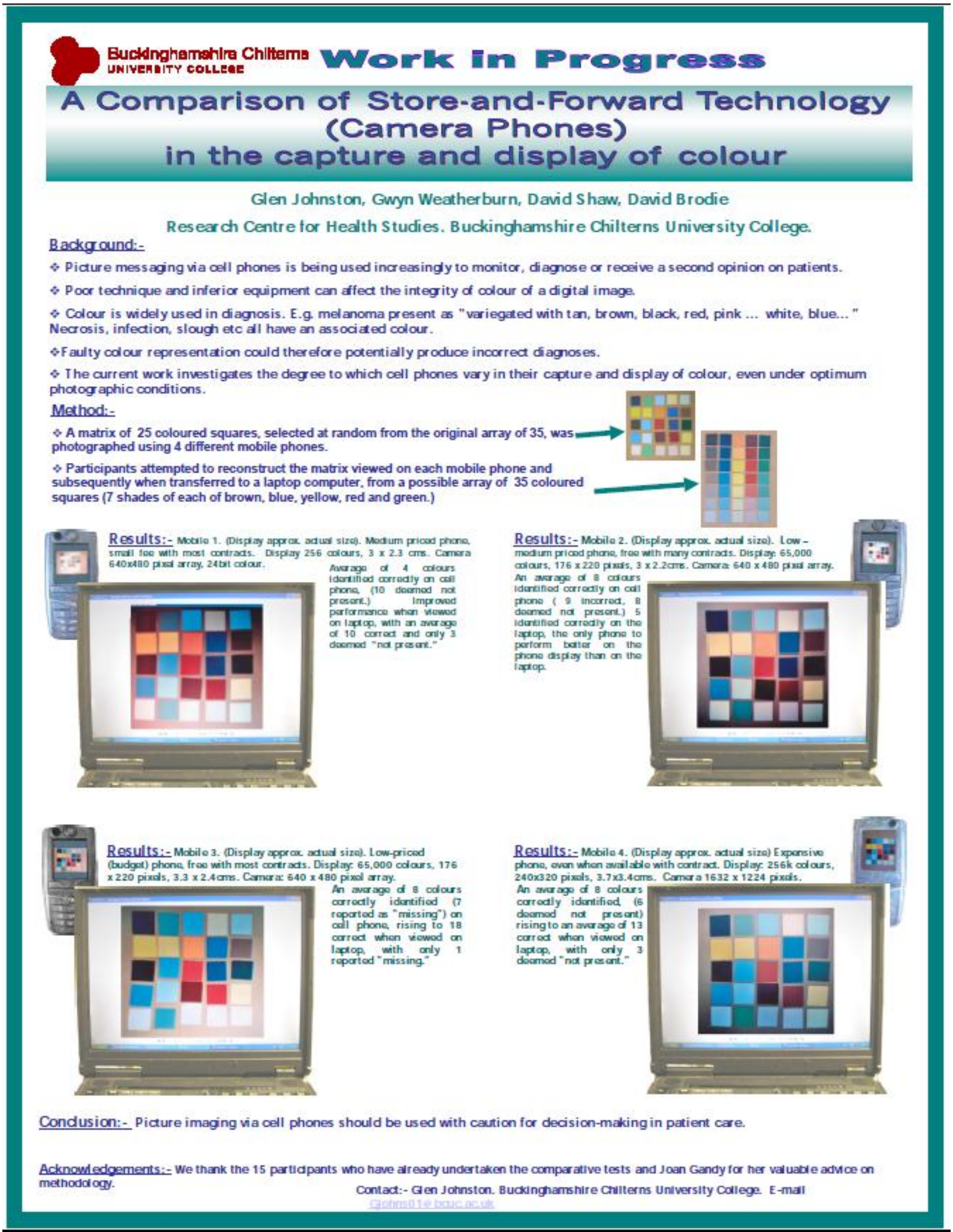
Four mobile phones and a digital camera were used to capture images of randomly constructed colour matrices and of a line-pair patterned grid. The images were transferred to a computer using either a direct USB or infra-red link. The colour matrices consisted of 25 blocks of colour selected at random from a possible total of 36 colours, comprising six shades of each of blue, green, red, yellow, beige and orange. Participants were shown a selection of images of the matrices, both on the screen of the mobile phones and on the computer. They were given the original 36 blocks of colour and asked to reproduce each matrix seen. The line-pair patterned grid consisted of 20 blocks of lines of varying thickness and spacing, surrounded by a border of squares. Three images were captured on each phone and camera, using an approximate angulation of zero, ten and twenty degrees. The images of the grid presented on the mobile phones and on the computer were assessed for definition and shape. The results show the variations in the quality of image display, the improvement when images are transferred to a computer, and the distortion arising from both the hardware and poor photographic technique.

<u>Oral and poster presentation</u> (cont. from previous page). Johnston, G., Weatherburn, G. Bodie, D.A., and Shaw, D. 2005. “A comparison of ‘Store and forward’ technology equipment.” Telemed and eHealth ’05 - Meeting Healthcare Challenges. 2005. Royal Society of Medicine, London.



Publications and presentations (cont.)

b) **Oral presentation.** "A randomised study to evaluate the role of telemedicine for patients with chronic heart failure". North West Cardiology Clinical Research & Audit Symposium. 6th October 2006.

Abstract.

A randomised study is currently being undertaken in Cumbria and Lancashire SHA, to evaluate the role of telemedicine in patients with chronic heart failure. The patients weigh themselves daily, using electronic weighing scales which transmit their weight to a central call centre. The patients are free to call for advice when they feel the need and in addition they are contacted when the weight is seen to vary outside parameters previously set by their specialist heart failure specialist nurse. A record of the patient's weight and any interaction with the call centre is sent to the heart failure nurse.

The views of both patients and nurses are being elicited at the start, middle and end of the study. The data collected to date will be reported and the research methods explained.

Publications and presentations (cont.)

c) **Oral presentation.** Johnston, G., Weatherburn, G. "Colour, definition and distortion in imaging equipment; Are they relevant in teledermatology?" to **1st** World Congress of Teledermatology & Annual Meeting of the Austrian Scientific Society of Telemedicine. Department of Dermatology. Medical University of Graz November 9 – 11, 2006. Abstract in Journal der Deutschen Dermatologischen Gesellschaft. Vol 4 issue 11 (p 999-1017**)** Published Online: Oct 25 2006

Abstract.

Colour, Definition and Distortion in imaging equipment ~ are they relevant in Tele-dermatology?

Authors: Mrs Glenis Johnston and Dr Gwyn Weatherburn. Buckinghamshire Chilterns University College.

Purpose of the research. Colour, size and shape are important considerations when monitoring chronic wounds. They are particularly important when patient care is the responsibility of a busy general nurse with little or no dermatology experience, and where access to specialist advice is achieved only by remote means. Digital cameras, picture messaging and real-time video communication are increasingly being used for this purpose. Even under optimum conditions the colour integrity, definition and distortion varies according to the item of equipment used. This study compares the performance of a range of equipment in the capture and display of an image and questions the safety of the practice related to the care of patients in the community.

Methods. The following items of equipment were selected for a comparison of performance.

- Four mobile cameraphones, ranging in quality from a low-cost first generation model to an expensive "top-of-the-range" model.
- Three real-time video systems, ranging in quality from a low-cost domestic model, to a professional video-conferencing system.
- A 4-megapixel digital camera.

Each item of equipment was used to capture, under optimum photographic conditions, images of a matrix of coloured squares (to assess colour integrity) and a pattern of line pairs and squares (to assess definition and distortion.) The images from the mobile cameraphones and digital camera were also transferred to a laptop computer for further assessment. 12 participants attempted to reproduce the coloured matrix from an image viewed on the display screen of each item of equipment, and also from those images transferred to a laptop computer. Participants assessed definition by reference to the finest array of line pairs which could be differentiated by the naked eye. Distortion was

assessed by comparing the measurement of the area of the squares in the centre of the image with those at the edge.

Results. There was very little difference in terms of absolute colour recognition between the best and poorest quality of mobile phone, when the image was viewed on the phone display. Only 32% of the colours photographed were identified correctly. When the images were transferred to a laptop computer, the image photographed on the least expensive cameraphone achieved the highest result, with 72% of colours being identified correctly. When comparing the areas of identical squares as they appeared over the face of the mobile phones, a discrepancy approaching 9% was demonstrated.

Conclusions. Distortion in colour representation and in shape occurs in imaging equipment even under best photographic conditions. When compounded by sub-optimal lighting, inexpert use and difficult patient conditions, it is possible that the degraded image might contribute to mis-management of the patient. Extreme caution is recommended when relying on pictures taken by equipment currently available and it is suggested that these factors are considered when new equipment is developed for tele-dermatalogical purposes.

Publications and presentations (cont.)

d) Oral presentation. Johnston, G., Ward, S., Weatherburn, G., Hendry, J. "Issues arising when a system of automated weight monitoring is introduced as part of the care for patients with chronic heart failure." Telemed and eHealth '06. "Transforming the Patient Experience" 2006, Royal Society of Medicine, London.

TE06/RE 35 **Issues arising when a system of automated weight monitoring is introduced into the home as part of the care for patients with Chronic Heart Failure**

G Johnston, G Weatherburn, S Ward, J Hendry (UK)

Correspondence

Email: gjohns01@bcuc.ac.uk

Introduction

For patients with CHF, changes in body weight may be an indication of fluid retention due to a worsened heart condition. Clinicians make judgements about which patients should have regular weight monitoring, because in those patients a worsening condition can be identified at an early stage and intervention in the form of a simple treatment such as taking diuretics can be implemented.

In this study, daily weight monitoring occurred using electronic weighing scales, connected via a wireless gateway to the telephone line in the patient's home. The data were sent automatically to a central call centre. Specialist staff at the call centre monitored the weight and provided feedback either to the patient or to the clinician, as required by the clinician.

Methods

100 patients having a history of chronic heart failure (CHF) and who were identified as requiring weight monitoring, were randomised into two groups. Both groups received normal care and in addition one group received a set of automated weighing scales which transmitted the patient's weight directly to a central call centre. "Normal care" in this context meant weight monitoring either by the patient themselves or by their specialist heart failure nurse as part of their schedule of care.

Three weeks into the study interviews were conducted with 20% of patients (5), their partners (4) and their heart failure nurses (3). Thematic analysis was conducted in order to probe their experiences of the illness and their perception of how telemedicine might impact on those experiences.

Results and discussion

The issues identified as being important to patients, partners and clinicians are discussed in the light of some experiences of the telemedicine technology to date.

For all patients and their partners, the issues most frequently reported related to:-

- The loss of confidence in their ability to function normally on an intellectual level. This was perceived as resulting in a loss of dignity and respect from others, in particular medical personnel; the loss of the leader role within a relationship; the fear of being unable to manage their condition alone and the loss of social interaction with others.
- Non-understanding of the concept of weight monitoring and its role in monitoring their condition.
- The importance of having medical support available at all times, 24 hour care, being "directed" rather than "empowered."

For those having received the telemedicine scales.

- Practical and technical issues arising from the setting up and use of the equipment.

For nurses the issues were centred on concerns about workload, potential changes to their role and how they would utilize the telemedicine scales. Two different strategies were offered as to how the technology could be used most appropriately in their practice. These strategies will be discussed.

27

Conclusions

The telemedicine scales have the potential to provide a higher level of care, in a number of ways, than is currently the case for patients living with chronic heart failure. However the benefits are not fully realised due to a need to educate and support patients during the initial period of introducing the scales into the home environment.

Publications and presentations (cont.)

e) Oral presentation. (Presented by Dr Weatherburn.) Ward, S., Weatherburn, Hendry, J. G., Johnston, G., "A study to evaluate the use of ECG Telemetry in Primary Care in the UK." Telemed and eHealth '06 Transforming the Patient Experience 2006, Royal Society of Medicine, London.

TE06/RE 23 **A study to evaluate the use ECG Telemetry in Primary Care in the UK**

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Correspondence

Email: Stephen.Ward@GP-P81076.nhs.uk

A study has been undertaken to determine the practical and clinical effectiveness of telemetric ECG machines when used by clinicians in the Primary Care Environment within the National Health Service in the UK.

Telemetric 12 lead ECG machines, which are used in an identical manner to conventional equipment, were used in a pilot study within the old Cumbria and South Lancashire SHA. The difference in the equipment is in the recording and reading of the result. Conventional ECG machines take a recording then produce a paper tracing which is interpreted by the clinician or the machine's built-in electronic reader. The new telemetric devices obtain the recording in the same manner but the reading is then transmitted by a normal land line to a call centre where a team of clinically trained cardiac staff are always available to interpret the results. When the ECG reaches the call centre, one of the cardiac clinicians, who has been made aware of the clinical situation by the referring doctor, nurse or paramedic provides an accurate interpretation and immediate result to enable appropriate management decisions to be made and to enable quality patient care.

A literature review of telemetric audit and research in Europe and America suggests that the use of this equipment is well received by the clinical staff, has a beneficial effect on patient care and clinical management, and by reducing inappropriate hospital admissions, enables the more effective use of healthcare resources. This study has focussed on the pragmatic application of the technology in general practices and walk in centres in order to determine the effectiveness of this equipment when used to assess patients who require ECG examinations. The technology has been made available and the primary care staff have been able to use it as they chose: either to establish an acute diagnosis for the cause of presenting chest pain or to review the progress of patients who require monitoring with regard to their long term condition, for example diabetes.

For the purposes of the audit, ECG machines were made available in 14 practices across the C&LSHA area and within two Primary Care Walk-in Centres. The ECG equipment was available for six months during which period examinations were undertaken by both medical and other clinical staff. They took the place of, or supplemented the use of, the conventional machines for the period of the project and were used according to the existing practice protocol, either as a screening tool or to establish an acute diagnosis.

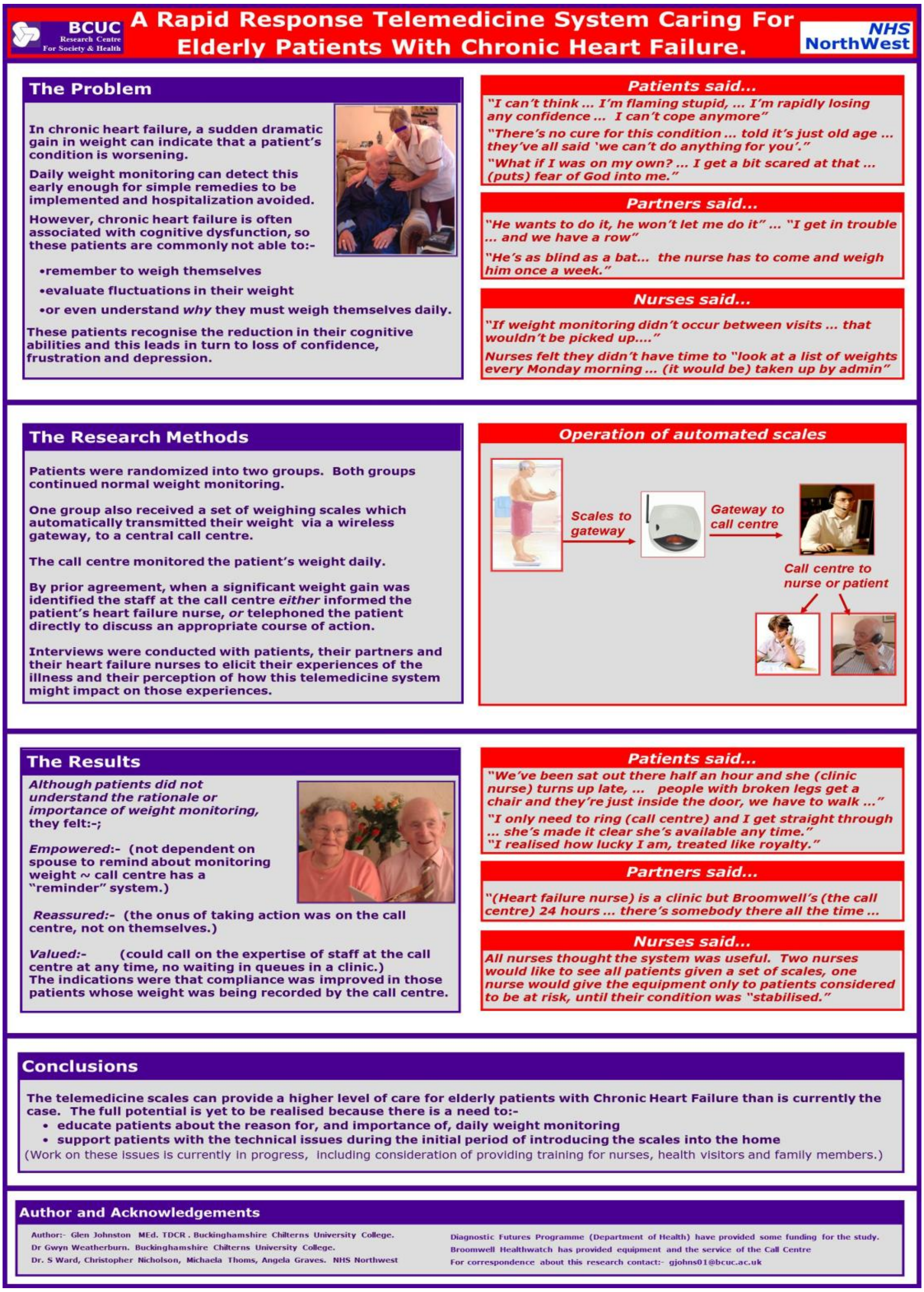
Each patient episode was logged on an audit questionnaire to record details of the use of the equipment and the outcome of the investigation. Data related to whether or not the equipment was convenient to use in practice, the manager and clinician's opinion of the service, the patient viewpoint and whether or not the clinical management had been influenced by this new technology. In addition the work was evaluated by a series of focus groups of clinical and managerial staff, led by Ipsos MORI to evaluate opinion. A separate report with regard to the service has been produced.

This project has compared outcomes with those produced by other workers and along with the Ipsos MORI report will be used to influence the future commissioning plans of the new Primary Care Trusts and Strategic Health Authority.

This work has been supported by funding through the Diagnostics and Futures programme at the Department of Health and the authors also acknowledge the assistance of Broomwell Healthwatch.

Publications and presentations (cont.)

f) **Poster.** Johnston, G. "A rapid response telemedicine system caring for elderly patients with chronic heart failure." The 9th Great British R&D Show Exhibition. March 2007. House of Commons.



Publications and presentations (cont.)

g) Publication. Johnston, G., Weatherburn, G., Ward, S., & Hendry;, J. "Problems arising when a system of automated weight monitoring is introduced as part of the care for patients with chronic heart failure." Journal of telemedicine and telecare. 2007. 13 (suppl 1) S1:29-31

G Johnston *et al.* Electronic monitoring system for heart patients

Problems arising when a system of automated weight monitoring is introduced into the home as part of the care for patients with chronic heart failure

Glenis Johnston*, Gwyneth Weatherburn*, Stephen Ward† and Julie Hendry†

*Research Centre for Health Studies, Buckinghamshire Chilterns University College; †NHS North West Strategic Health Authority, UK

Summary
Patients with a history of chronic heart failure participated in a study to evaluate a home telemedicine system which monitored their weight daily. Within three weeks of beginning the study, interviews were conducted with patients ($n=5$), their partners ($n=4$) and their heart failure nurses ($n=3$). A thematic analysis was carried out in order to probe their experiences of the illness and their perception of how telemedicine might affect those experiences. When asked, the participants and their partners did not consider that the electronic monitoring system would be much use to them. Nurses also had a number of misconceptions about the telemedicine service. The results demonstrated that patients needed better education, both in the management of their condition and in the use of the telemedicine equipment and the service provided by the call centre, before the telemedicine system could fulfil its potential.

Introduction

Diseases of the heart and circulatory system are the main cause of death in the UK, accounting for just over 216,000 deaths in 2004. The total cost of health care for this group of patients was about £14,750 million in 2003.[1] For patients with chronic heart failure, changes in bodyweight may indicate fluid retention due to a worsened heart condition. Clinicians make judgements about which patients should have regular weight monitoring, because in those patients a worsening condition can be identified at an early stage and a simple treatment such as taking diuretics can often be given.

In normal practice, clinicians explain the importance of daily bodyweight monitoring to their patients. The patients record their weight and it is reviewed either during clinic visits or when the clinician visits them in their home. This might occur weekly, monthly or every two months. In the present study, daily bodyweight monitoring was performed using electronic scales, connected via a wireless gateway to the telephone line in the patient's home. The data were sent automatically to a call centre. Specialist staff at the call centre monitored the weight and provided feedback either to the patient or to the clinician, as appropriate. Given the acute shortage of specialist heart failure nurses, and the benefits of improved quality of care and cost savings claimed for telemedicine,[2–4] this technique may be a useful and cost-effective method by which cardiac decompensation can be rapidly detected and treated.

We have studied the views of patients, their partners and their clinicians during the early stages of their encounter with this type of telemedicine.

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(*Fax: +44 1494 605 212; Email: gjohns01@bcuc.ac.uk*)

Methods

Ethics approval was obtained and patients with a history of chronic heart failure (CHF) were invited to participate, together with their spouse, partner or carer. The patients were randomized into two groups. In addition to their normal care, one group received a set of automated scales which transmitted the patient's bodyweight to the call centre. The other group received only normal care. 'Normal care' in this context meant bodyweight monitoring either by the patient themselves or by their specialist heart failure nurse as part of their schedule of care.

Journal of Telemedicine and Telecare 2007; **13** (Suppl. 1): S1:29–31

After three weeks in the study, interviews were conducted with patients ($n=5$), their partners ($n=4$) and their heart failure nurses ($n=3$). A thematic analysis was carried out in order to probe their experiences of the illness and their perception of how telemedicine might affect those experiences.

Results

When asked, the participants and their partners did not consider that the electronic monitoring system would be much use to them. These views are explored below.

1. Patients' perceptions of themselves

Loss of confidence, due to cognitive dysfunction, was the most frequently reported problem for all participants. This is common in elderly patients with chronic heart failure.[5] Loss of confidence affected their lives in a number of ways. The loss of a leadership role within their relationships was a common thread, partners tending to take over this role.

One way in which patients struggled to preserve normal intellectual function was in retaining control of scheduled tasks, such as taking medication or remembering to monitor their bodyweight each morning. This caused some tension within the relationship. Another common problem was fear of being alone and being unable to cope. The threat of social isolation was also important. Two participants found a solution by contributing to Internet chat lines.

Patients perceived a loss of dignity and respect from others and in particular felt that clinicians had no interest in them or their illness. They particularly appreciated the care they received at home.

2. Misconceptions about weight monitoring

Patients did not understand the relationship between fluid retention in CHF and weight gain. This confusion is perhaps not surprising, as dietary guidance is also a recognized feature of management of CHF.[6,7]

On one occasion, the call centre staff needed to alert the heart failure nurse about a patient's weight gain. The patient's nurse was on holiday, so, as agreed in the protocol the call centre nurse contacted the patient, discussed the situation and advised the patient to call his general practitioner (GP). Thus the call centre had provided rapid detection and had begun early intervention, but the patient exercised his choice which was to ignore the advice provided. Inadequate understanding of weight monitoring and the importance of detecting a change before he felt unwell, meant the patient risked negating the positive benefits which may be gained by early change in management.

None of the participants connected weight monitoring with the goals of treatment, which are to increase survival, reduce symptoms, and improve functional status and quality of life. Many patients had a negative view of their condition.[8]

3. Support from clinicians

Participants were unanimous in their dissatisfaction with the health care they had received in hospital, but expressed high praise for the care received at home and from their heart failure specialist nurses. They emphasised the importance of feeling that medical support was available to give advice and care at all times. They also emphasised that they wanted the support to be directive, not collaborative. Contrary to expectations, they did not want to be empowered.

4. Technology

Some participants did not have the confidence to set up the scales, but related this to the effects of heart failure and not to the complexity of the equipment. It was not always possible to site the scales in the bathroom, as the gateway device required an electrical socket and also needed to be within a few metres of the scales. One participant solved this by positioning the scales in the lounge.

Another problem was failing eyesight which meant that one patient still relied on his partner to tell him when he could get off the weighing scales. In fact the scales had additional cues for this purpose to indicate when the data had been sent. There was a bleep which indicated that the data had been sent successfully. In addition, none of the participants were aware that staff at the call centre would contact them if data were not received for a day or two, or if a significant weight gain were recorded.

5. Nursing practice

Nurses also had a number of misconceptions about the telemedicine service. For the cardiac nurses, there were concerns about workload, potential changes to their role and how they would utilize the telemedicine scales in their daily practice.

Two distinct strategies were suggested by the nurses. The first was a scenario in which all patients received the scales and the patient's nurse was happy for the patient and call centre to negotiate directly about simple measures such as increasing diuretics. In this case the patient's nurse was alerted only if the weight fell outside the range that had been set. The nurse would liaise with both the patient and the call centre until weight stability was re-established. If the nurse was unavailable, e.g. at holiday times or weekends, the GP would be alerted.

In the second scenario the scales would be given only to selected patients, for a period of about six months or until their weight was stable. The call centre would contact the patient directly, only if their nurse were not available. The patient's nurse would receive all the data, i.e. daily weights of all patients, and take appropriate action. Not surprisingly, this was expected to produce a higher workload.

Other workload implications were the time taken to complete the medical questionnaire required by the call centre as each patient was registered, and a potential requirement to set up the weighing scales for every patient.

Discussion

A number of interactions demonstrated that patients needed to be better educated, both in the management of their condition and in the use of the telemedicine equipment and the service provided by the call centre, before the telemedicine system could fulfil its potential. For example:

- not knowing when the weight measurement had been sent to the call centre and when it was safe to get off the scales;
- failure to take the advice provided by the call centre and delay treatment until their own nurse was available.

It is possible that the participant's reluctance to set up the electronic scales themselves might also be helped by better education or more user-friendly instruction. Alternatively, a high proportion of patients in this group may require assistance in setting up the equipment.

Participants were very impressed that there was someone on duty at the call centre all day and every day. Although daily weight monitoring does not constitute an emergency situation in the normal sense, patients still found this 'always available' service reassuring. The positive implications of the contact should be considered if there is a progression towards more automation in the future. For example, if the monitoring were automated and a recorded message sent to the patient instead of contact by a clinician this may be less acceptable to patients.

The telemedicine scales used in the present study have the potential to provide better care than is currently the case for some patients living with chronic heart failure. However, patients in the present study needed more education and support during the initial period when the automated scales were introduced into the home environment.

Acknowledgements: We thank Michaela Toms and Christopher Nicholson (North West NHS) and Broomwell HealthWatch who provided the electronic scales and telemedicine service.

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Publications and presentations (cont.)

h) **Oral presentation.** "Services closer to patients – Telemonitoring Telecare." Ready for Reform? Delivering no waits in 2008. Cumbria and Lancashire Strategic Health Authority. No abstract as this was a "question and answer session."

Cumbria & Lancashire
Strategic Health Authority
NHS
15/3/06

Ready for Reform?
Delivering no waits in 2008

Herons Reach
DeVere Hotel, Blackpool

Programme of the Day

09:30	**Coffee/Tea & Registration**	**Topic Leader**
10:00	Welcome & Introduction	**Joe Rafferty** Director of Performance & Improvement C & L SHA
10:20	Utilisation Management in Acute Care	**Seamus McGirr** Head of Urgent Care **Aidan Kehoe** Director of Operations BFW Hospitals Trust
11:00	**Coffee/Tea**	
11:10	A new approach to Mental Health Service Utilisation – Using Lean Methodology	**Catherine Webster** Head of Mental Health **Karen Holt** Acute Services Manager **Peter Kinhan** GE Healthcare
11:40	Fresh eyes on an old problem	**Joe Restuccia** Prof. Healthcare and Operational Management, Boston, USA
12:30	**Lunch**	
13:20	The Diagnostics Paradox – Understanding drivers in diagnostics	**Gerry Marchand** Healthcare Consultant
14:00	Services closer to patients – Telemonitoring Telecare	**Joshua Rowe** Chairman Broomwell Healthwatch Ltd **Julie Hendry** Assistant Director **Glenis Johnston** University of Buckingham
14:40	**Coffee/Tea**	
14:55	Moving from Waiting Lists to Patient Flow	**Lee Durant** Healthcare Consultant
15:30	Developing Clinical Commissioning – The Role for CATS	**Joe Rafferty** Director of Performance & Improvement C & L SHA
16:00	Closing Remarks	**Joe Rafferty**
16:20	**Close**	

Publications and presentations (cont.)

i) **Oral and video presentation.** Johnston, G. “What monitoring of CHF means to carers.”. Tele-Cardiology: closer to the patient. The Royal Society of Medicine. 8th Sept. 2009.

Abstract.

In patients with chronic heart failure, a change in body weight may indicate fluid retention due to a worsened heart condition. In normal practice, clinicians explain the importance of daily weight monitoring to their patients and set limits of weight fluctuation. The patient is instructed to contact their clinician if the weight exceeds this limit, so that an early intervention can be implemented, which might prevent hospitalisation..

This presentation offers the users’ perspectives on the role and usefulness of weight monitoring, and on remote automated weight monitoring in conjunction with a central call centre in particular. The users are defined as the patients who have used the telemedicine weight monitoring system, their families and the clinicians who care for them. The often conflicting perspectives, even among members of the same user-group, are emphasised. An innovative approach to caring for an elderly relative is described in one son’s contribution by video.

Publications and presentations (cont.)

j) **Oral and video presentation**. Johnston, G. "A patient's experience of a self-operated 12-lead ECG unit.". Tele-Cardiology: closer to the patient. The Royal Society of Medicine. 8th Sept. 2009.

Abstract.

This video presentation charts one success story of the use of a remote self-operated 12-lead ECG unit which accesses specialist medical support via a landline telephone. In the presentation one patient and her husband speak frankly about the devastating effect that 30 years of undiagnosed arrhythmic episodes have had on their lives. In particular they describe the frustrations and barriers they have encountered from the medical services. They describe their hopes for a satisfactory outcome from using the telemedicine equipment, but specifically of the failings within the healthcare system which continued to frustrate, even after the episodes of arrhythmia has been recorded by the telemedicine equipment and a diagnosis achieved.

Publications and presentations (cont.)

k) **Publication.** Weatherburn, G., Ward, S., Johnston, G., Chisholm, S. "Off-site expert support for nurses undertaking ECGs in primary care." Br J Nurs. 2009 May 14-27;18(9):551-4

TELEMETRY

Off-site expert support for nurses undertaking ECGs in primary care

Gwyn Weatherburn, Stephen Ward, Glenis Johnston, Sally Chisholm

Abstract

One of the aims of the Department of Health is to respond to patient needs by considering how services can be delivered in more innovative ways, including more services being provided in primary care and increased activities being undertaken by nursing staff. These activities may have previously been undertaken by the GPs, or patients would be sent elsewhere, such as the local hospital, for tests/investigations. Some general practices are already using cardiac telemetry while others are awaiting feedback from system users before deciding whether to purchase services from independent providers. However, identifying how generalized results and predicted benefits will apply in a specific practice is not always straightforward. This article aims to assist the decision-making process by providing the results of an audit from eight general practices and two walk-in centres in which the electrocardiograms (ECGs) were already being undertaken by nurses. The results, which are shown for each centre, showed that the frequency of use varied between one and 27 per month, depending upon the practice. As a result of the 373 patients who had an ECG performed in practice, 76 had altered management decisions, 14 were saved hospital referral (11 of these from one walk-in centre), 18 were admitted to an acute hospital (10 from the same walk-in centre), and another 24 were referred to hospital for investigation.

Key words: Electrocardiogram ■ Primary health care ■ Telemetry

The Department of Health (DH) white paper *Our Health, Our Care, Our Say* (DH, 2006) identified the need to maintain patients within the community and avoid the inappropriate use of secondary care services and hospital admissions. As indicated in the evaluation of the government's Closer to Home demonstration sites, most patients prefer to receive care nearer to where they live, or even at home (Leese et al, 2007).

In order to achieve this, primary care clinical staff need improved access to community based diagnostic services. New technologies, such as electrocardiogram (ECG) telemetry, are ideal for developing this new direction in health care and provide a new way of working for practice nurses who undertake, in this example, many of the ECG examinations.

For more than a decade, studies have shown that gains in clinical outcome and health economics could be achieved by using telemetric equipment for patients with possible cardiac-related events (Dhruva et al, 2007; Terschuren et al, 2007; Sillesen et al, 2008). Progress has been slow in the UK, but more recently there has been an increase in the use of Cardiac Call Centres to provide support to patients and staff in the community. This article provides data from which nurses who already undertake ECG examinations in the community, but do not use ECG telemetry, can make judgements about the potential benefits to be gained in their own working environment.

Conventional ECG machines, which are most often used by nurses or trained health-care assistants, are attached to the supine patient by 12 leads. A recording is then taken. The machine produces a paper tracing for the clinician or the machine's inbuilt electronic reader to interpret. Many nurses and doctors find interpreting ECGs difficult, especially as there are minor but potentially clinically significant changes that can occur.

Nurses are not trained to interpret ECGs unless they work on a specialized cardiac unit, and a doctor may not be immediately available to interpret the tracings of patients with acute symptoms, resulting in delays in commencing urgent treatment. The conventional machine's inbuilt electronic readers are often used to provide a diagnosis, but these may be misdirected by electrical interference or previous changes, which may no longer be relevant to the acute presentation (Goudie et al, 2007; Mant et al, 2007).

An ECG telemetry service has the potential to overcome these issues, but should be at least as reliable and as easy to use in clinical practice as conventional ECG machines and represent an improvement in patient care.

With an ECG telemetry service, the reading is taken in exactly the same manner as the conventional service. However, interpretation of the findings is done by trained staff through a call centre, which provides the practice staff dealing with the patient with reliable information upon which to base the care plan. This may lead to more rapid and appropriate care (Sillesen et al, 2008). The ECG machine provided is hand-held and easy to use. The ECG is stored in the memory of the device and is transmitted as an acoustic signal via a telephone to the Call Centre where it is captured and displayed on screen for interpretation.

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Table 1. ECG usage in primary care (N= 373)

Practice	A	B	C	D	E	F	G	H	WIC X	WIC Y
Time period (months)	4	3	6	4	6	2	7	4	6	2
Number of ECGs	69	24	21	8	49	21	7	107	55	12
Mean ECGs/month	17.3	8	3.5	2	8.2	10.5	1	26.8	9.2	6
Number of staff using units	7	3	1	1	3	3	4	9	Not given	8
Max % ECGs by one clinician (Range*)	58 (1–40)	58.3 (2–14)	100	100	87.8 (1–43)	71.4 (3–15)	42.9 (1–3)	86.9 (1–93)	–	25 (1–3)

*Range shows the maximum and minimum number of ECGs performed by individuals

In the case of practices that previously referred all patients needing an ECG to secondary care, the advantages with regards to cost savings and the convenience to patients have been demonstrated (Paynter, 2007), but these results cannot be extrapolated to other practices that undertake ECGs internally. The primary aim of the study reported in this article was, therefore, to determine the frequency of using a telemetric cardiology service in general practices where nurses were already undertaking ECGs. The secondary aim was to identify whether there were changes in patient management pathways as a result of receiving telemetry ECG reports.

Methods

Cumbria and Lancashire Strategic Health Authority (CLSHA, now part of NHS North West), supported by the Diagnostic Futures Programme at the DH, has been evaluating the use of telemedicine in the primary care setting. One aspect of this work was an audit of a telemetric ECG service provided by an independent sector company.

Several GP practices and two established NHS walk-in centres within the CLSHA area were approached and offered the opportunity to trial the use of telemedicine ECG machines and services instead of their existing machines for a period of six months. Eight GP practices (A–H) and two walk-in centres (X and Y) took up this offer and agreed to complete an audit questionnaire. In addition, focus groups were conducted at the end of the audit and the results of which have been reported elsewhere (NHS Northwest, 2007).

Telemedicine ECGs offer an alternative to conventional ECG equipment for undertaking patient diagnostics, but if introduced would replace conventional equipment. It was, therefore, essential to ensure that patient safety would never be compromized either by inaccurate diagnostics, system failure or breach of confidentiality due to problems of data transfer. Emphasis was, therefore, placed upon the need for each individual member of staff to maintain their usual practice, with participating centres being asked to investigate patients who required ECGs using the new technology rather than their usual ECG machine, but to make their own diagnosis and management decision in the usual way. The difference was that for each patient, the recorded ECG was also stored in the memory of the device and then transmitted as an acoustic signal via a landline telephone in the practice to the Broomwell Call Centre, where it was captured and displayed on screen for interpretation by cardiac clinicians. On receipt of an ECG trace, centre staff, who are available 24 hours every day, discussed the case history with the referring nurse by phone and then

Table 2. Reasons for performing ECGs

Practice	A	B	C	D	E	F	G	H	WIC X	WIC Y
Mean patient age in years (Range) (Standard deviation)	67.0 (13–94) (17.7)	55.5 (15–100) (21.0)	63.5 (40–84) (12.0)	62.6 (25–92) (21.1)	54.4 (24–92) (17.4)	61.1 (24–88) (21.0)	38.3 (17–83) (30.2)	63.6 (8–102) (15.5)	47.8 (17–100) (17.9)	73.3 (50–90) (20.8)
Reason for ECG*										
Symptomatic	43	16	14	7	1	12	6	8	49	12
Screening	25	8	7	1	47	8	0	98	6	0

* some data missing

Table 3. Patient management changes after ECG report received from Call Centre

Practice	A	B	C	D	E	F	G	H	WIC X	WIC Y
Management	4	7	12	0	9	2	3	16	23	0
Mean management changes/month	1	2.3	2	0	1.5	1	0.4	4	3.8	6
Reason for change in patient management										
Refer to hospital	3	3	5	1	2	0	0	10	0	0
Acute hospital admission	0	2	3	0	1	1	1	0	10	0
Refer to GP	1	2	0	0	3	1	1	5	2	0
Reassure and send home	0	0	2	1	2	0	1	0	0	0
Hospital visits avoided	0	0	2	0	1	0	0	0	11	0

gave a verbal report on the tracing. This was followed up by a written report which was sent to the practice with a copy of the ECG by email or fax as requested by the referring clinician in the practice.

The audit collected data relating to:

- The age range of patients attending for ECGs
- The clinicians who undertook the investigations
- The clinical reasons for requesting the test
- The ease of use of the new technology
- Whether or not problems were encountered in use of the telemetry ECG machine
- The outcome
- Whether or not the patient management plan was changed as a result of obtaining the ECG report.

Results

During the study period, data were received relating to a total of 373 ECGs all of which were recorded by nursing staff or trained health-care assistants. No ECGs were recorded during domiciliary visits.

There were very few occasions when the use of the telemetric ECG units proved to be problematic and any difficulties that were encountered, such as batteries needing to be changed, pads needing to be replaced, or difficulty positioning leads, would have still occurred if conventional ECG units had been used.

Since the time periods of ECG use varied between sites, the mean equipment usage per month is shown, which ranged between 1–27 ECGs being carried out (*Table 1*).

Patients' ages ranged from 8–102 years. There were two clinical indications for undertaking ECGs (*Table 2*): acute symptoms and screening procedures. The presence of acute symptoms such as chest pain, shortness of breath and dizziness accounted for 168 examinations while 200 were performed to screen for long-term conditions such as hypertension, or as a pre-requisite for clinic referral (e.g. memory clinic or cardiology rapid access chest pain clinic). As expected, due to the nature of the service provided by walk-in centres, the majority (61/67) of the ECGs undertaken were to investigate acute symptoms compared with 107/301 in the general practices.

There were 76 changes in care pathways (*Table 3*). After the ECG report had been received, 18 patients for whom admissions were not anticipated had acute admission and 24 were referred to hospital. These referrals were appropriate as hospital intervention was necessary because of the outcome of the ECGs, which identified conditions such as bradycardia, pericarditis and silent myocardial infarction. In another 14 instances, medical assessment within primary care with amendment of treatment resolved the problem and hospital visits were avoided.

Discussion

Decisions on how to manage patients can be improved when the telemetric ECG service is used. The ECG service enabled patients to be admitted or discharged with greater confidence by the clinical teams and saved the time of nurses who did not have to wait for a GP to give an opinion on the ECG.

A copy of the ECG should always be available to accompany patients admitted to hospital, to provide a baseline from which the hospital clinicians can establish a treatment plan. This is particularly important because early ECG changes seen before arrival at hospital may not be present on an ECG subsequently recorded in hospital (Drew et al, 2006). This may cause a delay in the correct diagnosis being made, leading to a delay in appropriate treatment being given. On six occasions, although the verbal report of the ECG had been received, the ECG and written report did not arrive by fax or email until after the patient had left the practice in an ambulance because of a combination of delays in the service and the verbal report meaning the hospital admission was so urgent, transfer could not wait for the arrival of the documents. However, to avoid this problem, the telemetry service can provide an ECG and report directly to the hospital by fax or email if requested.

Service specifications

Staff at the Call Centre who perform the ECG interpretation are all UK practising nurses or registrars with extensive cardiology experience in coronary care units. They are selected for their outstanding ECG interpretation skills and have to pass a written ECG examination before being accepted. All full-time staff at the centre are subject to further refresher courses and tests are arranged annually by a consultant cardiologist. Each ECG interpreted at the centre is checked again by staff on the next shift. ECGs are then subject to regular random checks by a consultant cardiologist or a specialist registrar in cardiology. Staff work in shifts to provide a 24-hour service every day of the year.

Conclusion

The findings suggest that if this telemetric ECG service was used costs could be saved within primary care by reducing the number of patients referred to hospital for investigation, and by early intervention in previously unsuspected disease. In this audit there were 14 occasions, mainly from one walk-in centre, where 11 of the 55 patients avoided hospital referral after the results of the telemetric ECGs were known. At the time of the audit, the cost of an ECG telemetric unit was £500 with an additional charge of £10 for each ECG sent to the centre. However, the usage varied between centres and so each centre will need to consider the appropriateness of the technology for their own practice, along with the current costs of the service. It must be emphasized that all practices in this study were already recording ECGs and so the potential cost savings are lower than for those practices reported elsewhere, which refer patients to hospital for ECG examinations. BJN

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The authors thank all staff in the practices and walk-in centres who cooperated with this study.

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Publications and presentations (cont.)

l) **Poster**: Johnston, G., Weatherburn, G. "Patient Pinball ~ One patient's experience of a remote system of ECG monitoring in arrhythmia." exhibited at Telemed and eHealth '09 "It's all about the patient" 2009, Royal Society of Medicine, London.

Publications and presentations (cont.)

m) Oral presentation. Johnston, G. " Users' experiences of a programme of automated daily weight monitoring in patients with chronic heart failure." TeleMed & eHealth 09. It's all about the patient. November 2009. Paper number RE 09.

Abstract.

Users' Experiences of a Programme of Automated Daily Weight Monitoring in Patients with Chronic Heart Failure.
Glenis Johnston & Gwyn Weatherburn

Introduction. Daily weight monitoring has been hailed as an important self-management strategy in patients with Chronic Heart Failure. The benefits claimed in a number of studies include the early detection of a worsening condition, which in turn leads to early intervention, thus improving the patient's wellbeing and reducing hospitalizations. This study relates to a system of automated daily weight monitoring in which the weight data is transmitted to a central call centre for assessment. If a patient's weight fluctuates outside pre-specified limits, a member of staff at the call centre acts to instigate an intervention. Depending on a previously agreed protocol, they might contact the patient directly to discuss an intervention such as increasing diuretic medication or they might simply alert the patient's heart failure nurse, who would take appropriate action. The purpose of the study was to identify strengths and weaknesses in the system, in order to evaluate its potential as a tool in caring for patients with chronic heart failure.
Method. Interviews with patients, their carers and with the specialist nurses who provide their regular health care were analysed to compare the claims made for tele-medicine weight monitoring systems with the experiences reported. Some verbatim communications from patients and carers also contributed to the data presented.
Results. The results demonstrated that patients value the personal contact of "their" heart failure nurse to the extent that they are prepared to ignore warnings from the telemedicine service, thus negating any benefit to providing the system. There are a number of factors pertaining to the installation and daily use of the equipment which affect both the patients and their partners or carers. There is some disagreement between specialist heart failure nurses on the underlying principles of the role of weight monitoring in chronic heart failure, on the way in which the telemedicine service should be used and which patients should be offered the service. This disagreement is reflected in the way in which national guidelines and advice from expert bodies are implemented. An operational fault has been identified in the telemedicine equipment.
Discussion. The implications of the results are discussed in terms of events which were perceived as either beneficial or detrimental by patients, carers and staff, as opposed to "potential" benefits claimed in other studies.
Conclusion. The study has shown that some of the claims made for a telemedicine weight-monitoring system may be based on incorrect assumptions. Furthermore, the users' experiences contradict some of those assumptions whilst other benefits have been largely unrecognized.

Publications and presentations (cont.)

n) Publication. Johnston, G., Weatherburn, G. "Remote weight monitoring in Chronic Heart Failure: The excluded majority." J Telemed Telecare 2010;16:190-192

Paper

Automated weight monitoring in chronic heart failure: the excluded majority

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Summary

We interviewed nurses and patients with heart failure who were participating in a research trial of home telemonitoring in which weight data were monitored automatically by a call centre. A total of 35 interviews were conducted and the transcripts were analysed thematically. The results indicated that nurses disagreed about the role of weight monitoring and the practicalities of telemonitoring in their daily practice, indicating that the process was idiosyncratic to each user. The lack of personal feedback and nursing contact discouraged patients from weight monitoring, suggesting that a feedback mechanism may have to be adapted to suit patients. There were other factors which created barriers to acceptance by patients and staff. Home telemonitoring for heart failure cannot be evaluated effectively using the standard approach commonly employed. New studies are required.

Introduction

'The high occurrence of readmission to hospital in patients with chronic heart failure is often due to causes which are potentially preventable, such as failing to seek medical attention when symptoms worsen or non-adherence to medication or diet plans'.[1,2] Disease management programmes incorporating weight monitoring have been suggested as effective strategies,[3–5] the efficacy being measured largely in terms of a reduction in mortality and in the number and duration of hospitalization events.[6–9] Studies relating to remote monitoring have, however, addressed a surprisingly low proportion of patients. Problems of poor participation, non-compliance and restrictive entry criteria in programmes have been reported previously[10] and in one recent study[11] the authors found that only 40% of heart failure patients originally assessed for eligibility went on to become participants in the study.

We have investigated how a remote and automated weight-monitoring system might affect the care of the patients in a wider sense than solely the cost-effectiveness achieved for the minority 40%.

Methods

Patients and staff participating in a research trial of automated weight monitoring in heart failure were interviewed. The study was approved by the appropriate ethics committee.

Patients who required regular weight monitoring, together with their partners, were invited to participate by their heart failure nurse. Patients were excluded if they:

(1) Were in heart failure NYHA class 1;
(2) Unable to stand to be weighed, including those in NYHA class 5;
(3) Had dementia and were unable to give informed consent;
(4) Had other weight changing conditions which might confound the results;
(5) Were aged less than 18 years;
(6) Were unable to speak English, which was the only language supported at the Call Centre.

In the research trial, patients were randomized 1:1 either to receive telemedicine weighing scales in addition to usual care or to receive usual care alone. The weighing scales transmitted the weight data to a central call centre where it was monitored daily against limits pre-defined by the patient's nurse.

A total of 35 interviews and one focus group were conducted. Those interviewed were:

(1) 14 patients (8 in the telemedicine group, 6 in the usual care group);
(2) 10 partners/carers (7 in the telemedicine group and 3 in the usual care group);
(3) 4 individual heart failure nurses and one focus group of nurses.

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In addition, four patients, two carers and one heart failure nurse who had been interviewed at the start were also interviewed at the end of the study. The interviews were recorded and subsequently transcribed verbatim. A thematic analysis was then conducted using NVivo software.

Results

The participants chose to address very similar topics but demonstrated fundamental differences in opinion and reasoning, often at extreme ends of the spectrum.

Recruitment

Some nurses were found to 'cherry pick' participants, one commenting 'I know (this patient) would not comply.' However that judgement was based on the nurse's experience of existing practice, which might not be relevant to telemonitoring, e.g. the telemonitoring company would telephone the patient if the weight was not received, so if non-compliance was due to forgetfulness that would be overcome. Thus, the nurse's difficulty in comprehending a different working practice obstructed the opportunity to investigate the potential benefits for this patient.

Similarly, some general practitioners declined the invitation to recruit patients because they 'didn't have any patients at a stage where they would benefit from weight monitoring' (a view later contradicted by some of the nurses) or because they had 'a good heart failure nurse and there are obvious benefits for patients in having local contact specialist support'. This misses the point of their own nurse using telemonitoring as a tool to assist her own practice. It seems that a cycle exists in which a new practice cannot be adopted until it is comprehended, and it cannot be fully comprehended until it is adopted in practice.

Out of 58 patients originally agreeing to participate, 34 (59%) did not return signed consent forms, subsequently saying they had 'forgotten', or 'put it down somewhere.'

Weight monitoring

Nurses agreed unanimously that weight monitoring was 'fundamental' in the early detection of fluid retention, but disagreed in assigning that importance to every patient. One nurse thought that 'not all are at high risk of fluid retention…' while another thought it was essential for every patient because 'they can develop fluid retention overnight.'

There was similar disagreement about the frequency of weight monitoring and at what stage of disease it should begin. Some thought that daily weight monitoring was counter-productive, 'reinforcing 'illness' and making patients obsessive.' Others considered the daily routine essential because of the potential for rapid deterioration, and thought that 'NYHA1 patients need to weigh themselves daily as well,' partly in order to 'get patients in the habit' before memory deteriorated.

Telemonitoring in practice

The telemedicine service was utilized very differently by each nurse, one retaining complete control, receiving and reviewing the data for each patient and others only alerted when the weight change exceeded pre-defined limits. One was content for the staff at the call centre to contact patients in the first instance, to check weighing procedures and discuss diuretic medication.

Two nurses were strongly in favour of using electronic weighing scales during periods of titration, but felt that once patients were stable they should be encouraged to monitor their own weight, until in the later stages of heart failure when poor eyesight or forgetfulness made telemonitoring a necessity again. These views were based on the negative assumption that funding would not be available for this service for every patient, even though they had no idea what the cost would be, or if using them to fulfil a training role in early stage disease would be offset by more effective monitoring in later stages.

Patients

In general, patients did not attach any importance to weight monitoring as a strategy for keeping themselves well, partly because they invariably linked weight gain with diet, but mainly because their 'weight didn't change much.' Monitoring 'wellness' was not valued because they received no individual feedback or confirmation, and in many cases perceived the nurse's acceptance of their poor monitoring performance as confirmation that it was not necessary.

Patients were disappointed that the telemonitoring had not led to an increase in nurse contact, to the extent that one withdrew from the study after a short time because 'nobody seemed to bother.' However, when the nurse commented that she had found it useful in keeping her informed of the weight the patient reversed her opinion and asked to keep the scales, because 'the nurse wanted to keep an eye on me.' Another patient refused to act on advice from the call centre because he preferred to wait until his heart failure nurse returned from holiday. The call centre continued to monitor the situation and the patient came to no harm. However, these examples suggest that the actual monitoring process is less important to patients than knowing that 'their' nurse is paying heed.

Practical matters

Remote monitoring had both advantages and disadvantages for the patients. On the positive side, one patient reported that he probably 'wouldn't have bothered getting out of bed some days' if it had not been for the fact that he was aware his failure to weigh himself would be noticed by the staff at the call centre; some carers felt reassured when they heard their husband's weight being sent to the call centre. One patient did not have access to a heart failure nurse and also did not understand the concept of daily weight monitoring.

However, in addition to the telemedicine company monitoring his weight, the data were sent to his son in Australia. The son used that information as a basis for discussion and reinforcement about health matters with his father, and telephoned other members of the family living near their father to take action if he felt it was necessary.

On the negative side, installation of the equipment was the most common problem. Three patients received assistance with installation, two from the telemedicine company and one from the nurse. This presented no problem to one nurse but another expressed some concern, due to lack of time and lack of confidence in her ability to undertake the installation.

The weighing procedure presented a problem for two patients, who had to stand on the scales for several minutes before the reading stabilized and the data were transferred. This problem was found to be due to the soft carpeting underneath the scales and was solved by standing the scales on a small piece of plywood.

One patient commented on the cost of the daily telephone call which was necessary to transmit the weight data. Although the daily rate was small, the monitoring cost was presented on his quarterly bill as a single total of just over ninety calls. Two carers commented that they had lost their own weight monitoring facility (for dietary purposes) as there was insufficient room for two sets of scales in their home and the electronic scales were specific to the patient concerned.

Discussion

Health-care professionals and patients hold numerous conflicting beliefs and opinions which, together with clinical problems, create barriers to the evaluation and adoption of telemonitoring in general. This also raises practical and ethical questions about the evaluation of appropriate care in chronic heart failure. Forgetfulness is common in patients with heart failure and may make them powerless to access resources which, paradoxically, may help to solve the problems caused by failing cognitive ability. In recruiting participants to a study, the boundary between ‘encouragement’ and ‘harassment’ is unclear, as is the boundary between ‘education’ and ‘behaviour modification’ in promoting daily monitoring. Patients cannot be coerced, and the moral and ethical dilemma between a patient’s right to autonomy and the obligation to provide care is a difficult one to resolve if the patients’ needs, both clinical and emotional, are to be met. In these times of rising patient numbers and dwindling resources, personal nursing contact may have to be rationed. Best practice may turn out to be a balance between continuous clinical monitoring, the overall wellbeing of the patient and effective use of health-care resources.

Heart failure care is idiosyncratic in nature, from the standpoints of both the professional caregiver and the patient. Such an idiosyncratic process cannot be evaluated effectively using the standard approach commonly employed. New studies should address the need to:

(1) Identify elements of best practice in terms of weight monitoring;
(2) Identify elements of best practice related to telemonitoring;
(3) Enable each health-care professional to deliver the best practice within his or her capability, acknowledging that those professionals do not have an absolutely identical toolbox of skills and therefore that ‘capability’ will be different for each;
(4) Expand the circle of telemonitoring care to include those patients who have traditionally been excluded by virtue of age or debility.

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Publications and presentations (cont.)

o) **Oral presentation**: Johnston, G. “A comparison of colour of images obtained using photographic equipment including mobile camera phones and video conferencing technologies.” eHealth & Telemed Evidence in action. Monday 13 – Tuesday 14th December 2010.

Abstract

A comparison of colour of images obtained using photographic equipment including mobile camera phones and video conferencing technologies

Introduction

Medical photography within the hospital situation has traditionally been subject to strict regulations governing the production of images, much of this regulation having the force of law behind it. The equipment purchased must conform to a high specification of performance and is subject to a rigorous programme of quality assurance. The operators are trained to produce high quality images with minimal distortion and degradation. This is not the case in some areas of health practice today where mobile phones are purchased virtually and literally "off-the-shelf" and used to record and transfer images of patients, in the assumption that because the equipment is sourced from a reputable manufacturer and boasts several megapixels, it is adequate for the task. This assumption cannot be deemed to be a safe one and thus casts doubt on the safety of the practice, particularly in a clinical situation where the photograph is taken by someone with neither photographic nor dermatology training and is viewed by a nurse who has neither the training nor the experience of a dermatology consultant.

Methodology

Studies have been undertaken to test the imaging quality capability of a range of equipment commonly used in the fields of dermatology and tissue viability. Colour, distortion and definition are addressed in a manner intended to simulate "best practice" conditions that might be available in a clinical situation within the community setting. That is, without the use of specialist hardware or software and without recourse to a professional photographer and associated laboratory, but under ideal conditions of amateur photography, utilising the best techniques so that operator errors are kept to a minimum. A matrix of 25 x 2cm squares of hues of five colours relevant to clinical practice were compiled and imaged on mobile camera phones and a digital camera. The images were transferred to laptop computers. In addition the matrix was transmitted via POTS and ISDN-2 videophones and ISDN-6 video conferencing technology. All images of the matrix were viewed independently by 12 viewers in the same locations with minimal ambient glare etc from windows, thus providing the best viewing conditions. Viewers were allowed to view each image by their chosen method and not under standard conditions such as viewing at the same distance from the image.

Results

The results showed that contrary to expectation, the higher priced and higher specification equipment did not always produce the best images. The greatest accuracy was for blue hues and the least accuracy for brown. Details of results will be presented and discussed.
The items of equipment behaved differently for different colours. For example, phone A was be better than phone B for replicating one colour , but phone B was better than phone A for replicating another colour and this could have clinically significance.

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Conclusion

There is variation in the colour of images of the same object when photographed using photographic equipment including camera phones. Caution must be used when relying on the colour of an image in a telemedicine service where diagnoses and patient management decisions are made dependent on colour.