

**“Early Breast Cancer Sharing the Decision:
A Critical Appraisal”**

by

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**A critical appraisal submitted in partial fulfilment of the
requirements of the University of Northumbria at Newcastle
for the degree of
Doctor of Philosophy by published work**

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THESIS DECLARATION

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THE DECISION - A CRITICAL
APPRAISAL

AUTHOR

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STATEMENT OF ADVANCED STUDIES UNDERTAKEN IN CONNECTION WITH THE PROGRAMME OF RESEARCH

A critical appraisal, in addition to outputs 1-8, based on research conducted, submitted in partial requirement of the University of Northumbria at Newcastle for the degree of Doctor of Philosophy by published work

The Publications

1. Maslin, A., Baum, M., Secker Walker, J., A'Hern, R., & Prouse, A., 1998, 'Shared Decision Making Using an Interactive Laser Disc System for Women with Early Breast Cancer.' NT Research, Emap Healthcare, London. Vol.3, No.6, pp 444-453
2. Maslin, A., Baum, M., Secker Walker, J., A'Hern, R., & Prouse, A., 1998, 'Using an interactive video disk in breast cancer patient support'. Nursing Times, Emap Healthcare, London, November 4, Vol.94, No 44, pp 52-55.
3. Maslin, A., Powles, T. 1999, Ed. 'Breast Cancer. Sharing the Decisions', Oxford University Press, Oxford
4. Maslin, A., 1999, 'Sharing the Dilemma' in Maslin, A., Powles, T. 1999, Eds. 'Breast Cancer. Sharing the Decisions', Oxford University Press, Oxford, pp1-14
5. Maslin, A., 1999, 'Ethics and Patient Access to Information' in Maslin, A., Powles, T. 1999, Eds. 'Breast Cancer. Sharing the Decisions', Oxford University Press, Oxford, pp14-38
6. Maslin, A., 1999, 'Clinical Effectiveness and Evidence Based Practice' in Maslin, A., Powles, T. 1999, Eds. 'Breast Cancer. Sharing the Decisions', Oxford University Press, Oxford, pp39-44
7. Maslin, A., 1999, 'Communication, Psychiatric Morbidity, Access to Information and Decision Making' in Maslin, A., Powles, T. 1999, Eds. 'Breast Cancer. Sharing the Decisions', Oxford University Press, Oxford, pp45-68
8. Maslin, A., 1999, 'Approaches to Shared Decision Making' in Maslin, A., Powles, T. 1999, Eds. 'Breast Cancer. Sharing the Decisions', Oxford University Press, Oxford, pp69-98

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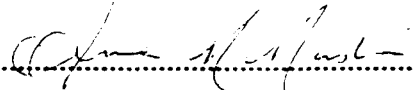
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Early Breast Cancer - Sharing the Decision: A Critical Appraisal

ABSTRACT:

Great debate surrounds the issue of patients with breast cancer participating in surgical/medical decision making and their ability to give an informed consent. Health care professionals must balance the need to safeguard the rights of patients, respect their autonomy and yet be sensitive to the changes and individual variations a patient may demonstrate as they progress from diagnosis to the end point of their disease.

The premise underpinning the study and literature review, reflected in the published works presented here, focuses on a woman's right to access, should she choose, accurate information to make an informed treatment choice based on an exploration of the literature which reviews the ethical issues including autonomy, informed consent, advocacy, communication, access to information, approaches to shared decision making, psychiatric morbidity and evidence based medicine.

Objectives of the Study Reflected in the Published Work Presented Here:

1. To determine the acceptability of an interactive video system, in addition to the standard informational care and support provided by the clinicians and clinical nurse specialist, as a means of providing information about the risks and benefits of treatment choices-surgery and subsequent adjuvant chemotherapy - to women with early breast cancer who are facing choices about treating their early breast cancer.
2. To determine whether providing information to women with early breast cancer using an interactive system significantly reduces anxiety and depression associated with the diagnosis and treatment of this condition.
3. To determine whether providing information using an interactive video system, to women about treatment choices significantly increases patient satisfaction with the choice they have made.

To assess this for a two year period patients attending for surgical treatment for early breast cancer were recruited, after full discussion and written consent, into a randomised control trial to evaluate the acceptability and effectiveness of the interactive video system.

Eligible patients (100) included all women with an early primary invasive breast cancer who had a genuine choice between treatment options. Patients excluded from recruitment and viewing the Interactive Video (IVD)/Shared Decision - Making Programme (SDP) were all women who did not have a straightforward choice.

All patients in the intervention group completed the following:

- a. Acceptability of the Interactive Video;
- b. Assessment of Health Status, The SF36 (Ware and Sherbourne 1992)
- c. The Hospital Anxiety and Depression (HAD) scale (Zigmond & Snaith 1983)

After nine months the patients were again asked to complete the three questionnaires but at this point Questionnaire 1. elicits the patient's satisfaction with their treatment choice.

Publications on which application is made.

The publications on which this application is made are listed below. They provide a comprehensive and systematic group. All the publications were subjected to external scientific review. The Oxford University Press book, *Breast Cancer Sharing the Decision*, was subjected to extensive multidisciplinary academic review prior to agreement to publish and has made a significant contribution to knowledge as demonstrated by the fact that on publication the book went to the top of the Science and Medicine list which is unusual for a publication in which a nurse is lead author.

The publications represent a strategy to reach a wide range of interested parties. The first two publications listed provide an overview of the research from hypothesis to implications of the results. These publications are primarily aimed at nurses with an oncology interest and specialist nurses in the field. The Oxford University Press book, *Breast Cancer Sharing the Decisions*, is aimed at oncologists, specialist nurses and other members of the multidisciplinary team. I designed the overall structure of the book and wrote a substantial portion of the text. I invited senior colleagues to provide additional material on their area of expertise to provide balance and breadth. The index of the book makes clear the authorship of each chapter

'Breast Cancer Sharing the Decision' aims to provide a logical account and critical appraisal of the issues relevant to the subject i.e. Everything from the ethics underpinning the prima facie case that a woman should have access to information to the practicalities of how this can be done. My research study is fully detailed and this

is followed by a discussion on the implications both in relation to my research specifically but also more widely in relation to other key areas i.e. from breast screening to medical management and radiotherapy.

I was the lead investigator and primary author of all the publications listed. The investigators listed provided feed back on the completed work but did not write up any of the papers. I acknowledged my colleagues because of their contribution to the study. I devised the research proposal, obtained the funding, and presented the proposal to the scientific review committee and the ethics committee, which received alpha rating. I set the study up and carried it out.

Professor Baum, a breast specialist with extensive research experience, was the Consultant in charge. Mrs Secker Walker assisted with the recruitment of patients. Mr A'Hern provided the statistical support and Mr Prouse assisted with software advice. Professor Powles was the head of the Breast Group at the time. He provided encouragement and wrote one chapter of Breast Cancer Sharing the Decision, on chemoprevention.

The Publications

Output 1

Maslin, A., Baum, M., Secker Walker, J., A'Hern, R., & Prouse, A., 1998, 'Shared Decision Making Using an Interactive Laser Disc System for Women with Early Breast Cancer.' NT Research, Emap Healthcare, London. Vol.3, No.6, pp 444-453

Output 2

Maslin, A., Baum, M., Secker Walker, J., A'Hern, R., & Prouse, A., 1998, 'Using an interactive video disk in breast cancer patient support', Nursing Times, Emap Healthcare, London. November 4, Vol.94, No 44. pp 52-55.

Output 3

Maslin, A., Powles, T. 1999, Ed. 'Breast Cancer, Sharing the Decisions', Oxford University Press, Oxford

Output 4

Maslin, A., 1999, 'Sharing the Dilemma' in **Maslin, A., Powles, T. 1999,** Eds.'Breast Cancer, Sharing the Decisions', Oxford University Press, Oxford, pp1-14

Output 5

Maslin, A., 1999, 'Ethics and Patient Access to Information' in **Maslin, A., Powles, T. 1999,** Eds.'Breast Cancer, Sharing the Decisions', Oxford University Press, Oxford, pp14-38

Output 6

Maslin, A., 1999, 'Clinical Effectiveness and Evidence Based Practice' in **Maslin, A., Powles, T. 1999,** Eds.'Breast Cancer, Sharing the Decisions', Oxford University Press, Oxford, pp39-44

Output 7

Maslin, A., 1999, 'Communication, Psychiatric Morbidity, Access to Information and Decision Making' in **Maslin, A., Powles, T. 1999,** Eds.'Breast Cancer, Sharing the Decisions', Oxford University Press, Oxford, pp45-68

Output 8

Maslin, A., 1999, 'Approaches to Shared Decision Making' in **Maslin, A., Powles, T. 1999,** Eds.'Breast Cancer, Sharing the Decisions', Oxford University Press, Oxford, pp69-98

The Value of the Study which forms the Basis of the Publications

The study which forms the basis of the publications submitted for consideration (Outputs 1-8,) was passed as, “scientifically rated alpha”, felt to have, “high clinical relevance.” and “was considered of a high priority”, by the Scientific Review and Ethics Committees of the Institute of Cancer Research & the specialist Cancer Centre at which the study was conducted. The study discussed fully in Outputs 1,2, & 8, was subject to annual critical peer review by Scientists, Clinicians, Nurses and members of the multidisciplinary team of the Cancer Centre, the Institute of Cancer Research, as well as by colleagues within the Kings Fund Development Centre. Progress throughout the study fulfilled all requirements of these bodies.

The intervention was the first providing explicit personalised information including risks of recurrence and mortality figures which had never been made available in that format to women with breast cancer before. The study was the first randomised evaluation of this novel intervention in women with early breast cancer. This was the first cancer group ever to use the system. This is the only randomised study of this intervention to have succeeded. Other investigators have tried and failed. Recruiting was extremely difficult. The actual study was time-consuming and involved a high degree of investigator/patient interaction. The nature of the areas covered was extremely delicate particularly in relation to the risks of recurrence and mortality figures. It was positive that the cohort was achieved with only a 6% loss to follow up.

The study and resultant publications, particularly Outputs: 1,2,3, & 8, form a distinct contribution to the knowledge of the subject and afford evidence of originality shown by the discovery of new facts and by the exercise of independent critical power. They consist of an overview of the literature a logical assessment of the key areas open for discussion, an account of my investigations and indications of where it appears to me to advance the study of the subject (Outputs 1,2,3,5,6,7,8).

As stated this study is the first and only (to date) randomised study evaluating this new intervention the Interactive Video Disc/Shared Decision-Making Programme in patients with breast cancer (Outputs 1,2,3,&8). This is more complex than a simple computer assisted learning programme. It is a system, which provides an individual woman with unique personalised information in areas where clinical uncertainty relating to surgical, and adjuvant treatment options exist. The aim was to facilitate decision making by enabling a lay person (should they so wish) to weigh up the risk/benefit of treatment options. The system also makes available to the patient and their family, personal risks of recurrence and mortality, this evidence based information has never been made available before in this format to individuals affected by early breast cancer (Outputs 1,2,&8).

The study and resultant publications provide valuable and in some cases previously unknown information re: the provision of this specific technology to assist decision making as compared to best standard practice (Output 8). The hypothesis and sampling frame used in the study were constructed with the assistance of the Institute of Cancer Research and ratified the Breast Group's senior statistician. The hypothesis, research proposal including sampling frame and outcome measures was explicit and

evaluated at the outset of the study by the Scientific Review Committee of the Institute of Cancer Research, the Cancer Centre and the Kings Fund (Outputs 1,2,&8).

The literature review for this study (published in full in 'Breast Cancer Sharing the Decisions by Oxford University Press', Output 3,4,5,6,7,8) focused on five key areas; i., The ethical issues which have an effect on a patients ability to access treatment related information including the impact of deontology, utilitarianism, respect for autonomy, the role of informed consent, and advocacy (Output 5). ii., The impact of the move towards evidence based medicine on women now facing treatment choices (Output 6). iii., The role of communication in the effort to access information and the impact of psychiatric morbidity on a woman with breast cancer's ability to benefit from this information (Output 7). iv., The practicalities of accessing good quality information and the relationship between accessing information and decision making (Output 7&8). v., Finally a survey of the approaches to shared decision making and a brief evaluation of their role including the role of computerised interactive videos (Output 8). Output 4 is included to demonstrate the patient and family perspective on the issues, the challenges and realities of being a patient in this distressing situation. It is phenomenological in approach (Burns & Grove 1987)

Although the literature review does discuss briefly the technical side of the interactive video disc system, as discussed above, it is not intended to be a thesis on the computer hardware or software (Outputs 1,2 & 8). The investigator takes at face value the fact that this technology has been developed and was now only assessing it in as far as it is a tool for shared decision making in the same way that a leaflet, tape recorder or linear video is. The publications detail in full the study undertaken including its aims, study

hypothesis, design, method of randomisation, duration of the study, and the role of the scientific review/ethics committees. This is then followed by the study's results, discussion and conclusion (Outputs 1,2 & 8).

THE STUDY HYPOTHESIS

The study hypothesis and null hypothesis were developed after a thorough consideration of the issues and literature discussed in Outputs 3,4,5,6,7,8,. The 'null hypothesis' tested was that the use of an interactive video system to inform patients about their treatment choices would not result in a significant difference in measured outcomes, when comparing those who saw the interactive video with those that didn't. The study hypothesis' tested was that the use of an interactive video system to inform patients about their treatment choices would result in a significant difference in measured outcomes, when comparing those who see the interactive video with those that don't. The study helped to answer the question of whether this interactive video system is a worthwhile adjunct to the usual process through which women receive information about treatment when diagnosed as having early breast cancer (Outputs 1,2,3,&8).

At the moment women facing a diagnosis of breast cancer may be advised of and offered treatment options, or not, as the case may, be in a variety of ways (Outputs 4,5,6,7,8). At one end of the spectrum lies the clinician that makes all decisions on the patient's behalf because he believes he knows what is best for the patient. At the other end of the spectrum is the clinician who aims to work in partnership with the patient and her family, offer choice where possible, and back up that approach with support services e.g. the availability of a Clinical Nurse Specialist (CNS), literature and on

occasions relevant video and audio recordings to encourage evaluation of alternatives (Outputs 3,4,5,6,7,8).

The centre in which this study was conducted adopts the latter approach therefore in this situation the 'usual process' includes discussion with the clinician and the availability to the patient of the CNS, in addition to any member of the multidisciplinary team, literature, and the use of any material available in the patient information office. The novel component being added to this fairly comprehensive support service is the use of the computerised personalised interactive laser disc system (the IVD) as an aid to decision making.

EXPERIMENTAL STUDY DESIGN

Outputs 1,2,3 & 8 detail how an experimental design was chosen to attempt to eliminate bias in apportioning the novel component i.e. the Interactive Video Disc System (IVD). Using randomisation allows the two options to be studied concurrently, aiming to avoid systematic errors and increase the validity of the statistical tests of 'significance' that are used to compare the two options. (Peto, Pike, Armitage et al. 1976). Uncertainty about which method of shared decision making was going to be of most benefit to patients was the reason for using randomisation as a methodology (Colins, Doll, & Peto 1990).

Although the study is a randomised study elements of the study particularly in relation to the patients thoughts and feelings (Output 4) required some consideration of qualitative as well as quantitative data (Burns and Grove 1987) and for that reason the study incorporates two questionnaires aiming to elicit patient preferences or views.

Till, Sutherland and Meslin (1992) noted that there are times when randomisation is not enough and patient preferences should be taken into account (Output 1,2,4, & 8). This is particularly true when different treatment options provide similar survival benefits but also induce very different quality of life experiences for example in the case of a woman with a small early breast cancer facing the choice between mastectomy or a wide local excision. Some patient preference research has taken place in the field of breast cancer care (Levine et al 1992, Fallowfield et al 1994a, Maslin 1994, Luker et al 1995,1996,). Problems do exist with the effects of framing questions and level of probability on patients preferences for cancer care (O'Connor, 1989). A difference in preference can be induced depending on whether outcomes are described in terms of risk of death (mortality) or chance of cure (survival) (Lenert 1996).

Outputs 1,2 & 8 summarise how for a two year period patients attending for surgical treatment for early breast cancer in a large Breast Unit were recruited, after full discussion and written consent, into a randomised control trial to evaluate the acceptability and effectiveness of the interactive video system. Eligible patients included all women who had an early primary invasive breast cancer. Patients excluded from recruitment and viewing the Shared Decision - making Programme (SDP) were all women who did not have a straight forward choice between the given treatment options and those who did not have the ability whether for psychological or language limitations to participate (Output 8).

One hundred patients were recruited. Of this cohort 6 patients were lost to follow up (this will be discussed in detail later). At nine months post recruitment 94

questionnaires were returned. This represents 94 % which is an excellent result for follow up by postal questionnaire (Burns & Grove 1987).

The target of recruiting one hundred women which represented (56.4%) of the 177 women who were eligible was attained which, was a significant achievement (Output 1, 2, & 8). It could be suggested that the patients in this study were a biased sample because many of these patients had proactively elected to come to this centre over other more local services. Many of these women actively therefore sought information and were willing to travel to obtain it. The reasons for this may be due to the fact that this study was conducted in a specialist centre (Maslin 1993). It may therefore be the case that these patients either were patients who wished to actively participate in decision making or the patients wished to support the specialist centre in improving information and support for breast cancer patients. The age range of the patients included in the study was broad 28 to 73 years but with a median of 50 years and a mean of 52.1 years the group of women involved were representative of the major group of breast cancer patients (CRC Breast Cancer Factsheet 1996). Due to the computer randomisation it was also possible to have an even balance of menopausal and premenopausal women in each group (Output 1,2, &8).

VIEWS ON IVD

With some of the other Shared Decision Making Programmes (SDP's) functional status and symptom severity following involvement in decision-making were the primary outcome measures, Shepherd, Coulter, Farmer 1995, and patient satisfaction with treatment choice was a secondary measure. With this study patient satisfaction with the treatment choice is of primary importance. As previously

discussed breast cancer is a chronic and unpredictable disease. The impact of treatment decisions could affect both functional status and the symptoms experienced but patients with breast cancer are often facing choices which have a huge impact on their quantity and quality of life. It is therefore not appropriate to judge the value of the IVD system based primarily on symptom severity and functional status (Output 8). Patients viewing the IVD may choose an option which increases the symptoms they experience but may never the less may be a choice with which they are very satisfied based on their own priorities.

The length of the IVD programmes had been debated extensively by the professionals who viewed the IVD's prior to the study commencing. To the professional who has a fairly extensive knowledge of breast cancer and the various treatment options the IVD can seem protracted and slow taking from as much as half an hour to view at minimum, an hour on average and at times up to two hours. Patients do not appear to perceive the IVD in the same way as professionals as indicated by 82 % stating they found it just about right in length. The reason for this difference in perception between the professional and the patient may be that whilst this information is well known to the professional it is for many patients new information. For the patients the fact is that in their case the topics being dealt with can explore the possibility of preserving or losing a breast or in the case of the adjuvant therapy the possibility of maximising quantity and/or quality of life. The impact of these possibilities cannot fully be conceived of by the personally uninvolved professional (Kfir & Slevin 1991) (Output 8).

Participants largely appeared to be absorbed by the IVD as evidenced by 96% stating they found the material interesting or very interesting. As stated the patients did not appear to find the IVD lengthy but they themselves were conscious not of their time but the Clinical Nurse Specialists (CNS) time. Patient's often commented that they were very content to sit and view the IVD for as long as it took but they did not want to take up too much of the CNS's time. The Clinical Nurses Specialists in this study reassured the patients that they were free to view as much or as little as they wished. They were also free to return to review the material if they wished at any time (Output 8).

It has been suggested that the IVD could save the Clinicians time (Rice 1992, Wennberg 1992, Mulley 1994,). Could the IVD be used to reduce the amount of time patients spend with health care professionals? The answer could be yes if it was used to replace rather than assist the multidisciplinary team in the provision of information. It is a fact that health care professionals do only have a limited amount of time to allocate to patients and it may be that facilitating more efficient use of this time should be a priority. Although a reduction in time spent specifically with the clinician, may be possible, in this study the use of the IVD did increase the time spent by the CNS with the patient. The reason for this was, the fact that, the patients required a full explanation of the study and the IVD, as well as all the usual care and support from the CNS, Clinician, and the Multidisciplinary Team. The overall time therefore spent with the multidisciplinary team particularly the clinical nurse specialist was increased by the time taken explaining the system, the actual time the IVD was being viewed and also by any questions/discussion which followed as a direct result. The majority of patients as discussed spent at least an hour viewing the IVD material in addition to the pre and

post viewing conversations. The majority of patients viewed the first section dealing with the basic information a patient would need to make a decision and the majority then chose to view part of the learn more section although the number of additional choices selected in the learn more section varied. As a result of having viewed the IVD information the patient was in a stronger position to ask more detailed questions than the average patient and therefore additional time was given to address these questions by the Clinical Nurse Specialist (CNS) (Outputs 1,2 &8).

Participants in this study as previously outlined had the full support of a CNS and were not left to view the IVD unattended in case of an adverse reaction to the material viewed. The principle investigator had been concerned that this might occur particularly as the patients viewing the adjuvant therapy IVD had the facility to view their own personal risks of recurrence and mortality statistics. It was felt by the principle investigator to be unethical to provide this level of information to patients without professional support immediately available. This concern however was unfounded. The patients viewing the risks of recurrence and mortality figures did not seem disturbed by this facility. Not all patients elected to look at their own possible risks of recurrence etc. and this decision was respected. It may be however that the presence of the CNS was a calming factor and therefore the patients felt secure when electing to view such sensitive material and that was the reason for the uneventful viewing. Of the 22 patients who viewed the adjuvant therapy IVD 11 (50%) decided they wished to view their own possible risks of recurrence and mortality. The way the current software has been designed seems to enable to patient to feel free to view the material or not as they wish (Outputs 1,2, &8).

At the outset of the study it had been thought by the investigators that the patients may find the material contained in the IVD to be at too high and specific a level. Concerns were also expressed that the Clinician presenting the material and some of the interviewees may not be easily understood because of their American accents. This does not appear to have been the case with 95.6 % (n44 out of 46) finding it easy or very easy to understand although one patient did suggest an English accent would be helpful. Another area which the investigators thought might pose a problem was the use of detailed graphs and statistics but 92% did not raise this as a problem when specifically asked.

The results of this study are similar to Maslin (1993) 'A survey of the opinions of women of a breast unit on the issues of giving informed consent to joining a clinical trial' in that when asked if there was anything else the patient would have included in the IVD content patients comments focused strongly on the provision of additional information rather than any suggestion of the removal of information e.g. Some of the patients would have liked more information on practical issues i.e. bathing, on treatment related issues i.e. tamoxifen and radiotherapy, side effects of all treatments, potential problems i.e. more on chest wall recurrence, more on the views of all concerned the women and their relatives. As in Maslin (1993) the patients wanted access to this information as a right not a privilege which they could chose to exercise if they wished.

Comments which related to the actual technology were few as mentioned an English accent would have been appreciated, an ability to delete music, and a fast forward facility were the main requests. The women did not find the technology difficult. To

the viewer it was simply a television screen with touch screen control providing personalised information on their disease. One facility the patients found particularly useful was the print out they received at the end of their viewing session which summarised the information they received.

The last three questions were useful indicators as to how useful the IVDs really are. The IVD did provide information which gave 72 % of the women a clearer understanding of their breast cancer and treatment options. The majority 66% likewise felt the IVD had been useful and possibly the most important indicator 90% stated they would recommend it to someone they knew who had a diagnosis of breast cancer. The recommendation of a service to a friend or relative is one of the highest forms of commendation for a product or service because individuals may tolerate imperfect service for themselves but they usually require a higher standard of care for relatives or friends. The fact that a patient would recommend the IVD to someone they knew with breast cancer is a strong indicator of the rating they give the system. Naylor, 1995 suggested evidence based medicine “offers little help in many grey zones of practice where the evidence about risk benefit ratios of competing clinical options is incomplete or contradictory”. The Interactive Video System appears to facilitate shared decision making, in these grey areas for those patients who would wish it, by providing a computerised database of established evidence based "knowledge" which helps to meet the information needs of patients and allow them to become involved in the decision making process if they so wish (Kasper, Mulley, & Wennberg, 1992) (Output 8).

Nine month questionnaire:

It was interesting to note that relatively few of the patients changed their minds about whether or not to have mastectomy or wide local excision 11.3 % (n5 out of n44) or adjuvant therapy 13.4 % (n3 out of 23) based on the information they saw on the IVD. The reasons for this could be:

1. The patients had received sufficient information to make a decision from their existing interactions with the Clinician, Clinical Nurse Specialist and Multidisciplinary Team.

2. The patients may have already formed a fixed view based on their own existing knowledge or after sharing and acquiring information from others i.e. friends and family.

3. The patients were not influenced by the data they viewed.

The results on who made the treatment decision reflected the view of the patients that they participated but in collaboration with the Clinician and the Breast Care Nurse. The largest single group was those who felt the decision was collaborative between them the Clinician and the Breast Care Nurse n41 (43.6%). Only n10 (10.6%) of the patients felt they had taken the treatment decision on their own followed by n15 (15.9%) who felt the decision was made between themselves and the Clinician.. The Clinician alone accounted for n20 (21.2%) of the decisions. The results confirm those of previous studies which indicate that although patients may wish to access information they may not wish to take sole responsibility for the decision (Beisecker & Beisecker 1990, Luker et al. 1995, Bilodeau & Degner 1996). It would also appear that the clinician as sole arbitrator of treatment decisions is largely past. The fact that

only 21.2% stated the clinician alone made the decision may reflect a number of things either;

1, The Clinician was responding to the patients request to decide on their behalf thereby the patient although not demonstrating autonomy by making the decision personally, demonstrated autonomy by delegating their autonomy to their clinician (Ingelfinger 1980) or

2, It may be that the Clinician was behaving in a paternalistic fashion (Brock & Wartman 1990)

3, It maybe that the patient did participate but the stress of the situation has negated that participation in their mind (Brock & Wartman 1990)

It could be suggested the question asking who made the decision in this study could have been improved. The questionnaire does not explicitly put forward the option of a partner making the treatment decision although this is implicitly explored when the patient's are asked if they felt their husband/partner was involved. Forty-nine patients (67.1 %) stated their partners were involved but n24, (32.8%) said they were not. Another potential flaw with the questionnaire as it stands is the fact that it does not include the possibility that the CNS could have made the decision on the patient's behalf although it does so for the Clinician. This may be important as the results indicated the CNS along with the patient and the clinician collaborated in the treatment decision in 43.6% of cases and the patient and CNS in 7.3% giving an overall CNS participation total of 50.9%.

As previously outlined Maguire et al (1978, 1980) established that nurses appropriately trained in assessment for psychiatric morbidity could successfully identify patients at risk and make appropriate referrals to a department of psychological medicine, nurses

especially clinical nurse specialists in breast care, have been taking a leading role in acting as advocates for patients diagnosed with breast cancer (Maguire et al. 1980, 1988b, NHSE COG 1996) The role has developed and continues to be widely endorsed (the Fforest Report,1986, Watson et al.,1988, Roberts & Fallowfield,1990, Cancer Relief Macmillan Fund's Minimum Standards for Breast Care,1994, the British Association of Surgical Oncologists guide-lines on treatment protocols, 1994, the British Breast Group's assessment of specialist cancer centres,1995, and the NHSE COG on Breast Cancer 1996, all of which have endorsed the supportive role of appropriately trained specialist nurses who are able to participate in information giving, decision making and psychological support. The patients in this study explicitly and implicitly looked to the CNS as a source of information and support. Although it may be true to say the CNS is not totally impartial she would appear to act as an advocate on occasions (Wells, 1986) and this role and function is endorsed by the patients. She is also seen to be part of the team facilitating informed consent (CRC, 1983).

This study does demonstrate strongly the supportive role of the CNS in Breast Care. Overall the patients in both groups of the study were satisfied with the tools used in information giving. Although the sources of information used varied in each arm of the study the continuing support both in terms of information and psychological support of the CNS remained. Working together with the clinician it could be suggested that this support rather than the tools used was of primary importance. Luker et al. (1995) suggested detailed clinical information was not within the scope of the average ward nurse but may well fall within the scope of practice of the specialist breast care nurse. This study would appear to support that position. The fact that the

CNS was seen by 51.% of the patients as being involved in sharing in the decision making process gives an indication of the strength of her input.

Overall the IVD was evaluated very highly but the IVD could be seen as being expensive in a number of ways. There is the initial capital purchase, the need for regular software updates, the need for a dedicated room during viewing of the programme and the associated manpower costs. The results of this study have indicated that viewing the IVD did not result in a significant increase in satisfaction or improvement in the intervention groups anxiety and depression scores over the group who received standard care as both arms of the study were comparable. It could be suggested the comprehensive, individual support the patient received from the Clinician, the CNS and the multidisciplinary team was the a key factor in satisfaction and adjustment rather than the specific method of information sharing used. If this is the case and if cost is a major issue for carers provided the appropriate support from the clinician, clinical nurse specialist and members of the multidisciplinary team is available to the patient other less expensive forms of technical information support could be used to aid the provision of more detailed information. It could be suggested, literature, cards, other computer software or a straight linear video dealing with specific scenarios could be just as effective as aids to information giving. This result is similar to the findings of Bilodeau & Degner (1996) who likewise found women preferred personal sources of information (physician, nurse, friend or relative) over written.

The IVD has the ability to store and provide consistent protocol based information at a uniformly high rate which would be difficult for a clinician or nurse given the influence

of the stresses of a working week to match. The professional has the ability to gauge a patients' mood and assess patient requirements which the machine cannot do (Maguire et al 1980, 1983, Watson et al 1988). It would be interesting to evaluate how the information given by the clinician and clinical nurse specialist varies as the week progresses and how other factors e.g. time, stress, personal factors affect the quantity and quality of information given to patients. This issue may be important when considering the debate on informed consent Baum 1986, Baum & Houghton 1988, Williams 1992. With the IVD professionals can demonstrate that a certain level of specific information was presented to the patient and this was reinforced verbally by the CNS and in writing by the summary print out. The professional still has the problem of knowing exactly what impact stress and selective perception is having on the patient and therefore can never be sure exactly how much information the patient has absorbed. This however is balanced by the fact that in an imperfect world where no method of information giving will be entirely correct for every patient this system provides an useful vehicle for facilitating the informed consent process not just for information in which risks and benefits must be assessed, but also for very technical information or in clinical trials (Williams 1992). The system could be useful to those conducting clinical trials by providing high quality, evidence based, personalised information which outlines the nature of clinical trials, the specifics of the trial, the advantages and the disadvantages of participation (Schafer 1989).

One important issue relates to the updating of software. Breast cancer research is constantly updating the information available and it will be important that any system or software has the capacity to incorporate new information at an affordable level. What is known and accepted today may need updating within a relatively short period

of time e.g. Early Breast Cancer Trialists' Collaborative Group, 1998. One solution could be an annual fee which covers software updates which subscribers to the system could support. Although this study does not address the subject of the multitude of computer/CD systems available it may be that in view of the fact that computer technology is advancing at such a rapid rate the principles used in the production and use of the IVD may be achieved more easily and less expensively today.

Other than in this study no randomised control trials have been run to establish the value of this Shared Decision Making Interactive Videodisc Programme in Breast Cancer (SDP/IVD) in a genuine patient cohort (Chapman et al.1995). The reasons for this have included, 1, lack of funding due to the perceived low status/value of such enquiry (Kasper, Mulley et al 1992, Mort et al 1995) 2, the resistance of medical colleagues to the system (Mort et al 1995). When discussing the difficulties of recruiting to this study and the time involved in assessment it was interesting to note that in this area even within a relatively short period of time technology and information systems have moved on so quickly. There is substantial research to support the view that good communication is important in patient adjustment to a cancer diagnosis (Maguire, 1978, Buckman 1986, Fallowfield et al 1986), the key players in the area of breast cancer appears to be the clinician (Fallowfield et al 1990 a & b, 1994 a & b) and the breast care nurse (Maguire et al 1978, 1980, 1983). It would appear many patients do want access to good quality information on their disease, treatment options and side effects (Thornton 1992, Maslin 1993), and some patients though not all may wish to participate in the decision making process (Bilodeau & Degner 1996). This study demonstrates that the IVD is highly evaluated by those who used it as tool to assist decision making. Those using the IVD system did not appear

to suffer any adverse psychological affects and found the system simple and easy to use. Equally this study showed that patients in the standard care group were very satisfied with their level of information. Does this mean providers of health care should opt for the simpler methods of reinforcing information giving provided the backbone of support and information is provided by healthcare professionals

SDP/IVDs are not only about patient choice they could also act as a valuable resource in the standardising of treatment protocols, promoting evidence based practice, and potentially helping to collect valuable clinical/research data and provide a measure for quality assurance (Kasper et al 1992, Mulley 1994, Breast Cancer COG 1996). It may be that these additional functions could provide a rationale for the expense incurred by the provision of these resources. The system could facilitate protocol-based practice but would this be acceptable to the majority of clinicians? It would be interesting to discover how many hospital-based consultants would support the introduction of such systems more widely. Can clinicians be induced to change their practice in line with the patient's expressed preference as a result of using the SDP? In this study with supportive clinicians the answer was yes but this was equally true in the standard care group with the same consultants. Subjective experience seems to suggest enthusiasts for SDP/IVDs are quality assurance officers, patient information groups, or nurses, the very people who often lack the authority or resources to make tangible change in the health care system.

Is there then an added value in the use of IVD/SDPs in terms of data collection, quality assurance and medical audit over time? This is a hypothesis, which would need to be tested, but with compliance and co-operation in the use of the system it could be

suggested the system could provide a useful tool. It is possible that the IVD could act as a tool in helping to safeguard the multidisciplinary team from litigation because of its very specific and uniform delivery of information. As previously discussed viewing the SDP ensures a quantifiable amount of information has been provided for the patient. It cannot ensure the information has been received but it can be used to substantiate the fact that certain information was covered. This could be useful particularly in difficult situations like patients giving consent to participation in clinical trials.

CONCLUSION

Outputs 1,2,&8 demonstrate that the study determined that providing information to women with early breast cancer using an interactive system did not significantly reduce the anxiety and depression associated with its diagnosis and treatment. Both the control and intervention groups within this study experienced a reduction in anxiety and depression at nine months but this reduction could not be attributed to the IVD.

Outputs 1,2,& 8 also demonstrated that the study determined that providing information using an interactive video system, to women about treatment choices did not significantly increase their satisfaction with the choice they made. Both groups were largely satisfied with their choices and there was no statistically significant increase in the satisfaction expressed by the IVD group over the controls. The skill appears to lie in the professionals ability to discern the information requirements of the patient and being able to explain the way forward including advantages and disadvantages in such a way that the patient is able to participate to the level they wish

(Maguire 1978, Maguire & Faulkner, 1988). The interactive videodisc system however does offer a unique opportunity to attempt to provide information with limited bias to patients and to facilitate real choice.

The study does appear to support the significance of effective communication by the Clinician and Clinical Nurse Specialist (CNS) in Breast Care. The control group demonstrated equally high levels of satisfaction with their quantity and quality of information. It may be that if the IVD had been evaluated in a centre where the clinician was not open to dialogue with patients and where the services of a CNS was not available the results between the two groups could have been quite different.

The study also ascertained that the use of the IVD technology is acceptable to the women. The majority of the women who used the IVD were comfortable with the touch control screen and with the visual display unit. The data from this study is helpful in that it demonstrates that the use of an IVD with explicit but empathetic information does not appear to be harmful to those women who choose to view it. This fact does not exclude the possibility that some patients choose to exercise their rights by delegating them to their clinician and this too is a valid treatment choice (Ingelfinger 1980, Maslin 1993, 1994, Baum 1994, Fallowfield, Hall, Maguire, Baum 1990).

Dr Maureen Roberts, Clinical Director of the Edinburgh Breast Screening project, 1979 to 1989, who succumbed to breast cancer said "Communication is all important. Proper truthful accounts of diagnosis, treatment and aftercare must be written and made available everywhere, so that women become well informed and most important,

start to take part in the decision making process for themselves (1989).” Outputs 1,2,3,4,5,6,7,8, demonstrate and provide a coherent argument that appears to support the IVD appearing to be a valuable tool in this process, but it remains an expensive one, both in terms of capital cost and manpower. For those patients who wish to participate in the process of deciding their treatment option the IVD provides an opportunity to view personalised detailed information which as well as detailing the risks and benefits of treatment options, clearly explains, in an objective but empathetic manner the possible treatment outcomes in a format where the content and quality of the information is at a predetermined level. It is difficult to put a price on the value of this to patients (Outputs 1,2,3,4,5,6,7,8).

In conclusion the publications on which this application is made makes an original contribution to knowledge in three ways. Firstly, it presents a coherent and logically ordered review of the literature and issues in relation to the existing perspectives surrounding the issues which underpin a woman’s right or ability to access personalised treatment information on which to make a treatment decision and secondly, uses that review to develop this further by devising a hypothesis and research study to test a de novo process for delivering personalised cancer based treatment information. Finally it contributes to health policy discussions by demonstrating that although the results clearly demonstrate the high level of satisfaction and ease of use of the system there are other issues which must be considered when considering novel forms of information and support. As stated the control arm of the study was equally satisfied with their less technologically based care. With this in mind there are issues that need serious reflection relating to what the health service can provide given the

rapid development of technology and research, the hardware/software costs and the implications for professional human resources.

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Shared decision-making using an interactive video disk system for women with early breast cancer

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This study piloted and evaluated an interactive video disk system (IVD) using a shared decision-making programme (SDP) for women with early breast cancer. The study aimed to determine the acceptability of an interactive video disk system, in addition to the standard informational care and support provided by the clinicians and clinical nurse specialist, as a means of providing information about the risks and benefits of treatment choices. An experimental randomised study design was chosen, using as its main outcome measures the SF36, the Hospital Anxiety and Depression (HAD) scale, and a further questionnaire aimed at eliciting patients' satisfaction with their treatment choice. One hundred patients were recruited, and at nine months 94% of questionnaires were returned. The HAD scale overall summary scores, for both groups, indicated a significant fall in anxiety at nine months ($p < 0.001$). The SF36 Questionnaire demonstrated nil of significant note. The IVD system was very highly evaluated. When patients were asked if they would recommend the IVD to someone they knew with a diagnosis of breast cancer, 92% said 'yes'. Overall there was a high degree of satisfaction in both groups. The study does support the significance of effective communication by the clinician and clinical nurse specialist (CNS) in breast care. The use of the IVD technology appears to be acceptable to and highly rated by the women.

INTRODUCTION

Great debate surrounds the issue of patients with breast cancer participating in surgical/medical decision-making and their ability to give an informed consent (Baum, 1982; 1986; Baum and Houghton 1988; Williams 1992; Maslin, 1994). Healthcare professionals must balance the need to safeguard the rights of patients, respect their autonomy and yet be sensitive to the fact that patients may change their minds and their attitude as they progress from diagnosis to the end point of their disease (Gillon, 1992; Maslin, 1994).

Providing information is only one part of the process of enabling patients to share more fully in decisions about their care if they so wish (Cassileth et al., 1980; Luker et al., 1993; NHSE, COG 1996a,b). Making that information meaningful and the choices realistic means addressing how health risks are conveyed, how healthcare is delivered and how uncertainty is addressed (Calman, 1996). Questions that need to be asked include: Who should provide patient information? How can the information given to patients be made consistent and unambiguous considering the number of healthcare professionals who give information to patients? If information about choices is given to patients does the healthcare setting allow patients to exercise choice? If not, is the result increased frustration for patients? Are patients more satisfied with the care they receive if they are informed and share the decision-making process?

Some studies have shown that the anxiety and depression found in women with early breast cancer can be reduced if they are seen by a clinician who communicates effectively with them and who aims to incorporate patient choice into treatment decisions, if this is possible and if the patient wishes (Fallowfield et al., 1990a,b). Women receiving treatment for breast cancer constitute a patient group in whom some of the questions surrounding communication, choice and shared decision-making have been explored

KEYWORDS
 Shared decision-making,
 Interactive video

(Fallowfield et al., 1990a,b); Thornton, (1992); Maslin 1993, 1994); (Beaver et al., 1996). This study aimed to address some of the issues relating to shared decision-making in those areas where a choice of treatment option involves some degree of risk/benefit analysis.

AIMS AND OBJECTIVES OF THE STUDY

The study aimed to pilot and evaluate the usefulness of a shared decision-making programme (SDP) for women with early breast cancer, looking at surgical and adjuvant treatment options using a personalised, interactive video disc system (IVD) (Kasper et al., 1992a,b). The system aimed to provide the patient with information in areas where there is a genuine, but difficult, treatment option choice.

Specifically, the study aimed to determine:

1. The acceptability of an interactive video system in addition to the standard information and support provided by the doctors and the clinical nurse specialist, as a means of providing information about the risks and benefits of different treatment choices — surgery and subsequent adjuvant chemotherapy — to women with early breast cancer.
2. Whether providing information to women with early breast cancer using an interactive system significantly reduces anxiety and depression associated with the diagnosis and treatment of this condition.
3. Whether providing information to women about treatment choices using an interactive video system significantly increases their satisfaction with the choice they have made.

The interactive video disc/shared decision-making programme (IVD/SDP) system provides research-based information on local and systemic treatment for early breast cancer and also explores areas of uncertainty and variations in practice. The programme provides patients with research-based evidence which is directly applicable to their own situation. They are able in the adjuvant therapy section to access general information about a hypothetical patient's risks of the disease recurring and the mortality rate, but they are also able to access information on the risks to them. The patients are advised, though, that this information might not necessarily apply in their case because the information is based on statistics that would apply to a group of individuals in their situation.

The information is presented verbally, visually and diagrammatically and includes figures for relative risk reduction, absolute risk reduction, difference in event-free survival, and the number of patients needed to treat to achieve benefit.

The first shared decision-making programme for patients with cancer was produced in 1994 and was aimed at women with early breast cancer (Kasper et al., 1992a,b). That programme summarised treatment options, with results for each option based on efficacy. The results included the odds for relapse, and for survival.

The interactive component of the IVD/SDP system has two parts;

1. The patient's own details, for example, age, tumour size, lymph node status.
2. A 'learn more' section with which the patient is able to interact at will; for example, choose material to watch, go over previous material, access new material.

The IVD is different from a standard linear videotape in that it provides information which is unique to each patient: it is tailored to each patient according to the personal details that are keyed in. The interactive nature of the system means that patients can go forwards or backwards in the system, and they can review material or opt out if they wish. The system also has

SHARED DECISION-MAKING

programmed pauses to allow patients to take a break if they wish.

The purpose of the system's database is:

1. To offer information on the management of individual patients with early breast cancer based on the current overview of randomised controlled trials.
2. To offer information on current areas of debate concerning the management of breast cancer, and a rationale for treatments on offer.
3. To address issues relating to benefits and disadvantages of treatments based on the impact of a treatment on quality of life balanced against the possibility of extending life expectancy.
4. To address areas of current controversy and uncertainty.
5. To recognise that individual patients will have legitimate personal views, values and preferences which may influence their choice of local or systemic treatment.

Mort et al., (1995, p5) state that:

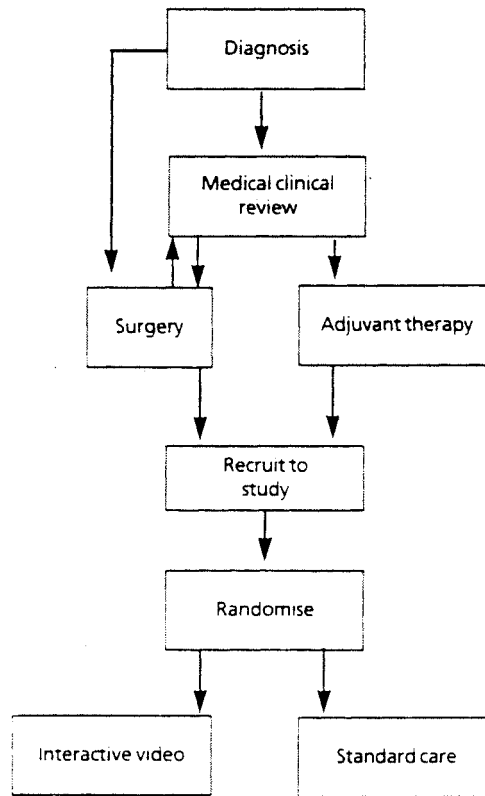
'When women with early stage breast cancer who are suitable candidates for either surgical option (wide local excision followed by radiotherapy or mastectomy +/- reconstruction) learn that their survival outcome is the same in either case, a broad range of outcomes become important to consider...Although many physicians and patients would agree that the most important outcome for women with early-stage breast cancer is survival, it is less likely that physicians and patients would agree in the relative importance of outcomes that relate more to the patient's quality of life. One woman may feel strongly that conserving the physical appearance or sensation of her breast is extremely important. Another woman may feel that removing the involved breast and reducing her chance of dealing with an in-breast ipsilateral recurrence and subsequent mastectomy is more important than conserving her breast. It bears emphasising that having a choice is not the same as having to make a decision.'

Morte et al. (1995) believe that after using the IVD system and receiving standard information and care from their doctor and clinical nurse specialist, patients should be able to make an informed treatment choice, and have a rationale for the chosen treatment as well as understand the benefits, trade-offs and impact on quality of life which may occur as a result of the choice. They note that the women should also be given a hard copy of the personalised information they have accessed.

STUDY DESIGN

An experimental randomised study design was chosen to attempt to eliminate bias in apportioning the novel component, the IVD system. One hundred patients were recruited from a specialist multidisciplinary breast unit. The women were recruited upon confirmation of a breast cancer diagnosis either by fine needle aspiration cytology or biopsy. All the women had a small localised primary breast cancer with no evidence of metastatic disease. They were fully informed of the study before giving their written consent and were randomised to one of two groups: one where patients received standard care based on information they were given and who were receiving support from the multidisciplinary team, or to the experimental group where, in addition to support from the multidisciplinary team, the women were offered use of the IVD to aid them in decision-making if they wished (Figure 1). Patients completed questionnaires at the time of recruitment and again at nine months post-diagnosis.

FIGURE 1
Recruitment to study



Patients randomised at the time of surgical choice also have the opportunity to view the adjuvant video, where appropriate.

MAIN OUTCOME MEASURES USED

(a) Acceptability of the interactive video

This was assessed using a simple Likert (Burns and Grove, 1987, p748) questionnaire asking the patients' opinion about the information given in the interactive video, how it was presented and what impact they felt it made on their decision about what treatments to choose.

(b) Assessment of health status

A general health status questionnaire (SF36) was used to measure changes in health status. This questionnaire was chosen for a number of reasons:

1. It measures a wide number of variables including physical mobility, emotional and social well-being, and social life.
2. It is easy for patients to use. The version used is the Short Form 36 which has been developed from the much longer original (Brazier et al., 1992), with 36 questions covering eight dimensions.
3. Its reliability and validity (McHorney et al., 1992; McHorney et al., 1993).
4. It was anticipated that this questionnaire would be used by other groups evaluating other interactive video programmes from the Shared Decision-Making Foundation (Kasper et al., 1992a, Kasper et al., 1992b), thus enabling some cross-comparison of data.
5. Normative data exist, so enabling useful interpretation.

With 100 patients in the study it was possible to detect a difference in the changes of scores between the two groups of 0.6s where 's' is the standard devia-

SHARED DECISION-MAKING

tion of the change within each patient that would be reliable. This difference can be detected with a probability of 85%. If attention is focused on the percentage of patients who experience a fall in the SF36 item scores with respect to their pre-treatment value, then it will be possible (with 85% probability) to detect differences between the groups in the percentage showing a fall in the order of 35% v. 10% or 50% v. 20%.

(c) *The Hospital Anxiety and Depression (HAD) scale* (Zigmond and Snaith, 1983)

This is a self-assessment scale for the detection of anxiety and depressive states in patients in a medical outpatient clinic (Bowling, 1991) which was developed by Zigmond and Snaith (1983). It offers a way of achieving a brief assessment of anxiety and depression, in which the patient rates each item on a four-point scale. Items relating to both emotional and physical disorder, for example, headaches, are excluded so that items included are only those which are based on the psychic symptoms of neurosis (Bowling, 1991).

Items on the scale are scored from 0-3 to 3-0 depending on which way the question is worded. High scores indicate the presence of a problem. HAD depression scores of 7 or less are considered to be of no consequence; scores of 8-10 could indicate the possibility of anxiety or depression and scores of 11+ indicate a definite problem (Bowling, 1991).

After Nine Months

After nine months, all the patients were asked to complete three questionnaires — the HAD and SF36 questionnaire and one aimed at eliciting the patients' satisfaction with their treatment choice at nine months post-diagnosis. Patients in the control group were asked to complete their initial questionnaires when they made their treatment decision and again as outlined above after nine months.

Exclusion Criteria

Certain women were excluded from the study for various clinical reasons in addition to those who did not understand English (Figure 2).

Figure 2. Medical conditions excluding women from the study

- Pregnancy
- Clinical or mammographic evidence of bilateral breast cancer
- Clinical or mammographic evidence of multicentric breast cancer (including gross multifocal disease or diffuse microcalcifications by mammography)
- A large tumour in relation to the size of the breast
- Histopathological findings after biopsy of Paget's disease or inflammatory breast cancer
- Tumours fixed to the chest wall
- Ulcerated tumour
- Axillary lymph nodes fixed and/or matted
- Supraclavicular lymph nodes
- Chest X-ray indicative of lung metastases
- Liver function tests suggestive of metastases
- Hepatomegaly revealed on physical examination
- Evidence of bone metastases as a result of a bone scan
- Clinical or diagnostic evidence of metastases
- Overall health would make mastectomy too life-threatening to be an appropriate alternative
- Absolute contraindications to radiotherapy
- Severe hearing, visual or cognitive impairment

RESULTS

One hundred patients were recruited over a two-year period; 51 were randomised to see the IVD and 49 to standard care.

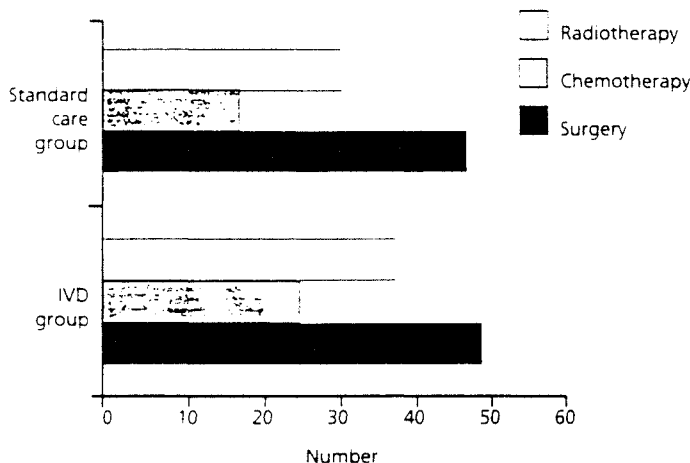
The comprehensive exclusion criteria were necessary to ensure only patients with a genuine treatment choice were included in the study. Six patients were lost to follow-up. The women's ages ranged from 28 to 73 years with a mean of 52.1 years with an even distribution between pre- and post-menopausal women.

At nine months, 94% of questionnaires were returned, which was an excellent result for follow-up by postal questionnaire (Burns and Grove, 1987).

The SF36 general health status questionnaire: The general health score indicates evidence of a slight fall in anxiety overall, which was not significant. The scores for physical functioning indicated that the median score fell from 90 to 85 ($p=0.01$). Likewise in physical role functioning there appears to be evidence of a fall overall, the median score falling from 100 to 50 ($p=0.04$) at nine months. The mental health scores suggest a significant improvement in the IVD group, the median score rising from 60 at the outset to 68 at nine months ($p=0.02$); however, the median score was at 68 at both pre-treatment and nine months in the group receiving the standard care. The scores for emotional role functioning indicated an improvement overall at nine months.

The women's treatment option choices (Figure 3) showed no statistically significant difference, $p=0.08$, using the Mann-Whitney U Test (Burns and Grove, 1987, p494).

FIGURE 3
Number of women recruited who chose surgery, chemotherapy and/or radiotherapy



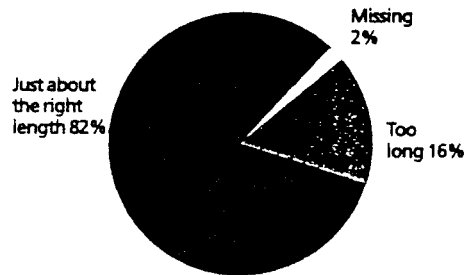
The Hospital Anxiety and Depression scale: Overall summary scores for both groups indicated a significant fall in anxiety at nine months ($p<0.001$). There was no real change in the depression scores in either group, which were low at the start when compared with a normal age matched population.

Opinions on the IVD (Figure 4a-4f): Of the 51 patients who viewed the IVD, 82% found it just about right in length (4a). Of those patients, 96% found it interesting or very interesting (4b), while the majority of the participants (92%) found the IVD easy/very easy to understand (4c). Questions which related to whether the woman felt or did not feel she had gained a clearer understanding of breast cancer revealed that 72% felt they now had a much clearer idea about breast cancer (4d). Sixty-seven per cent of the viewers were

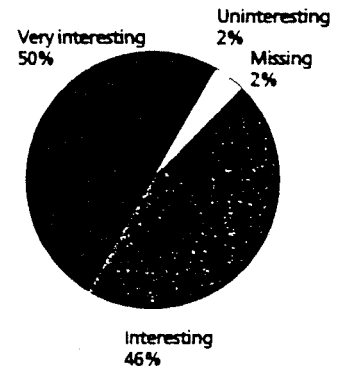
SHARED DECISION-MAKING

FIGURE 4(a)-(f)
Responses to interactive
video at recruitment

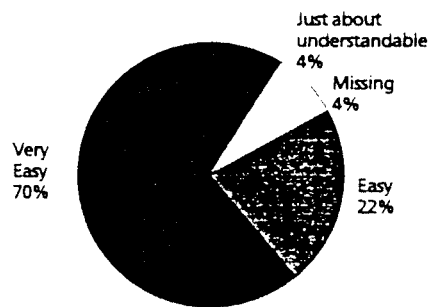
(a) Length



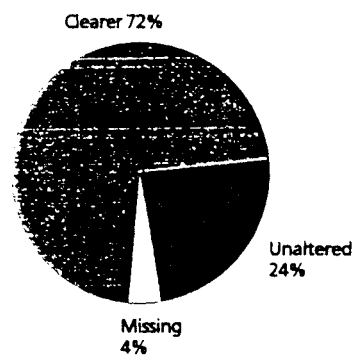
(b) Response



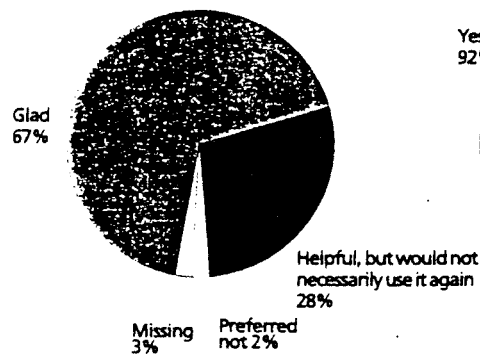
(c) Understanding



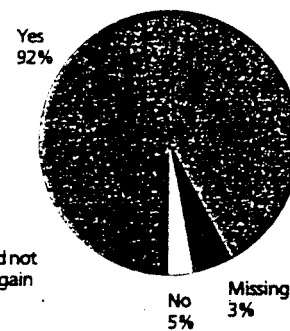
(d) Knowledge



(e) Appreciation



(f) Recommendation



'Glad they had used the video and would use it again', but 28% stated that they 'Found it helpful but would not necessarily use it again' (4e). Overall, 94% found using the IVD beneficial. Patients were asked if they would recommend the IVD to someone they knew with a diagnosis of breast cancer, and 92% said 'yes'.

Patients gave a mixed response when asked if the IVD had actually helped or influenced their decision. Just over half (54%) stated that it had been interesting but that it had not influenced their ultimate decision, while 30% felt it had definitely influenced their treatment decision. When asked if they had found any of the information worrying, 62% said they did not.

Views on the decision taken at nine months post-diagnosis: Of the patients who were asked if the IVD on surgical treatment options had changed their choice of surgical treatment, only 12.5% indicated it had. Of those patients who were asked if the IVD or adjuvant therapy changed the choice they ultimately made, 14.2% stated it had. The majority (85%) said that the IVD had not changed their adjuvant therapy choice.

The majority of patients (81%), in both arms of the study stated quite clearly that the doctor made the treatment decision by taking the decision on his own (21%), sharing the decision with the patient, (16%), or sharing the decision with the patient and the clinical nurse specialist (44%). The clinical specialist featured strongly in the decision-making process: only 11% of patients stated that they alone had made the decision on the choice of treatment option. When patients were asked how they felt about the treatment decisions that were made, 75% were happy or very happy, with no statistical difference in either group. When asked their feelings about the amount of information they had received overall, 72% were satisfied or very satisfied.

DISCUSSION AND CONCLUSION

This study showed that providing information to women with early breast cancer using an IVD/SPD system did not significantly influence the degree of anxiety and depression associated with its diagnosis and treatment in comparison with the best standard practice.

Both the control and experimental groups demonstrated a significant reduction in anxiety by nine months post-treatment. The study also showed that providing information to women about treatment choices using an IVD/SDP system did not significantly increase their satisfaction with the choice they made. Both groups were largely satisfied with their choices and there was no statistically significant increase in the satisfaction expressed by the IVD/SDP group over the controls.

The study does demonstrate quite strongly the supportive role of the clinical nurse specialist. Overall, the patients in both study groups were satisfied with the tools used in information-giving. Although the sources of information used varied in each arm of the study, the support of the clinical nurse specialist was constant. It may be that it was this support rather than the tools used that was of primary importance. Luker et al. (1995) suggested that the giving of detailed clinical information was not within the scope of the average ward nurse but may well be appropriate for the specialist breast care nurse. This study appears to support this possibility. The fact that the clinical nurse specialist was seen by 50% of the patients as being involved in sharing in the decision-making process gives an indication of the strength of her input.

Overall, the IVD/SDP system was evaluated very highly but it could be seen as being expensive in a number of ways: there is the initial capital purchase, the need to update the software regularly, the need for a dedicated room during viewing of the programme, and the associated manpower costs.

It could be suggested that the comprehensive, individual support the patients received from the doctor, the clinical nurse specialist and other healthcare professionals was the key factor in satisfaction and adjustment rather than the specific method of information-sharing used. If this is the case and if cost is a major issue for carers, provided the appropriate support from all the healthcare professionals is available, less expensive forms of technical information support could be used; for example, literature, cards, other computer software or a normal linear video dealing with specific scenarios. Nevertheless the IVD/SDP system is able to store and provide consistent protocol-based information at a uniformly high rate which it would be difficult for healthcare professionals, given the stresses of their working week, to match. However, they have the ability to gauge a patient's mood and assess her requirements, which a machine cannot do (Maguire et al., 1980, 1983; Watson et al., 1988). It would be interesting to evaluate how the information given by the doctor and the clinical nurse specialist varies as the week progresses and how other factors, such as time and stress and personal issues affect the quantity and quality of information given to patients. This issue may be important when considering the debate on informed healthcare consent (Baum 1986; Baum and Houghton, 1988; Williams, 1992).

With the IVD/SDP system, healthcare professionals can demonstrate by means of a print-out that a certain level of specific information was presented to the patient and that this was reinforced both verbally and in writing by the clinical nurse specialist. Nevertheless, healthcare professionals still have the problem of knowing exactly what impact stress and selective perception are having on the patient and therefore it can never be assessed exactly how much information the patient has absorbed. However, in an imperfect world, no method of information-giving will be entirely correct for every patient, but the IVD/SDP system does provide a useful vehicle for facilitating the informed consent process — not just for giving information so that risks and benefits can be assessed, but also for giving very technical information if patients are taking part in a clinical trial (Williams 1992). The system could also provide high quality, evidence-based, personalised information outlining the nature of the trial, the specifics of it, and the advantages and disadvantages of participating (Schafer, 1989).

One important issue is the updating of software. Breast cancer research is constantly producing new information and it is important that any software has the capacity to incorporate this material at an affordable level. One solution could be to charge subscribers an annual fee which would cover software updates. Although this study does not address the subject of the multitude of computer/CD systems available it may be that because computer technology is advancing at such a rapid rate the production of IVDs will become less expensive.

There is substantial research to support the view that good communication is important if patients are to adjust to a diagnosis of cancer (Maguire et al., 1978, 1980, 1982, 1983); and that the key players in the area of breast cancer appear to be the doctor (Maguire et al., 1978; Fallowfield et al., 1990a,b) and the breast care nurse (Maguire et al., 1980, 1982, 1983). It has been shown that many patients do want access to good quality information on their disease, treatment options and side-effects (Thornton, 1992; Maslin, 1993; Maslin et al., 1993), and that not all patients wish to participate in the decision-making process (Bilodeau and Degner, 1996). However, the study reported here has shown that the IVD was rated highly by those who used it as a tool to assist their decision-making. Moreover, they found it simple to use and did not appear to suffer any adverse psychological affects. However, the study also showed that patients in the standard care group were very satisfied with the level of information they

received. This could indicate that healthcare providers could opt for simpler methods of reinforcing information-giving, provided the basic support and information were provided by a healthcare professional.

IVD/SDP systems are not only about offering patient choice; they could also be a valuable resource in the standardising of treatment protocols, promoting evidence-based practice, and in helping to collect valuable clinical/research data, and provide a measure for quality assurance (Kasper et al., 1992 a,b; Mulley, 1994; NHSE Breast Cancer COG 1996 a,b). It may be that these additional functions would justify the expense of these resources. The system could also facilitate protocol-based practice, but would this be acceptable to most doctors? It would be interesting to discover how many hospital-based consultants would support the widespread introduction of an IVD/SDP system, and whether they would change their practice in line with their patients' satisfaction with the system. In this study, with supportive clinicians, the answer was 'yes' but from subjective experience, enthusiasts for IVD/SDP systems are quality assurance officers, patient information groups, or nurses — the very people who often lack the authority or resources to make tangible change in the healthcare system.

Is there, then, added value if IVD/SDP systems are also used for data collection, quality assurance and medical audit? This is a hypothesis that would need to be tested, but it is possible that the IVD, with its very specific and uniform delivery of information, could act as a tool to safeguard the multidisciplinary team from litigation. As previously discussed, the IVD provides a quantifiable amount of information for the patient, and although it is not possible to ensure the information has been received it can be used to substantiate that certain information was covered. This could be particularly useful for patients who are being asked to give consent to taking part in a clinical trial.

The IVD/SDP system is an expensive tool in terms of its capital cost, the need constantly to update it, and for the manpower required to operate it. This study has shown that psychological support and information on treatment given by a doctor and clinical nurse specialist trained in communication skills can provide an equally satisfactory service. It may be that if the IVD/SDP system had been evaluated in a centre where the doctor did not communicate well with patients and where the services of a clinical nurse specialist were not available, the results for the two groups would have been quite different.

The study showed that the IVD/SDP system was acceptable to the women. The data from this study are helpful in that they demonstrate that the use of an IVD/SDP system with explicit but empathetic information does not appear to be harmful to those women who choose to view it. For those patients who desire it, the IVD/SDP system provides an opportunity to view information that clearly outlines the risks and benefits of treatment options in an objective but empathetic manner, the content and quality of which is at a pre-determined level.

● The views expressed in this paper are the authors' alone.

KEY POINTS

- Good quality explicit information on breast cancer and its treatment is acceptable to the patients who request it
- The IVD/SDP system ensures that a consistent research-based level of quality information is made available to patients
- The IVD/SDP system can be a very useful tool in breast cancer treatment decision-making.

SHARED DECISION-MAKING

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Review:

Shared decision-making using an interactive video disk system for women with early breast cancer

Kinta Beaver

The issue of how much involvement service-users prefer in decision-making receives increasing attention. This paper describes how technology can be used to enable women with breast cancer to receive information about treatment options using an interactive video disc (IVD).

The authors acknowledge that the IVD did not have an impact on anxiety, depression or health status and that support from healthcare professionals was equally effective. This is an encouraging finding for breast care nurses who provide information and support as part of their role, although the authors have a valid point in noting that the IVD may be more beneficial in areas where less specialist expertise is available. It may be useful to evaluate the IVD in other study sites and primary care may be of particular interest.

With a primary care-led NHS this type of interactive information system may be useful prior to primary treatment or further from diagnosis when contact with specialist services can be minimal. Luker et al. found that, even though women with breast cancer still had information needs up to two years from diagnosis, professional sources of information were few. This type of system may benefit both healthcare professionals and service-users in a primary care setting.

Additional outcome measures may have been appropriate, including an assessment of whether women had wanted involvement in decision-making. The IVD may be more beneficial for women who prefer involvement in treatment decisions than for women who prefer a more passive role. Further, it may have been useful to assess if the IVD had an impact in meeting the information needs of the women involved in the study.

There were a large number of exclusion criteria, indicating that the system was not able, in its present form, to assist women who faced more complex situations. This is understandable in this early pilot

stage of the work. However, it is arguable that it is these women who could derive most benefit from such a system, although the authors comment that the IVD could be useful for individuals requiring very technical information or those involved in clinical trials. The system also excludes women who could not speak English and it may be that different ethnic groups could benefit from this type of information if the IVD was produced in different languages. However, the high cost of the technology may be a limitation in this respect.

Although 62% of the women said that they had not found the information worrying, it is perhaps a cause for concern that 38% had found the information to have some worrying aspects. With the availability of a skilled multidisciplinary team this concern may be unfounded, and indeed anxiety levels were no higher in the experimental group, although open access to the system in areas with little specialist support may leave some individuals feeling distressed and unsupported.

The authors present an honest discussion of their findings, acknowledging the expense of the equipment and the potential problems of having to update the IVD at regular intervals. Although the small sample sizes limit the generalisations that can be made from this pilot study, nonetheless the study raises some interesting points and the authors present a well balanced paper presenting the potential advantages and disadvantages of the use of this type of technology in healthcare.

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Output 2

**Maslin, A., Baum, M., Secker Walker, J., A'Hern, R., & Prouse, A.,
1998, 'Using an Interactive Video Disc In Breast Cancer Patient
Support' Nursing Times, London, Nov 4, Vol 94 No 44, pp 52-55**

Using an interactive video disk in breast cancer patient support

Abstract

A randomised-controlled trial compared outcomes for women recently diagnosed with breast cancer who either received support and information from a multidisciplinary team or used a shared decision-making programme on an interactive video disk (IVD) system.

Using the IVD did not have a significant effect on the decisions women made about treatment, yet it was evaluated positively by those who used it.

The results suggest that the role of clinical staff is more significant than the form of information provided.

Potential benefits for the IVD were apparent such as standardising the information received by patients, promoting evidence-based practice and providing a measure for quality assurance.

Keywords:

Patient involvement, patient information

Anna Maslin and colleagues assess the benefits of using an interactive video disk system in the treatment of women with early breast cancer

There is much debate about patients with breast cancer participating in surgical medical decision-making and about their ability to give informed consent. Health care professionals must balance the need to safeguard patients' rights respect their autonomy and yet be sensitive to the fact that patients may change their minds and their attitude as they progress from diagnosis to the end point of their disease (Maslin, 1994).

Providing information is only one part of the process of enabling patients to share more fully in decisions about their care if they so wish (Cancer Guidance, 1996a,b; Luker et al., 1995). Making that information meaningful and the choices realistic involves addressing how health risks are conveyed, how health care is delivered and how uncertainty is addressed (Caiman, 1996).

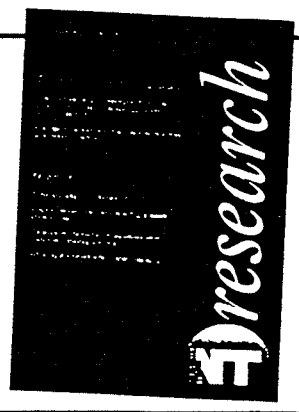
Questions that need to be used include: Who should provide patient information? How can the information given to patients be made consistent and unambiguous considering the number of health care professionals who give information to patients? If information about choices is given to patients, does the health care setting allow them to exercise choice? Are patients more satisfied with the care they receive if they are informed and participate in decision-making?

Some studies have shown that the anxiety and depression found in women with early breast cancer can be reduced if they are seen by a clinician who communicates effectively with

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them and who aims to incorporate patient choice into treatment decisions, if this is possible and if the patient wishes (Fallowfield et al., 1990a,b).

Some of the questions surrounding communication choice and shared decision-making have been explored with women receiving treatment for breast cancer. This study aimed to address some of the issues relating to shared decision-making in those areas where a choice of treatment option involved some degree of risk/benefit analysis.

Aims and objectives

The study aimed to pilot and evaluate the usefulness of a shared decision-making programme (SDP) for women with early breast cancer, looking at surgical and adjuvant treatment options (chemotherapy) using a personalised, computerised interactive video disc system (IVD) (Kasper et al., 1992).

The system aimed to provide the patient with information on areas where there is a genuine, but difficult, choice of treatments.

Specifically, the study aimed to determine:

- The acceptability of an IVD system in addition to the standard information and support provided by the doctors and clinical nurse specialist, as a means of communicating the risks and benefits of different treatment choices;
- Whether providing information to women with early breast cancer using an interactive system significantly reduces anxiety and depression associated with diagnosis and treatment;
- Whether providing information to

women about treatment choices using an interactive video system significantly increases their satisfaction with the choice they have made.

The interactive video disk shared decision-making programme (IVD SDP) system provides research-based information on local and systemic treatment for early breast cancer and also explores areas of uncertainty and variations in practice.

The programme provides patients with research-based evidence that is directly applicable to their own situation. In the adjuvant-therapy section they are able to access general information about a hypothetical patient's risks of the disease recurring and the mortality rate, as well as accessing information on the risks applicable to themselves.

The patients are advised, however, that this information might not necessarily apply in their case but that it is drawn from statistics that would apply to a group of women in their situation.

The interactive component of the IVD/SDP system discussed in this paper is expressed in two ways:

- The first part of the IVD concerns the patient's own details such as age, tumour size and lymph-node status.
- The second part contains a 'learn more' section with which the patient can interact at will.

The IVD is different from a videotape in that it provides information unique to each patient according to the personal details that are keyed in. The interactive nature of the system means that patients can go forwards or backwards within it, they can review

material or opt out if they wish. The system also has programmed pauses to allow patients to take a break.

The accompanying database offers information on the management of individual patients with early breast cancer based on a current overview of randomised controlled trials. It also outlines current areas of debate concerning the management of breast cancer and rationale for treatments on offer. The information addresses issues relating to benefits and disadvantages of treatments based on the impact of a treatment on quality of life, balanced against the possibility of extending life expectancy.

Wentz et al. (1998) believe that after using the IVD system and receiving information from a specialist breast cancer nurse and a nurse specialist, the patient is able to make an informed treatment choice and have a better understanding of the proposed treatment options. It is felt that a woman should also be able to make a choice of the person with whom she has accessed

Study design

A prospective, randomised study design was used. One hundred patients with a diagnosis of a specialist breast cancer consultant were recruited upon diagnosis of early breast cancer diagnosis. The study had a therapeutic objective, with the aspiration of a cure for the disease. All had a small, early stage breast cancer with no evidence of metastatic disease.

All women were fully informed of the study, having given their written consent and were randomised to one of two groups: a control and an experimental group.

The control group received standard care. This is a combination of information they were given and had support from the multidisciplinary team. The experimental group, in addition to support from the multidisciplinary team, were offered use of the IVD system to aid them in decision-making if they wished. Patients completed questionnaires at the time of recruitment and again at nine months post-diagnosis.

Some women were excluded from the

study for clinical reasons: for example, advanced breast cancer and metastatic disease and co-existing malignant pathology. Patients were also excluded if they had sensory impairment or were unable to understand English.

Acceptability of the interactive video

This was assessed using a simple Likert questionnaire (Burns and Grove, 1987) asking the patient's opinion about the information given in the interactive videos, how it was presented and what impact they felt it made on their decision about what treatments to choose.

Assessment of health status

A general health status questionnaire was used to measure changes in health status. This questionnaire has been tested for reliability and validity and is easy to use. The version used is the Short form 36 (SF-36) which has been developed from the much longer original (Brazier et al., 1992) with 36 questions covering eight aspects.

The hospital anxiety and depression (HAD) scale

This is a self-assessment scale for the detection of anxiety and depressive states in patients in a medical outpatient clinic developed by Zigmond and Snaith (1983). It offers a way of achieving a brief assessment of anxiety and depression in which the patient rates each item on a four-point scale.

HAD depression scores of seven or less are considered to be of no consequence, scores of eight to 10 indicate the possibility of anxiety or depression and scores of 11 and above indicate a definite problem (Bowling, 1991).

Results

One hundred patients were recruited over two years. 51 were randomised to see the IVD and 49 to have standard care.

Comprehensive exclusion criteria were necessary to ensure only patients with a genuine treatment choice were included in the study. Six patients left the study. The women's ages ranged

from 28 to 73 years with a mean of 53 years and an even distribution between pre- and postmenopausal women, nine months. 94% of questionnaires had been returned.

The HAD scale

Summary scores for both groups indicated a significant fall in anxiety nine months ($p < 0.001$). There was real change in the depression scores either group, which were low at start when compared with a normal age-matched population.

The health status questionnaire

The general health score indicated evidence of a slight fall in anxiety, which was not significant. The scores for physical functioning indicated that the median score fell from 90 to 85 ($p = 0.0$). Likewise in physical role function there appeared to be evidence of a fall, the median score falling from 100 to 94 ($p = 0.04$) at nine months.

The mental health scores suggested significant improvement within the IVD group, the median score rising from 60 at the outset to 68 at nine months ($p = 0.02$). However, the median score was 68 at both pre-treatment and nine months in the group receiving standard care. The scores for emotional role functioning indicated a general improvement at nine months.

The women's treatment options (Fig 1) showed no statistically significant difference between the two groups.

Views on the IVD

Of the 51 patients who viewed the IVD, 82% found it just about the right length. Of those patients, 96% found it interesting or very interesting, with the majority (92%) found it easy to understand or very easy to understand.

Questions relating to whether women felt or did not feel they had gained a clearer understanding of breast cancer revealed that 72% felt they now had a much clearer idea about breast cancer.

Sixty-seven per cent of the viewers

Fig 1. Numbers of women recruited who chose surgery, chemotherapy and radiotherapy

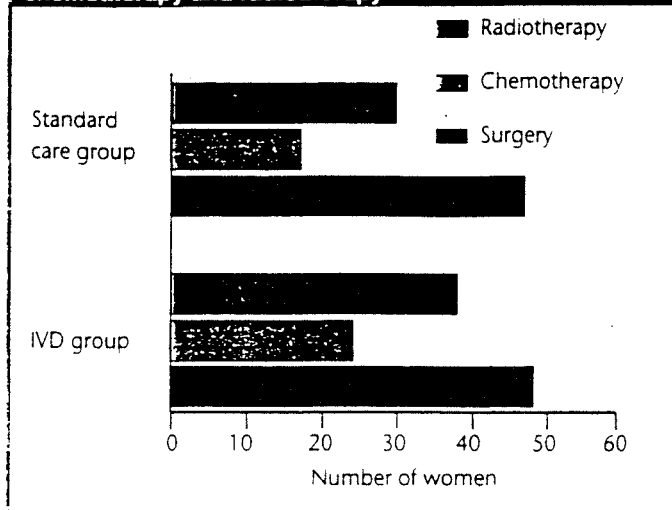
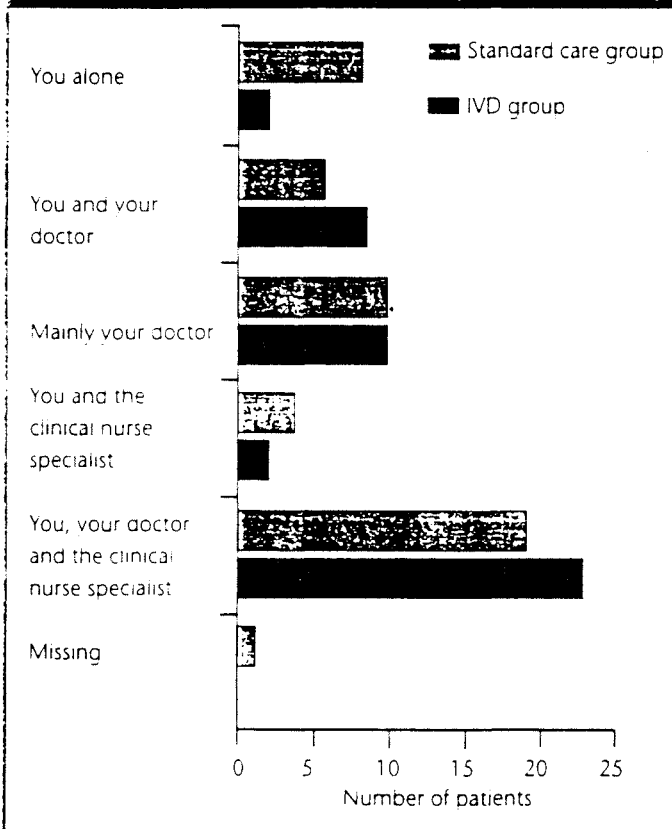


Fig 2. Replies to the question: Who do you feel made the treatment choice?



sponded that they were glad they had used the video disk and would use it again... but 28% stated that they found it helpful but would not necessarily use it again.

A total of 84% found using it beneficial. Patients were asked if they would recommend the IVD to someone they knew with a diagnosis of breast cancer and 92% said yes.

Patients gave a mixed response when asked if the IVD had actually helped or influenced their decision. Just over half (54%) stated that it had been interesting but had not influenced their ultimate decision, while 30% felt it had definitely influenced their treatment decision.

When asked if they had found any of the information worrying, 82% said they had not.

Views on the treatment decision

None of the patients and diagnosis of the patients were asked if the IVD had changed their choice of surgical treatment, only 12.5% said it had. Of those who were asked whether the IVD or adjuvant therapy changed the choice they ultimately made, 14.2% stated it had.

The majority (85%) said that the IVD had not changed their adjuvant therapy choice.

The majority of patients (81%) in both arms of the study stated quite clearly that the doctor made the treatment decision by taking it on his own (21%), sharing the decision with the patient (15%), or sharing the decision with the patient and clinical nurse specialist (44%).

The clinical nurse specialist featured strongly in the decision-making process, only 10 patients (11%) stated that they alone made the decision on the choice of treatment option (Fig 2).

When patients were asked how they felt about the treatment decisions that were made, 75% were happy or very happy with no statistical difference in either group. When asked their feelings about the amount of information they had received, 72% were satisfied or very satisfied.

system did not significantly increase their satisfaction with the choice they made. Both groups were largely satisfied with their choices and there was no statistically significant increase in the satisfaction expressed by the IVD group compared with the controls.

Role of clinical nurse specialist

Although the sources of information used varied in each arm of the study, the support of the clinical nurse specialist was constant and the patients in both study groups were satisfied with the tools used in information-giving.

The study therefore demonstrates quite strongly the supportive role of the clinical nurse specialist, and it may be that this support, rather than the information tools used, was of primary importance.

Luker et al (1995) suggest that providing detailed clinical information is not within the scope of the average ward nurse but may well be appropriate for the specialist breast care nurse. This study appears to support this possibility. The fact that 44% of the patients regarded the clinical nurse specialist as being involved in sharing in the decision-making gives an indication of the strength of her input.

The comprehensive, individual support the patients received from the doctor, the clinical nurse specialist and other health care professionals may be the key factor in satisfaction and adjustment rather than the specific method of information-sharing used. Health care professionals also have the ability to gauge a patient's mood and assess her requirements, which a machine cannot do.

Costs and benefits

The IVD was evaluated very highly but it is expensive in a number of ways: there is the initial capital purchase, the need to update the software regularly, the need for a dedicated room during viewing of the programme, and the associated staffing costs.

If cost is a major issue for carers, less expensive forms of technical inform-

Discussion

In this study, provision of information to women with early breast cancer using an IVD system did not significantly influence the degree of anxiety and depression associated with diagnosis and treatment in comparison with the best standard practice. Both the control and experimental groups showed a significant reduction in anxiety by nine months post-treatment.

Providing information to women about treatment choices using an IVD

tion support could be used — provided that the appropriate support from all the health care professionals was available, for example, literature, cards, other computer software or a standard linear video dealing with specific scenarios.

Nevertheless, the IVD provided consistent protocol-based information of uniformly high quality which it would be difficult for health care professionals to match, given the stresses of their working week. With the IVD, health care professionals can demonstrate by means of a print-out that a certain level of specific information was presented to the patient and that this was reinforced both verbally and in writing by the clinical nurse specialist.

Health care professionals still have the problem of knowing exactly what impact stress and selective perception are having on the patient. How much information the patient has absorbed at the time may never be precisely assessed and the method of information-giving may not be correct for every patient. The IVD system provides a safe vehicle for facilitating the informed consent process — not only for giving information so that risks and benefits can be assessed, but also for giving very technical information about taking part in a clinical trial (Graham, 1992).

Quality assurance, audit and litigation

However, SDP/IVD systems are not only about offering patient choice; they could also be a valuable resource for standardising treatment protocols, promoting evidence-based practice, helping collect valuable clinical research data and providing a measure of quality assurance (Cancer Guidance, 1996a; Kasper et al 1992; Mulvey, 1994). These additional functions may justify the expense incurred by the provision of these resources.

The system could also facilitate protocol-based practice, but would this be acceptable to most doctors? It would be interesting to discover how many

hospital-based consultants would support the widespread introduction of an IVD system and whether they would change their practice in line with their patients' satisfaction with such a system.

This study suggests that — given the presence of supportive clinicians — the answer would be 'yes'. However, enthusiasts for SDP/IVDs tend to be quality assurance officers, patient information groups or nurses — the very people who often lack the authority or resources to make tangible change in the health care system.

Is there, then, added value if SDP/IVDs are used for data collection, quality assurance and medical audit? This hypothesis needs to be tested, but it is possible that the IVD, with its very specific and uniform delivery of information, could act as a tool to safeguard the multidisciplinary team against litigation.

The IVD ensures that a quantifiable amount of information has been provided for the patient. It cannot ensure the information has been received but it can be used to substantiate the fact that certain information was covered. This could be particularly useful for patients who are being asked to give consent to taking part in a trial.

Conclusion

The IVD is an expensive tool in terms of its capital cost, the need to constantly update it, and because of the staff required to operate the system.

It appears that the provision of psychological support and information on treatment given by a doctor and clinical nurse specialist trained in communication skills can provide an equally satisfactory service. Had the IVD been evaluated in a centre where the doctor did not communicate well with patients and where the services of a clinical nurse specialist were not available, the results for the two groups could have been very different. **NT**

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Output 3

Maslin, A., Powles, T. 1999, Ed.

'Breast Cancer, Sharing the Decisions', Oxford University Press, Oxford

(NB Full Text to be found in Vol. 2 of the submission)

reviews

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Breast Cancer: Sharing the Decision

Eus Anna M Masim, Trevor J Powles



Oxford University Press
£24.99, pp 263
ISBN 0 19 262967 0

Rating: ★★

As we enter the new millennium, patients reasonably expect to be involved in decisions about their treatment, but engaging in this process is not easy for healthcare professionals. Each patient is individual and must be provided with information and allowed to participate in the decision-making process to the extent that he or she wishes. For patients to be involved, there must be effective communication between healthcare teams and patients

who must be able to access appropriate information about their illness and the treatment options available in a form that is understandable to them. This is the basis of truly informed consent. However, the participation of patients raises a potential ethical conflict between the right of individuals to be fully informed about their illness, and the risk of causing distress by giving this information to vulnerable patients. Nowhere is this better exemplified than in the diagnosis and treatment of breast cancer.

If women with breast cancer are really to participate in important decisions about their surgical management and adjuvant therapy, they have to assimilate a large amount of unfamiliar information in a short time, during which they also have to deal with the emotional turmoil associated with their recent diagnosis. Providing them with support and guidance so that they can decide which treatment is most appropriate is quite a challenge. This task can only be accomplished by a multidisciplinary team, as no one doctor can have all the necessary knowledge and skills to facilitate this process.

Breast Cancer: Sharing the Decision uniquely examines the complexities of

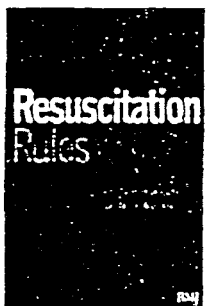
facilitating patient participation in treatment decisions. Much of the book is devoted to relating the experience of healthcare professionals involved in the care of women with breast cancer, but it also summarises the theory and research evidence suggesting that the integration of patients' values and priorities into treatment decisions can have a positive impact on treatment outcome and quality of life. A patient's perspective is conveyed in the form of anecdotal accounts of her experiences.

Although the book primarily focuses on patient participation in decisions about treatment for early stage breast cancer, similar issues are often encountered in the management of patients with other types of cancer or serious illness. I believe this book would be of interest and value to any healthcare professionals with a genuine desire to ensure that their patients are well informed and have the opportunity to participate in decisions about their treatment.

Peter Simmons *Senior Lecturer in Medical Oncology, CRC Messex Medical Oncology Unit, Royal South Hants Hospital, Southampton*

Resuscitation Rules

Tim Hodgetts and Nick Castle



BMJ Books £13.95, pp 106
ISBN 0 7099 1371 9

Rating: ★★

Cardiopulmonary resuscitation is a procedure that most medical and paramedical professionals are rarely, if ever, required to perform. A Dutch general practitioner, for example, is generally confronted with a resuscitation only once every 18 months. Most trained lay people will never deal with a resuscitation. In order to retain knowledge and skills, it is important to study and practise regularly.

Reviews are rated on a 4 star scale
4=excellent

This book contains 60 important rules for basic life support, advanced cardiac life support, medical emergencies, and paediatric resuscitation. In order to stimulate learning and encourage the retention of knowledge, this book is designed to make learning fun while providing easy to remember rules for a crisis. It systematically presents each rule, gives the reason why, and discusses the exceptions to the rule if there are any. The authors have found the right humorous and light tone and have left out the parts that are not essential for using the rules. The design is unusual and only otherwise used in a companion book *Trauma Rules*.

Resuscitation Rules provides a discussion of practical issues and pitfalls in the management of critically ill people, in order to prevent cardiorespiratory arrest. The content is based on the various 1998 guidelines from the European Resuscitation Council. The approach chosen has some clear disadvantages. It is fragmentary and cannot replace a standard textbook. For a reader who wants to place the rules in their theoretical context or to understand the rules thoroughly, this book will not be adequate. The fact that various rules are accompanied by some relevant articles only

partly remedies this limitation. Another disadvantage is the difficulty in retrieving information from this book. Although it has an appropriate index, readers are more likely to pick out a few pages at random. Therefore, the book should be considered as an additional help for a professional who is interested in a different angle and perspective and a number of relevant and easy to remember rules.

Despite the limits of its approach, the book contributes to learning about resuscitation. It will be useful for experienced and inexperienced professionals, and its pleasant design provides a nice stimulus to keep the reader's attention.

Bart Berden *director of medical affairs, Academic Hospital, Nijmegen, Netherlands*

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Output 4

Maslin, A., 1999, 'Sharing the Dilemma' in

Maslin, A., Powles, T. 1999, Eds.

'Breast Cancer, Sharing the Decisions', Oxford University Press, Oxford,

pp1-14

CHAPTER 1.

SHARING THE DILEMMA

The Patient's Dilemma

To set the scene for this book here is the true account of one patient's journey through her diagnosis, decision making process and treatment for breast cancer. It is her story and unique to her it does not represent the experiences of all women and yet there are themes, which recur in many accounts.. This patient was chosen at random not because her story was a 'good' experience or a 'bad' experience. As professionals we often only see in part what the patient experiences as a whole. On occasions it is sometimes helpful to see the situation from the patient's point of view.

Jane

Although my story may seem a series of catastrophes, at the beginning, for me, the experience proved to be a positive one. I went from being a passive accepting person to one who now feels much more in control and more positive. In 1981, our son went to prep school aged nine. Unfortunately he was unhappy there. It was a very traumatic and emotional time for us as a family. We told him at half term that he was going to leave the school but we all suffered for half a term while he was still there. It seemed like an eternity and during that time I began to feel quite breathless. Looking back I think it was just sheer angst. I went to the doctor because I thought perhaps I had a heart condition or something.

The doctor examined my breasts and said he had found a lump. It was about the size of a little dry pea. This was the autumn term and he suggested I came back before Christmas just to see if it had altered. By Christmas it hadn't changed in shape or size. I was quite happy with it and so was he so we did nothing about it. I was thirty seven years old at the time. I suppose I was quite young and so we felt confident it wasn't anything serious and left it. Within quite a short period of time I virtually forgot about it.

About five years later in 1986 I thought I'd better have a sort of an MOT and so I went off for a private well woman check-up. At the check up they noticed the lump and so I had a mammogram. The mammogram showed up little calcifications. As a result things began to happen fairly quickly and my own family doctor referred me to a specialist Cancer Centre. He was very supportive and said "Well, go to the best place. I know somebody there" so that's how it all started really.

I had a lumpectomy in June 1986 and was diagnosed with in situ breast cancer. To tell the truth I didn't really think too much about it. It was very painful but I recovered well and after two years I just let it go. I had lots of check-ups and my final mammogram was in May 1993. It was nearing ten years by then and all seemed clear.

I had my fiftieth birthday in November 1993, which was fantastic. I felt on top of the world although I felt quite tired. A week later I had a party. I had arranged for some girlfriends to come and have lunch with me. That morning at about half-past seven, I was rushing off because of the busy day ahead but I was conscious of having insistent little pains in my breast that I'd been ignoring. I'd been too busy. As I rushed

to the bathroom this little insistent pain came again and I popped my hand on my breast and felt a lump. This lump was different from the first one, it was like a knuckle. I felt it through my night dress. I whisked into the bathroom and said to David, my husband, "Oh God, I've got a lump". My first thought was, well I haven't got time to think about this today I'm far too busy so I just put it out of my mind, had everybody to lunch and then booked myself straight in to see my Consultant.

That was a Wednesday and I got into the clinic the following Tuesday. I wasn't overly worried because the Breast Unit had been keeping such a good eye on me and because I had, had the experience of in situ cancer and this lump was in exactly the same place. When I went up to the hospital I actually took a packed holdall with me because I thought they'd whisk me straight in, but no. I had a late appointment. It was a long time before I was seen so it was just before everything closed. The Consultant confirmed he could feel a lump but said "I think it's probably going to be hormonal, don't worry about it, come back in a month and we'll see how it goes". Because it was the time of the month, my period and everything I accepted this but when I was getting dressed I was suddenly overcome with this feeling, this is not right, did he feel what I felt? It was so obvious to me what it was so when I got dressed I called a nurse and said "I really need to talk to the Consultant again because I'm really not happy".

The nurse relayed messages and in the end the Consultant came out and spoke to me. I explained I really was unhappy about this lump and I just didn't feel that I wanted to wait for a month. I didn't feel it was hormonal. I felt it was something serious. The Consultant listened and said "If it is cancer I can absolutely guarantee it

will be in situ cancer so don't worry about it". I saw him on 23 November and my next appointment was the 7th of December so I waited that time to see whether it was hormonal or not. I felt very reassured by him being so definite.

I went back on the 7th of December and they then drew off some liquid from the lump. Once again I had a late appointment so everything was closed. I couldn't have a mammogram because the department was shut. The nursing staff were very good, they said well next time you come we'll give you a form and you can go and have the mammogram first so that I would have had it prior to the appointment. On the 14th of December I got the results and was told there was something amiss and so I had a core biopsy, which I think was clear. There was some contradiction here and so I had another appointment and my case was discussed with the Professor. They thought in view of my history I ought to have a biopsy although they were, even at that time, quite sure that it would be in situ cancer. By then I was sure there was something amiss but because I'd had in situ cancer before I wasn't bothered really. I went on a very nice holiday and my biopsy was scheduled for the 5th of January.

The day before the operation I went up to London and stayed the night and went to the hospital the following day as a day patient. I checked in and had all the usual checks before I went down to surgery. There was a backlog so I was on the trolley for a long time but that didn't bother me. While I was on the trolley, just about to go into the theatre the Professor came past and the person, I never did discover who it was, who was going to do the operation said to him "I'd like you to check this patient". So I was sitting the trolley with my notes on my knee and the Professor was sheafing through and decided, "in view of her history" he said "I just have a hunch, I

think you should go for it" and I kind of said "what does that mean" and he said I should have a wide local excision rather than a simple biopsy. I wasn't worried by this, in fact it felt good to be a part of the decision making process, I appreciated the fact it was happening there in front of me. Other people might think what an awful thing to do, you know, have your notes on your knee but I liked that, I preferred to be involved. Shortly after that I went in and had it done but I was surprised at how much was taken away. It seemed like a piece this size in my hand with quite a big scar.

When I came round I went back into the day ward. The events that followed felt like a nightmare. I realised that I couldn't take morphine because I hallucinate terribly. My blood pressure was very low. I lay there recovering but I felt very dizzy, sick, and I was in a great deal of pain. I had a suppository for the sickness and pain. At about four o'clock they came and sat me up but I was feeling dreadful. The 'powers that be' came round and said they didn't have a bed for me to stay over night. I felt that I had to get myself together enough to get home because they kept coming to check on me and saying "well I don't know, perhaps you will be okay to get home".

David came at five o'clock. It was decided that I was well enough to go home and he had to dress me. It was just dreadful. At that time I had the character that I wanted to please, I wanted to be okay, to fit in. I wasn't well enough to go home and I knew that. Feeling very sick I managed to get to the car. It's a two and a half hour drive home. I was constantly being sick into some bags I'd been given. I also had awful diarrhoea from the suppository. I hadn't been round from the anaesthetic very long. My scar was painful. It was about four and a half inches long and I was having to stop at service stations. I kept telling David I can't hang on I've got three minutes before I

just let it all out. I was going into these service stations on the way back absolutely feeling and looking like death, rolling into the lavatories coming out again, I mean, it was just horrific. I finally got back home and thankfully got into bed. It was late at night and no home care had been arranged.

I was at home until I went back on 14th of January to have my one continuous stitch removed. The pain continued and by the time I got up to the hospital quite a lot of fluid had collected in the wound. I realised then that was why it was so painful. When I was waiting in the cubicle for the fluid to be drained off a young chap stuck his head round the curtain and said "Oh Mrs ****, we're going to have to do some more surgery". Those were his first words to me before he'd even come in. David was sitting in the out patients because neither of us were expecting any unusual news simply that it was in situ breast cancer which we had coped with before.

So that was a huge shock. David was out there in the waiting room and I was in there on my own and I had this news that it was whatever, I can't remember exactly what he said but it was not in situ, it was invasive breast cancer and they wanted to have a look to see if it had spread. I remember looking at the nurse who was very sweet and supportive but it was like I'd actually gone into shock. I kept thinking well I've just got to cope with this. It didn't occur to me to say David's out there could he come in I was in too much shock.

My initial reaction was that I couldn't stand any more surgery just then because it was only, what, nine days since the last operation. I told them I couldn't bear the thought of any more surgery. I kept saying over and over I just I can't! They said well,

we'll make a date. It doesn't matter for a few weeks but we would like to do it fairly quickly. Looking back, at that point I should have been asked by someone if I had anyone with me? How was I going to get home? What was my situation? so that I could gather my wits and sort of say, "Oh yes, David's here I would like him to come in to be with me."

To complicate matters the operation diary had gone AWOL so I couldn't sort out the date. At that point I came out of the examination room, and went over to David. I think he saw the look on my face. We were both in shock. Because of the situation with the diary I then had to make my own appointment. For some reason it was very difficult to get through to the secretary. I did manage it in the end and we made an appointment for me to come into hospital to have the operation but this would be confirmed. I didn't hear anything from the hospital so after a while I did check up to see why I hadn't received confirmation. It was quite extraordinary. When I rang I was told that my bed had gone. I lost my slot because somebody who was more needy had taken it. They hadn't let me know, so we had to make another appointment for me to come in.

I did come in on the 27th of January and saw a really nice young doctor who was sort of preparing me. He did an examination of my breasts prior to the operation the next day. At that time I was very stiff, I couldn't get my arm up. I think I had so much scar tissue in the breast that the scar had shrivelled and my breast was all puckered up and pointing upwards. It looked a real mess. I felt it was horrible. The doctor bent over me and said to me, his very words were "Oh you have been unlucky here". As a result we got talking and talked about possible treatments and I suddenly

had this idea, I think I said, "Oh well, I might as well have the whole lot taken away it looks so awful." I then asked "If I have a mastectomy will I have to have radiotherapy?". The doctor looked at me and replied "no you wouldn't." So that set me thinking. I thought this breast looks so awful I might as well have it off.

The following day I had my axilla operation. I know this sounds like one long moan, but I didn't have a very good experience coming round from that operation because there were two people in recovery, a man and a woman, who were talking endlessly about the theatre, everything and anything, but not to me. Finally someone else came over and took charge she was absolutely super. I came back to the ward and recovered well. It was a Wednesday I think, but by the weekend, I realised that I really wanted to talk about having a mastectomy and what that would involve.

I got an appointment to see the surgeon who had done the operation but was somewhat saddened, at his reaction which was, what a pity it was I hadn't made up my mind before, because they could have saved on the surgery time and bed space and I could have had the whole lot done on the Thursday. I explained that I hadn't had the idea until the Wednesday and it was really rather close to have made such a major decision. I think he was very pressured. I could understand his position but I found it was the last straw. After he'd gone I burst into tears and the staff all rushed around. It was then I knew I needed to take control and it was then that I decided I wanted to know everything about what having a mastectomy would entail.

For whatever reason it was only at that point that I met the Breast Care Nurse who was great. For the first time I began to access more detailed information. I really

felt that I was being heard and began to get the kind of information and psychological support I needed. Another thing that happened was because I was so distressed they sent me a young man, I don't know who he was. He came and sat with me for half an hour and I was able to tell him my story about the day surgery and all the things that had gone wrong. I told him how I really felt and he wrote it all down in my notes. I really felt a lot better because it had been a series of kind of misses somehow and I'd coped with each one. I'd made allowances each time and then for me this was the last straw.

On the 4th of February I came back for the results of my axillary surgery and got good news the axilla was clear. So for me the prospect of further chemotherapy treatment seemed to be fading. David and I were so happy we thought we'd go down to the pub and have some champagne. We didn't actually get there because I was also given the news that because of the nature of cancer, they did want to give me chemotherapy. This was obviously another shock but this time I was being told in a more caring way. David was with me. I felt I had options, I felt I could be part of the decision making process. I felt it was presented very well, I was informed this is what they would like me to do, I didn't have to, but they recommended it. There was no problem except that the chemotherapy was the one thing that I had really dreaded.

Once I came home I rang Cancer BACUP and a friend who was a breast surgeon in Leeds who was brilliant, absolutely brilliant. It was at that time, I really began to get serious about having a mastectomy. My friend was brilliant. She gave me endless time, hours and hours, talking through on the telephone, the mastectomy the possibility of reconstruction, chemotherapy, radiotherapy, and just everything I

wanted to know. She was absolutely brilliant. I did want to know all I could. I really felt I wanted to make a decision for myself, with guidance obviously, but I felt it needed to be an informed decision. I read lots of material I had pamphlets from a variety of sources.

When I saw the surgeon next time, I said that I had decided I would like to have a mastectomy and he suggested that I saw the Professor again to talk it all through. I think this time they could sense that I was really serious and that I really needed to go to the top. The surgeon suggested if I had a mastectomy I might want to consider an immediate reconstruction but I had decided I didn't want a reconstruction at that point. I felt if I was unhappy with the mastectomy after say, six months, I could perhaps have an implant then. The surgeon wasn't too happy. He said he would prefer to do the reconstruction at the same time and take it out if I was unhappy with the result. I knew I didn't want to do it that way round. I felt I could cope with a mastectomy but I wasn't sure. I felt like I was on the top diving board looking down into the swimming pool way beneath about to jump and not knowing how I'd land, or how I'd feel when I landed. The decision to have the mastectomy was like that. I didn't know how I'd cope. I thought I'd be all right but I really didn't know.

When I did see the Professor he said that if the cancer recurred then they would definitely give me a mastectomy and I thought I'm not waiting for that. I'd had enough. I had carefully considered all the possibilities. As the Professor spoke to me I looked him in the eye and said would you do this operation for me and he agreed. He informed me that the statistics for a lumpectomy, chemotherapy, radiotherapy was as

good as mastectomy and chemotherapy. I knew I had a choice and I felt happy that it was my choice, so we booked in, and on 23 February I had the mastectomy.

Strangely enough from then on I felt good about everything that happened. I felt I was being consulted, I felt I was in control. I had personal counselling for 'mind clearing' which was absolutely brilliant. We had some really wonderful sessions about chemotherapy because I was very frightened about having it. It seemed to me that being sick was the only thing that seemed to stop me in my tracks. I hated feeling sick. It was a big thing for me to accept chemotherapy but I felt I needed to give myself and my family every opportunity for me to remain well. I wanted us all to know that I had done all I could, so that if I had died, there wouldn't have been a question mark for them of if only she'd had the chemotherapy.

For me once the chemotherapy was completed that was the end of all my treatment. I had the mastectomy prior to the chemotherapy and I had the most beautiful scar. After the operation I had the physiotherapy provided by the hospital but I was also able to arrange some locally. I felt physiotherapy once a week was not going to be enough. My local physiotherapist massaged my scar. She gave me the confidence that I could stretch and not do any damage. She tailored a programme of exercises for me to do. I took it all very seriously spending at least half an hour a day and that paid off well. I was worried about possible scarring, I didn't want a repeat of my first experience. We really took care of the scar and I'm so pleased with the result.

The Professor made a comment about the scar when I saw him in the outpatients department. I can't remember what it was exactly but the words were was

so valuable to me. When I'd had the lumpectomy the first time I saw the scar was when I took the dressing off at home. I nearly fainted because it was such a shock to see the scar, which seemed so long. I was so upset I felt cold and clammy and had to go to bed. After the mastectomy, I had a transparent dressing on my scar so I was able to look down and see it straight away. I know that wouldn't suit some people but for me it was brilliant because there was nothing hidden. There was nothing I had to steel myself to see. Another important aspect for me was that when I came round from the operation I could take the cover off to look down the flat chest on that side. It wasn't a shock because I remembered pre-puberty. Odd as it may seem I felt I'd only gone back in time. For me it wasn't like losing a limb that you've always had, it was quite different and it really helped me a lot to realise that.

I never did have a reconstruction. The Breast Care Nurse arranged for me to meet someone on the ward who'd had a reconstruction and have a look. The reconstructed breast looked very good but I still thought if I could go it alone without any other complications I would be happier. I preferred the simplicity and so far I am absolutely satisfied with it.

The experience of having my prosthesis fitted was good. My daughter came with me and she said "Yes, mum, that looks all right". For me there was no problem at all. It was all done in a caring but matter of fact way. I don't know why but the mastectomy was very painful because of the nature of the operation and the stretching of the skin to meet the old scar, but the scar itself never bothered me. When I came home a week after I'd had the operation, the first night I was at home with David, who was in bed. I just stripped off as I normally do and turned towards him to get my

night dress out of the bed not even thinking about it. He didn't make it an issue, I knew he was totally accepting and I somehow accepted it too. I think it was because I'd done all the work previously and it wasn't imposed.

Prior to the mastectomy I came across a useful psychological exercise in a magazine. What it suggested was if you were going to lose a part of yourself to work through the grieving process in advance. So that's what I did with my counsellor. I used to visualise my breast before it came away. I would visualise letting go of it, and saying goodbye to it, and really appreciating its usefulness, and all the rest of it, then letting it go. In the exercise it recommends going into the garden and burying it, making a hole and symbolically burying it. What I did was just to use the visualisation. I know this sounds very corny, but for me it was like my breast went away from me with tiny little sort of Christmas tree angels around it flying away with it. To tell the truth I do think that's helped me to do the grieving, saying goodbye, knowing that my breast was in good hands. After that for me the operation was a doddle. I can't really explain it. I was completely without worry, without fear, without embarrassment, without self-consciousness. It was quite extraordinary.

The Partner's Dilemma

David

When Jane was diagnosed with invasive breast cancer it was in many ways like picking up a thread because of her previous experience. In a sense it was like rediscovering where we were before and then going forward with it. The immediate

fear that everybody has I think, and it was in my case, in both our cases, is how we would view the continuity of life. There is the theoretical abstract reasoning but individually, personally, of course there's the immediate personal fear of "I'm going to be alone". I suppose most people would share that fear. Jane and I share a philosophy of life which has helped us face the prospect of death, but never the less, personal fears and hopes remain, so there is a real contradiction. It's not black or white, it's sort of feeling both things at the same time.

Jane was at first concerned primarily with survival and then later she took a more philosophical perspective. For me being immediately faced with the possibility of Jane's non-survival you wonder how it will be, how it will be for Jane, how it will be for me. You wonder, how will I cope, can I cope with the process, and can I cope with the possible loss? That's the sort of wondering, will I rise to our ideals, knowing that, theoretically, yes I could, wondering whether, in fact, I could.

In relation to taking part in decisions, with Jane, on occasions, I was not physically present to be support her. This was not through any fault of our own but because of the circumstances; for example when she was on the trolley just prior to theatre or when she initially received the diagnosis of invasive cancer. Having said that however, I felt very much that Jane was the one who basically needed to decide. I didn't ever feel that somehow I needed to make the decisions for her. I didn't feel very well equipped to make decisions for her anyway. I never felt that it was down to me to make the decision, to take it away from her because she was both emotionally and mentally, able to grapple with it herself. I saw my role as supporting Jane in whatever course of action she felt was right.

I wanted to participate in the decision making process by being there for Jane and on occasions giving my view but not in terms of feeling she must do this or she should do that. I thought very much that she intuitively sensed was the right thing to do. I was happy to support Jane in this way because I felt my view, was by definition mine, and therefore, slightly biased, which had to be in some senses.

One thing I did feel is that we could have had loads, loads, and loads more information both at the beginning and also through the course of events. The outside agencies, the outside help that we had, was tremendous but it wasn't through the system, it was through BACUP and through a friend who was a breast surgeon. Gathering information wasn't a coping strategy in itself for me. I didn't think that activity was the solution but without adequate information you can't make a reasoned decision. In terms of seeking out the information it was very much Jane who was doing the searching and I was there as a support. She was the one who actually did the pursuing and my impression is that the information wasn't easily available.

As the husband I felt I was not given the information that would have been helpful not just in terms of anatomy or treatments but also in terms of support. As it was, Jane felt able to pursue her information needs and she was able to take control. If Jane had been a different person someone who was unable or unwilling to access what she needed then that might have forced me to take a more proactive role. I felt that if she needed me to then I would have had to become involved although I expect I would have found it quite difficult.

There seem to be a combination of factors which make accessing information difficult. Hospitals and doctors are obviously busy people but there is also this culture of being busy, if you understand what I mean. The view seems to be the busier you are the more important you are. Oddly on the whole it doesn't apply to the nurses. Nurses were very good indeed. They had the time but were not always in the position to have all the information or take the decisions. In my view I think that probably there needs to be someone who has the time and expertise to answer the clinical questions, someone to provide the emotional support and someone to answer the day to day queries. The whole information issue seems to get jumbled up as one. Questions on hospital visiting times are not questions the clinician wants to spend time answering but there needs to be someone set aside who can answer these sort of disparate problems and then the clinician can concentrate on key issues like the prognosis which you really need to have answered but they never seem to have the time to address.

Sometimes key appointments with the Consultant only lasted five minutes. Our consultation when Jane discussed the mastectomy with the Professor was longer although admittedly a lot of that time was in deciding whether he could find the time in his diary to do the operation. The hard core discussions on the kind of issues like prognosis, like options, like risk, like probability of success and so on were very, very brief. There was a lot of time spent doing other things rather than spent actually giving you the information or the answers to questions. In our case we had filled these information gaps from outside sources but this is not always possible. Another issue professionals should take on board is the effort and time it often takes patients to get up to hospital especially if they have travelled a long way. To wait for prolonged

periods and spend often a very short period of time with the doctor is not really acceptable.

At the key appointments I would have preferred a clearer explanation of options rather than saying we recommend this and leaving the patient to then come back with questions like: “well what about so and so and what if so and so and what about so and so” which, in that style of interview situation you can't think of. You often only think about the key questions afterwards. If professionals were more analytical in their presentation for example more willing to say, these are the options; a, b or c; with a. the implications are i,ii & iii but with b. it is i, ii, & iii etc. and you also need to consider x, y, & z, it would be much clearer. Often it seemed to me they were shooting from the hip. They may have been analysing the information themselves but I don't think they were thinking about presenting it logically. They would give a recommendation, a view and that was it, not a multiple view. I suspect this way of working is not deliberate. It's sub-conscious. As it stands based on the information we received at the hospital without the additional information we accessed we were not given adequate information on which to actually make a reasoned decision.

Another difficulty in the area of decision making is that if you do have reasonably full information you may choose an option which is not the doctors preferred choice. Our experience is that some doctors are not genuinely open to free choice in areas where a legitimate choice could be made. I think they would much rather you do what they recommend. I mean, in the case of reconstruction, for example, the whole idea that you should not have reconstruction is considered extraordinary. Why? Jane for valid reasons did not wish to have a reconstruction.

They found this hard to accept. What was the basis for this fixed position? There was never any reason given for it. There wasn't look, this is the situation you can do this or you can do that. It felt at times that if you went against their guidance, in a sense they were taking it a bit personally. It seemed to me they felt it was like a personal affront to their professional judgement. Their professional judgement is this and if you choose that, well, you know, you are rejecting my advice.

In my view in areas where there is genuine choice, where there isn't an absolutely right or wrong answer, if you are the sort of person that wants to be involved in the choice, then you need to have that information. You need the information, the information takes time and, of course, it means that you're liable to have your advice rejected.

Jane & David's Adult Son

All the information I had about my Mother's breast cancer was relayed to me through my family, mainly through Jane and that tended to be based on what was happening at the time. In other words she had got to a certain point and then I was told this was what was happening next. Jane shared her thoughts with me for example that she had decided to do this or that and my response was reactive to the situation rather than seeing how any of the decisions were made.

The year prior to Jane being diagnosed a very good friend of mine's mother was diagnosed with breast cancer. She had had to take an active role but that was

more because she had to convince her G.P. she had a lump, she was sure it was cancer and she needed treatment. Jane's experience was dealt with in a totally different way. Sadly my friend's mother is now dying. Over all, for me, it was a more positive experience because I saw the experience as more to do with getting well although it was quite traumatic at the time. I even gave up smoking which pleased Jane.

I only went up to the hospital once and that was enough. I felt quite distant and more reactive. Jane seemed to have everything under control and my parents would update me as necessary. I never felt the need to actively seek any information. At the time, it seemed right. Looking back however, it's always better to understand what someone is going through, so yes, in retrospect, to have been more involved, and more fully informed may have been better because my view was based on this one view in my head which related to my friend and his mother.

On the whole I think I coped well. I guess I realised that Jane was finding out an awful lot of information. She was very well informed and therefore was able to answer my questions. She gave me the impression the situation under control. I do have a sister but at the time she was abroad so I didn't have the opportunity to talk to her about the situation. I realise now Jane had some fairly traumatic experiences initially but at first I wasn't totally aware of what was going on but that is partly the way Jane is. She doesn't want to worry anyone so she won't tell anyone what's happening until she has an idea of the outcome so you aren't overly involved. I didn't really understand exactly what the situation was until after the event and that sort of goes back to what I was saying to start with, it was more being updated on what was happening and what had happened and the dilemmas involved.

Postscript: Jane is keeping well, looking radiant and her family remain a constant source of support to her.

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CHAPTER 2

ETHICS AND ACCESS TO INFORMATION

It may seem dry and uninspiring to look at the impact ethics has on a patient's ability to access information but the ethical position adopted by society and health care professionals can have a profound effect on a woman's ability to participate in treatment decision making. Today it would appear patients in the West automatically have this right. The premise that underpins the right of a patient, in this case a woman with breast cancer, to access information (or be protected from it if she wishes) is based on a number of ethical principles e.g. beneficence (a duty to do her good) non-maleficence (a duty not to do harm) and respect for autonomy, to accord to the individual the full rights of self-determination (Glover 1990, Waldron 1990, Gillon, 1992). There are two main moral theories Deontology and Utilitarianism (Ross 1930, Kant 1964, 1972, Mill 1962, 1974). These patient rights are interpreted differently depending on whether a deontological or utilitarian perspective are adopted (Kant 1964, 1973, Mill 1962, 1974). Unless a case can be made for a woman having the right to access the information on which treatment decisions are made and which can impact on the quality and on occasions her quantity of her life the issue of how a woman copes with different treatment options becomes immaterial. This section aims to review ethical principles which underpin a woman with breast cancer's right to access information or be protected from it.

a, DEONTOLOGY

The term deontology comes from the “Greek word 'deon' meaning duty not from the Latin 'deus' meaning God” (Gillon 1992, p 14). It has come to represent the group of theories which are concerned with duty based ethics. These theories focus in on the intrinsic rightness of an action (Kant, 1964, 1973). The essence of morality depends on a person acting according to certain principles, which are their duty (Ross 1930, Gillon 1992). This belief that a person simply by existing is owed certain rights, (MacDonald 1990) can either come from a philosophical belief in a form of natural rights (Kant 1964,1973, McCloskey 1965, Feinberg 1966/67) or it could be a directly prescribed belief from a religious conviction (Calvin 1960, Tournier 1957, Cook 1983, Stout 1990 p109-163). It could be argued healthcare professionals have a duty to tell patients the truth, if a duty to tell the truth generally, exists in society (Kant 1964, 1972, Glover 1990, Waldron 1990, Gillon 1992).

MacDonald(1990 p31) states “The word ‘right ‘ has a variety of uses in ordinary language, which include the distinction between ‘legal right’ and ‘moral right. A has a legal right against B’ entails B has a duty to A which will be enforced by the courts. A has a claim against B recognised by an existing law. No person has a legal right which he cannot claim from some other (legal) person and which the law will not enforce. That A has a moral right against B likewise entails B has a duty to A. But it is not necessarily a duty, which can be legally enforced. A has a right to be told the truth by B and B has a corresponding duty to tell A the truth. But no one, except in special circumstances recognised by law, can force B to tell the truth, or penalise him, except by censure, if he does. No one can, in general claim to be told be truth, by right, under penalty. But a creditor can claim repayment of a debt or sue his debtor“

Telling the truth may cause harm, for instance psychological suffering and therefore an alternative duty, the duty to do no harm, or non maleficence should take precedence (Tobias 1988). This can be seen for example in this illustration; If we cannot cure all cases of breast cancer does a national breast screening programme help women by encouraging them to come for treatment earlier or does it simply give them more years to worry about the disease. Does the psychological harm in this case outweigh the benefit?

The Classification of Deontological Theories

Deontological theories are concerned with types of actions rather than with individual action (Kant 1964, 1973, cf Beauchamp and Childress 1994)

i, Kantian philosophy/Rule Deontology

Immanuel Kant was a Prussian philosopher. Although he held Christian beliefs he was convinced a duty based theory of rights could be hypothesised and defended independently of a faith in the existence of God or religious based ethics. “Kant believed that the truth of his moral theory was a necessary consequence of the rational nature of human beings. He believed that he could prove that any rational being necessarily recognised himself to be bound by what Kant called “the supreme moral law” (Gillon 1992 p16). This perspective suggested that consequences are not the issue when it comes to moral actions. All duties arrive from two universal principles (Kant 1964, 1973);

In summary Kant’s view holds:

Kant expounded 'The Principle of Universality' that individuals must: a, act as though your action could become a universal law applicable to all men. and b, never treat yourself or another person as a means to an end. Kant developed a series of 'Deontological Precepts' which in summary included:

i, To be moral a person must perform their preordained duty whatever the consequences.

ii, Some actions/obligations are right and good in themselves without regard to their consequences. They are not based on the ability to calculate consequences but on human reason. Because of this premise philosophers have gone on to argue that generally it is right to save life rather than to kill (Glover 1990, Gillon 1992).

iii, Although it is important to consider the consequences of action, some duties are supreme and have abiding importance e.g. telling the truth or keeping promises. These duties are moral in themselves and just ought to be done by people. Although a woman may suffer by having the knowledge that she has a cancer diagnosis it could be argued denying her the truth would cause greater harm.

Kant (Metaphysics of Morals) held that 'to duty every other motive must give place because duty is a condition of will good in itself, whose worth transcends everything' and that 'a truly moral act is not influenced by self interest, nor by consideration of overall social benefit. The key to morality is that the person who is acting must do so out of pure motive of doing their moral duty.'

The 'Kantian Categorical Imperative' promoted the view that :

1. Act only on that maxim which you can at the same time will to be a universal law.

2. Always treat human beings as ends in themselves and neither as a means to further ambitions and ends of others.

3. Act as a member of a community where all the other members are 'ends' just as you are (Kant, 1964, 1973).

These principles provide the basis of Kant's deontological theory which he believed allowed for equal respect for persons inspired by ideas of impartiality and forces a person to examine their conscience. The concept of 'ends' provides a standard by which to assess if an action is right or wrong. If mutual respect operates this should allow freedom in decision making. On the other hand it could be argued that it is impractical for certain duties to become universal laws.

How realistic is it not to take account of the consequences of actions? In the case of a woman with breast cancer it could be argued from this point of view that the woman may not have an intrinsic right to the truth because it may potentially cause her psychological harm through fear or worry). There is also a problem with the concept of 'ends'. There is often a conflict between theory and reality. Resources are not unlimited and therefore decisions are often made which consider more than the person as an end in themselves (Williams 1973).

Failure to Observe the Precepts results in; standards being bent or overruled leading to a 'slippery slope' where responses are made contingently according to what seems to be right at the time (Beauchamp and Childress 1994). If basic duties are shunned some individuals could rationalise immoral acts in pseudomoral language. For example: If a clinician finds it personally difficult to cope with the strong emotions a

woman may express at the time of her diagnosis with breast cancer he may choose not tell a patient the full facts of her disease and he may rationalise this to himself by concluding it was not in her best interests to know such distressing information. Kant (1964, 1973) suggests even if it appears better to break faith in the short term the consequences will not be better in the long term. 'Breaking faith' in this context would be the clinician making the decision not to tell the truth. The short term benefit of the patient not knowing harmful information may result in her confusion when toxic or disfiguring treatments are suggested and/or her loss of trust in her clinician if she eventually discovers he with held information from her.

ii, Act Deontology/A Critical modification of Utilitarianism

There are times when duties come into conflict e.g. it may be right to tell the truth but if a terrorist asks me where my child is I may refuse to tell the truth in order to save my child. Utilitarianism holds that the rightness of an action is based on the consequence of that action. There are duties in which there is a special relationship between the duty and the outcome. These duties are variable but often include duties of telling the truth, paying a debt, and being just. Scanlon (1990 p137) stated deontologists "frequently call attention to the abhorrent policies that unrestricted aggregate reasoning might justify under certain possible, or even actual circumstances. They invite the conclusion that to do justice to the firm intuition that such horrors are clearly unjustified one must adopt a deontological moral framework that places limits on what appeals to maximum aggregate well-being can justify."

With this form of deontology;

*principles and duties for actions are not defined beforehand.

*There is no onus to follow rigid rules.

*The focus of moral action is not on rules but on informed human judgement in the context of each situation.

*Each situation is unique.

*Everything in morality rests upon the person who is to judge or decide.

*The overriding duty in act deontology is for a person to be true to themselves (Ross 1930).

The advantages of this position are that a person is seen to be true to themselves, the uniqueness of each situation is acknowledged, it claims to explode the myth of professional vs. personal conflict because the professional is duty bound to accord the person i.e. the patient their full rights. The disadvantages are that it can be impractical (Could any health care system incorporate this theory?), it makes the assumption that everything about a given situation is unique and who is to make the judgement about the duty owed in any particular situation)?

For the woman with breast cancer this could mean that there is no general onus on the part of health care professionals to tell the truth to the patient and therefore the patient is left facing a situation in which the healthcare professional takes decisions and makes judgements based on their own assessment of each individual patient.

Merits of Deontology

Deontological theory has an advantage in medical ethics. Actions as a result of this theory are predictable and standardised therefore there should be a high code of clinical practice,

1, Deontology seems closest to what could be described as ordinary daily ethics. In the Western World it is generally held that the truth must be told, people must not steal, justice is desirable and autonomy should be respected. This reasoning would appear to support the view that rational patients should have their autonomy respected and therefore be given whatever information they request in order to enable them to make considered treatment choices (Gillon 1992, Maslin 1993, 1994, Baum 1994). This position does not exclude the possibility that some patients may choose to exercise their rights by delegating them to their clinician and this too is a valid treatment choice (Ingelfinger 1980, Maslin 1993, 1994, Baum 1994, Fallowfield, Hall, Maguire, Baum 1990). There will also be for some an inability to express a rational treatment choice whether as a consequence of mental or physical impairment.

2, Deontology acknowledges the diversity of moral relationships. Moral life is not seen just in terms of a means/end relationship, but as wealth of moral relationships e.g. parent/child, husband/wife, employer/employee or doctor/patient all which generate a different set of rights and duties (Ross 1930).

3, Deontology acknowledges the importance of the past in generating moral duties. Duties can be owed because of promises or because of a previous relationship e.g. he promised to marry her or the doctor promised to treat the patient.

4, Deontology seems able to give the best account of justice, which seems to underpin society.

Problems with Deontology

i., What happens when there is a conflict of moral duties? Which duty takes precedence to tell the truth or to protect from psychological harm e.g. to tell an asymptomatic woman she has metastatic breast cancer or to wait until she reports a problem? Ross (1930) distinguishes between prima facie rightness and actual rightness. An action is decided upon based on weighing up the situation. Some writers developed a 'lexical ordering' deontological duties. In this approach some rules or duties take precedence over others (Rawls 1958).

ii., Does deontology leave the individual with a plethora of confusing ultimate principles (Kerner 1990)? It could be suggested that the theory merely reflects the complexity of actual morality rather than trying to oversimplify reality. It is impossible to argue for absolute guide-lines in truth telling for every individual. The Cancer Research Campaign Working Party (1983, p1118) accurately stated "To have a right is one matter. Choosing to exercise it is quite another. There will be some (perhaps many) who will decline to be fully informed but this pragmatic consideration cannot modify the intrinsic nature of the right itself. It is only the person who possesses the right, in this case the patient, who can decide whether she wishes to exercise it."

iii., Does deontology result in the complete divorce of duty from action? If this is the case a person could in theory do his duty but cause considerable harm to others

in the process. This is not in essence the case a deontologist regards morality as a necessary part of a good life not simply a means to it (Kant 1964, 1973).

b, UTILITARIANISM

Utilitarianism is a subset of consequentialism classically associated with the goal of happiness or pleasure (Sidgwick 1907, Bentham 1948, Mill, 1871, 1962, 1974). For consequentialists the rightness or wrongness of an act can only be judged on the grounds of whether its consequences (actual or intended) produce more benefits than disadvantages.

For utilitarians the essence of morality from this perspective rests upon a calculation of the benefits and disadvantages of the consequences of actions. Bentham's classical statement said 'A person should attempt to achieve the greatest happiness of the greatest number'(Bentham 1948). For Bentham the sole intrinsic good is pleasure and the sole intrinsic evil pain. Other things are only bad or good in so far as they produce pain or pleasure (Hedonism). The aim is to maximise (maximisation) utilities like pleasure, happiness, and fulfilment there by minimising negative quantities like pain, suffering and misery.

The Classification of Utilitarian Theories

Utilitarian theories are concerned with consequences of actions rather than with the duty owed to an action.

i, Basic Utilitarianism

In this theory good, evil, happiness and pleasure must be quantifiable. The decision making agent must be considered of equal importance as others in the assessment of good, evil etc. Agents must be impartial, disinterested, benevolent and sacrifice self-interest to the general good (Mackintyre 1980, Singer 1994).

ii, Act Utilitarianism

In every situation an individual should assess which of the acts open to them is most likely to produce the greatest amount of good or evil, however defined, (maximisation) e.g. telling true but potentially upsetting information - one would be obliged to weigh up the pros and cons of telling the information in terms of the likely outcome, mental, physical and social, to all concerned. Should women who carry a genetic predisposition to develop breast cancer be given this information? As the disease cannot for the present time be prevented nor can all cases of breast cancer be guaranteed a cure (Powles and Smith 1991) this information is potentially harmful to the woman. She could be burdened with frightening information over which she has little control and which could affect her career prospects or eligibility to procure life insurance. The woman on the other hand may feel it is her right to know so she can exercise her autonomy by taking action to try and safeguard her health or decisions regarding her fertility and whether or not to have children who may also carry the gene(s).

Act Utilitarianism can be seen as a form of opportunism in that it may allow evil actions to take place if the action produces more good than evil in the end. It may have the effect of diminishing professional integrity e.g. If an antiemetic agent was in

short supply and a wealthy person said they would fund more supplies provided they received treatment first, one could argue that the ends justify the means? The theory however is difficult in practice because we cannot actually make utilitarian calculations in an unbiased way. In healthcare this mode of reasoning could result in reductions in service, reduced standards of care, the introduction euthanasia, involuntary euthanasia and infanticide if it could be argued that a greater number of individuals benefit than are harmed (Gillon 1992).

iii, General Utilitarianism

This is similar to Act Utilitarianism but incorporates the concept of Kant, when a decision is made one must consider what would happen if everyone did as they proposed (Beauchamp and Childress 1994).

iv, Rule Utilitarianism

This stresses that obedience to certain rules are fundamental to morality. Rules of conduct are established by calculating the greatest balance of good and evil. Emphasis is placed on keeping certain rules, which produce the greatest good in the long-term. If on balance ignorance of distressing information protected a woman with breast cancer from gross psychological harm then in spite of her personal desire to acquire knowledge that knowledge could be withheld from her (Kerner 1990).

Merits of Utilitarianism

1, Utilitarianism claims to eliminate the mysterious and non empirical. It is a secular philosophy and therefore not bound by religious precepts. Difficulties with the theory could therefore be suggested to be technical and not fundamental.

2, If suffering is evil and happiness is good (Bentham) then the aims of utilitarianism are clear they are based on a linear continuum. It is suggested there are no competing principles as there are at times with deontology.

3, Utilitarianism "claims to provide a consistent and reliable procedure for making decisions in one or other variant of the hedonic calculus." (Gillon 1992,p23)

Problems with Utilitarianism

a, It is possible for the situation to arise where an individual's needs are not met because the interests of the majority take priority (Glover 1990, Gillon 1992). An individual patient may request information but that request could be rejected because it is in the interests of others (e.g. clinicians, family, society or science) not to disclose to the individual the full facts of her case. This can easily result in the "individual versus society" conflict (Rawlings 1992, p30).

Another manifestation of this type of reasoning is the 'Quality Adjusted Life Year' (Williams 1973). This is a calculation to decide which treatments provide the greatest benefit to patients at the lowest cost. This means an operation like a hip replacement may have a high priority because, it is relatively inexpensive, provides excellent surgical results, enables an individual to enjoy many years of pain free

mobility but a treatment like renal dialysis, which is expensive and non-curative, may not. Another facet to this is that only those who are known to benefit are offered treatment. This may mean that the elderly and patients with metastatic breast disease may not be selected for expensive treatment with a variable success rate.

b, Utilitarianism may increase favourable consequences but those acting may be motivated by evil or immoral intentions. Utilitarianism can be seen as morally objectionable (Kerner 1990, Gillon 1992). It is possible for the innocent to suffer or for torture to be justified. Utilitarianism leaves out key elements like justice.

c, Another difficulty is that utilitarian calculations cannot always be performed. Utilities are not always quantifiable. How can one judge which of two women with breast cancer is more valuable, needy, worthy etc. and therefore should take precedence over the other. The consequences of a utilitarian action are not always simple to measure and evaluate (Gillon 1992).

It could be suggested that the application of one theory in every situation is not appropriate or adequate (Glover 1977, Calabresi & Bobbit 1978, Gillon 1992). Rules and principles often come into conflict. The analysis of principles is necessary in the context of a situation to see what is most applicable. It is important to consider alternatives and thereby weigh up their advantages and disadvantages. Decisions must be justified on the basis of appropriate principles or benefits of the expected outcome. The consequences must be fully considered including legal consequences for example

some may feel a person with poor quality of life is better off dead but the law in the United Kingdom does not allow for voluntary or involuntary euthanasia.

c ,AUTONOMY

Autonomy come from the Greek 'autos' and 'nomos' meaning literally self-rule or self-government (Harris 1985). This has been interpreted as the ability to think, decide or act freely without coercion or hindrance (Kirby 1983, Faulder 1985). Autonomy as a concept incorporates the notion of personhood (Lock 1690, Aristotle 340 B.C., Glover 1977, Benson 1983). Autonomy is an important concept when shared decision making is considered. It accords to the individual the right to information, which will enable him to make decisions about his own future.

Types of Autonomy:

There are many different types of autonomy and expressions of an individuals autonomy e.g.:

- *Autonomy of thought; to make moral assessments or decisions.

- *Autonomy of will; freedom to exercise ones will after due deliberation.

- *Autonomy of action; ability to execute autonomy of thought and will.

- *Autonomy is rarely absolute. Individuals are restricted by law, social conditions, respect for the autonomy of others, finance health etc. (Glover 1977).

- *Autonomy is determined by the individuals physical facilities. Environment plays a part in encouraging or discouraging autonomous behaviour. An individual must have the knowledge to pursue an end and select routes to that end and they must be rational enough to select appropriate ends. With this in mind how reasonable is to expect any woman recently diagnosed with breast cancer, to inform herself accurately

about her disease, prognosis, proposed treatment options their success/failure rates, then to weigh them up and finally after making a calculation of risk/benefit to come to a treatment decision (Thornton 1992)?

The Principle of respect for Autonomy

If a deontological perspective is adopted there is a moral requirement on us to respect the autonomy of others. This is generally accepted in western society but limitations are imposed when there is potential harm to others and in a limited sense to oneself (Gillon 1992, Williams 1992). Kant argued that autonomy and respect for the autonomy of all other autonomous agents were features of rationality (1964, 1973). Mill suggested that respect for autonomy was necessary to maximise human welfare as long as no harm was caused to others and where the individuals respected possessed a degree of maturity (1962).

How much autonomy does a person have to possess in order to be respected as a moral agent? Who decides how much autonomy a person possesses? In the case of the patient clinician relationship it is the clinician that continues to make the decisions. Patients now have the right to access information (Patients Charter 1992, NHS Executive Clinical Outcome Guidelines for Breast Cancer, 1996) but this right has the proviso that if the clinician feels it is not in the patient's best interest physically or psychologically this information can be withheld. Who is to make the judgements or decisions for those who are deemed to be non-autonomous or incompetent? Should we respect the autonomy of individuals in every case? Should respect for autonomy be maintained if it leads to harm for the individual. Should we respect the autonomy of the individual if it leads to harm for others? The British Medical Association sanction

the divulging of information concerning the diagnosis of Acquired Immune Deficiency Syndrome to the partners of those who are H.I.V positive on the grounds that harm may result if the partners can not protect themselves. All these questions raise awareness that respect for autonomy is not always straightforward.

Harris (1985) discussed the issues surrounding the disclosure of false or incomplete information. If a patient is deliberately given false or incomplete information this could be seen as negating their personal autonomy. The fact that the issues surrounding autonomy are complex does not alter the fact that a mature rational woman who has been diagnosed with breast cancer should have the facts of her case explained to her in the amount of detail she requests and should in collaboration with her clinician share in any decisions regarding her future treatment if she so wishes. This would be a tangible expression of respect for her autonomy (Maslin 1993, 1994, Fallowfield 1987, 1990a, 1994 a & b).

Baum, Zilkha & Houghton (1988 p253) summed up the view of many clinicians "Autonomy, however, is not the only ethical imperative that should be considered, and perhaps an exaggerated regard for this single principle will put at risk not only the practice of scientific medicine but the whole concept of the doctor/patient relationship. Traditionally, the duty of doctors is to do their best for their individual patients (now the consumer) select according to their needs and desires. If a doctors are to continue to have the duty of care they must also bear in mind the other ethical principles when they treat each patient. For example non-maleficence-could informed consent come into this category since further information and uncertainties are forced upon patients at a time when they are feeling most vulnerable? Justice-should

information be given about treatments which if available would drain the resources of the health service so that future patients may have to remain untreated/”

The current trend in the United Kingdom and United States of America is to facilitate autonomy within the healthcare system (USA Commission 1982, The Patient's Charter 1992 , Williams 1992). The primary aim of healthcare continues to be the creation of circumstances in which personal autonomy and the ability to thrive and persevere can be achieved in spite of the trauma suffered (Seedhouse 1986). The Kings Fund (1996 p2) stated “ Individualised or patient-centred care involves as a fundamental principle, respect for a clients autonomy. The health professional works to empower the client through communication, information giving, involvement in (or devolvement of) decision making and support.”

The 'World Health Organisations' definition of health states (1977, p552) "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". For many individuals respect of their legitimate personal autonomy, however it is expressed, leads to enhanced mental well-being (Ingelfinger 1980, Kirby 1983, Thornton 1992,).

The Right to Refuse

It is acknowledged that stages of collaboration exist when patients are involved in decision Making (CRC 1983, Brooking 1989, Baum 1994, BASO 1994). This can be expressed by rational adults choosing to exercise their autonomy by being proactive and taking their own decisions (Thornton 1992) or by deciding they want to pass the responsibility for decision making on to a professional (Ingelfinger 1980).

A mentally competent adult has the right to refuse treatment and can take their own discharge contrary to medical advice. This refers to any kind of treatment, e.g. blood transfusions, surgery or chemotherapy, except in the case of harm to others. A mentally competent adult can delegate their autonomy (Ingelfinger 1980, CRC Working Party 1983,). Most competent adults usually make treatment decisions in consultation with health care professionals. It is also advised that psychiatric patients are consulted when treatment decisions are taken (1982 USA Commission). In the case of children informed consent is requested from the parents or guardians. Children should also be consulted. Parents/guardians refusing treatment on behalf of a child may have the child made a ward of court if the treating clinicians feel treatment is in the best interest of the child. Likewise emergency treatment can be carried out on unconscious patients if that is deemed to be in the patients best interests. Relatives have no right in law to refuse life saving treatment.

The majority of women diagnosed with early breast cancer are rational mature adults who are able to express a view on their desire whether or not to be involved in decision making about their disease (Maslin 1993, CRC 1996).

d, INFORMED CONSENT

There is now significant public and professional interest on the issue of patient decision making, access to information, and participation in the informed consent process (Wells 1986, Fallowfield, Hall, Maguire & Baum 1990, Patients Charter 1992, Klimowski 1992, Williams 1992, Maslin 1993,1994, Saunders, Baum & Houghton 1994). "The public is demanding the right to make informed decisions in most areas of

healthcare but lay person and professional alike are finding difficulty in giving the phrase 'informed consent' tangible practical meaning" (Maslin, 1994 p153)

Saunders, Baum and Houghton (1994) summarise "The first mention for the need for informed consent in medical practice came from William Beaumont in 1833, and was enshrined in the personal code of ethics of the 'father of experimental medicine', Claude Bernard, in 1856.

But the public took little interest in the issue of consent, either in routine clinical practice or research until after World War II when the horrendous experiments performed by the Nazi doctors on the inmates of concentration camps came to light. The public outrage and disgust engendered by these atrocities led to the formulation of the Nuremberg code in 1947, laying out guidelines for experimentation on humans. This was followed in 1964 by the Helsinki Declaration, last revised in 1989, which remains a code of ethics for those engaged in medical research on humans. Later statements include those by the Research Medical Council (1962,63), and the British Medical Association (1981) and the Belmont Report of the National Commission for the Protection of human subjects of Biomedical and Behavioural Research (1978)."

Barkes (1979) suggests informed consent is the right of every human being to determine what shall be done to his/her own body. Cardozo (1914) summed up, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; a surgeon who performs an operation without the patient's consent commits assault." This concept implies respect for the autonomy of the individual. Faulder (1985) suggests this can be defined as the 'individual's freedom to

decide his or her own goals. Inherent in this principle is the notion of personal responsibility.' The term 'informed consent' is frequently used to denote the interaction, which takes place when an individual consents to treatment or participation in research.

Informed consent has several components these include;

- 1, that the person is mentally competent/mature enough to give consent.
- 2, that the consent is given freely without coercion.
- 3, that the person is given adequate information on which to base their decision

(Kirby 1983, The Royal College of Physicians of London, 1986, 1990 a & b).

During a medico-legal case (Salgo,1957) it was stated the doctor had a duty to inform a patient of 'any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment'. Unless a woman has access to relevant and accurate information about her disease, treatment and prognosis how can she exercise her autonomy and give consent to treatment in any meaningful way?

A number of ethical principles are employed when due accord is given to the practice of informed consent. These include respect for the person, truth telling, justice and beneficence. The concept of 'informed consent' is an attempt to equalise or develop partnership in the relationship between clinician and patient by respecting the individuals autonomy (Kirby 1983).

Kennedy (1988, p213) suggests it is the question of information which "provokes the greatest discussion and raises the most difficult problem". A clinician owes a duty of care to his patient. This duty includes informing the patient of the most

appropriate course of treatment for that patient and all the information that he feels is necessary for a patient to make a decision. The clinician can argue that if provision of distressing information maybe harmful to a patient he may on his professional discretion omit to inform a patient fully. The clinician must however answer truthfully any question posed by the patient unless he deems it not to be in 'the patient's best interest' (Wells, 1986). "Should a doctor be found to have breached his duty to inform his patient, the patient may recover damages if he can prove that had he been given the information, he would not have consented to treatment, and that he has suffered harm as a consequence, in that a risk he was not warned of materialised (Kennedy 1988, p214). In the United States women with breast cancer constitute a group of health consumers who have initiated more open communication. In several American States physicians are legally bound to inform patients with breast cancer about breast cancer(Gantz 1992). "In these States, higher rates of breast conserving surgery have been found, suggesting that patient participation in medical decision making does have an effect on the type of treatment selected (Hack et al. 1994 p 279).

Kirby (1983 p69) suggests an informed consent "is that consent which is obtained after the patient has been adequately instructed about the ratio of risk and benefit involved in the procedure as compared to alternative procedures or no treatment at all." Some would suggest (de Vahl Davis, 1992, p13) this is virtually impossible and pose the question "Can professionals ever give enough information for patients really to know how they will feel if they consent to a procedure?"

Michael Baum has participated in the debate on informed consent for many years (Baum & Houghton 1986, Baum 1988, Saunders and Baum 1993, Baum 1994,

Baum, Saunders, & Houghton 1994). Baum (1995 p199) after discussing the value of informed consent argued "There are however, arguments on the other side. How can consent be fully informed? How can the patient without the benefit of six years of training understand the disease, and for that matter understand the logic of scientific empiricism? If you tell a patient we are really uncertain whether treatment A is better than treatment B, you undermine his or her confidence. Doctors like to practice beneficently. We do not like to frighten and alarm our patients. Yet when we do tell them our uncertainties and fully disclose to the patient the hazards of the disease itself and the hazards of the operation down to the finest detail, we cause them illness. We make them distressed and anxious".

Some patients (Thornton 1995, p 9f) argue strongly that patients often slip into stereotypical submissive roles when they interact with their clinicians and this is reinforced by the fact that they are in an unequal situation as far as possessing relevant information to make informed choices and decisions. Kirby (1983, p70) states "it is hard to define the expression 'informed consent' in a way that will accommodate all the ramifications of interpersonal relationship that can arise in a dependent environment of health care." It is for this reason other forms of information may be made available to equalise the patient information gap e.g. literature, visual material and audio recordings. Bond (1992 p.53) suggests "In medicine an increasing emphasis is being placed on consumer opinion with regard to what constitutes appropriate treatment. Doctors have realised that what constitute desirable patient outcomes should not be left to professionals alone, but should be viewed in the light of patients' needs and wishes".

It is the clinician who has the obligation to obtain informed consent but it is not a legal duty in the United Kingdom (Kirby 1983, W.M.A. Declaration of Helsinki 1964 Amendments 1975, 1983, 1989, Baum 1986, Wells 1986, The Patients' Charter 1992). This situation is further confused by the fact that nurses in the United Kingdom particularly specialist nurses caring for patients with breast cancer have taken on a role as information giver, advocate and assistant in the treatment decision making process (R.C.N. Ethics Related to Research in Nursing 1977, Lazewski, 1981, C.R.C Working Party on Breast Conservation 1985, Wells 1986, Copp 1986, Fallowfield et al. 1990, Maslin 1993, 1994). Melia stated (1986 p27) that "Consent to medical treatment is not an area in which nurses can ever truly be held responsible. It would perhaps be not only prudent but also morally sound to recognise this fact and leave doctors' business to doctors. The handmaiden image, from which nurses are striving to free themselves, is in danger of coming back into play in a positively dangerous way in the guise of a new found professionalism and the call of team-work."

Melia's comments are hard to reconcile with this current onus on nurses, especially specialist nurses to provide additional medical information to enable patients to make treatment decisions (Watson et al. 1988). This role and function is not straightforward and should never be taken on without appropriate education and support (Roberts & Fallowfield 1990). Melia correctly points out that if such functions are taken on by nurses they must be prepared to be legally responsible for their actions (1986).

Wells (1986, p22) suggested "Too often we make assumptions about the ability of patients to understand what is being told to them and this leads doctors and nurses

unwittingly (or otherwise) to keep important information from them". In the United States the concept of the 'prudent patient' (*Canterbury v Spence* 1972) has been adopted attempting to incorporate in law the view of the intelligent average patient when trying to assess if a patient has been adequately informed. Kirby (1983) strongly supported however the notion that if a patient did not wish to be informed this must be respected as this in itself is the expression of the patient's autonomy. The individual can exercise autonomy but it can also be delegated by the individual to her clinician.

Clinicians and nurses are expected to ensure patients are able to make informed choices when they consider conventional surgery or treatment options (Faulder 1985, Melia 1985, Copp 1986, Diamond 1990). Patients are also demanding the right to give or refuse consent to participation in clinical trials which may or may not benefit them directly based on full disclosure of information (Breast Care Nursing statement on informed consent, C.R.C Working Party in Breast Conservation 1985, Copp 1986, Baum & Houghton 1988, Tobias 1988, Feinmann 1988, Faulder 1992, Maslin 1993, 1994) but how can this requirement be met equitably and to the satisfaction of all concerned? Baum (1982, 1994) argued strongly that the management of carcinoma of the breast has been one of the most hotly debated subjects among surgeons in modern times. Patients are often not aware of the many areas of uncertainty and debate in the treatment of their disease. This raises the issue of how without readily available information in an acceptable format for the lay person can a patient be able to participate in decision making

Maslin, Powles, Baum, Ashley and Tidy (1993) aimed to survey by self completed questionnaires the experiences and opinions of 300 randomly selected

women (100 cancer patients in a clinical trial, 100 non-cancer patients in a clinical trial and 100 patients not involved in a clinical trial) attending a breast unit of their experiences when being asked to give consent to join a clinical trial and their opinions as to what they would consider appropriate to be able to give 'informed consent'.

The results indicated a number of areas in which the women were satisfied with the provision of information and support e.g. having good verbal/written information and having time to reflect prior to making any decision also areas where improvements could be made e.g. having more explicit information on side effects of drugs and treatment. When the patients expressed their views on their requirements, in relation to information and support, over 90% of the women responding wanted access to all the information and support listed including: verbal and written information, an indication of personal time commitment to the clinical trial,, outline of information the trial would produce, information on possible and probable side effects, physical and emotional discomforts, withdrawal rights, also wanting on-going information and support throughout treatment (Maslin 1994).

Kirby (1983) suggested "A recurrent feature of our civilisation is said to be respect for the autonomy of the individual human being, 'with inherent dignity and value' ". This respect for the autonomy of the individual is now being given tangible expression by allowing patients access to all the material facts which have a bearing on their medical and nursing care (Gillon 1992, Patients' Charter 1992, Silverman & Altman 1996). The mechanism of informed consent'(Kirby 1983, Royal College of Physicians Reports 1990) is also a safeguard to this autonomy.

Informed consent has been summed up as 'adequate disclosure from the informant met by adequate understanding from the person receiving the information, thus enabling the latter freely to give or refuse her consent' (Faulder 1985 pg 37.). This description begs the question of what is adequate and who decides when this has been achieved? Where is the balance of power to be held, by the clinician or the patient? If patients demand the right to make these decisions are they always prepared to accept the corresponding responsibilities of their decisions? The situation could arise where a patient's considered decision results in harm to them which may have been prevented if the clinician's advice had been taken.

Schafer (1988, p34) argues strongly "every potential research subject is legally and morally entitled to assess the risks and benefits of participating in a clinical trial. The procedure of informed consent is the mechanism whereby the patient becomes a partner in the enterprise rather than a mere guinea pig." Many patients with breast cancer are given the opportunity to take part in clinical trials (Stiller 1988, Williams 1992, Maslin 1993, Saunders et al 1994, Baum 1994, 1995). If researchers wish to address the issues of breast cancer prevention and cure they need the co-operation and commitment of the women they recruit information and collaboration appear to be fundamental to this relationship for many women (Fallowfield et al. 1990, Maslin 1993).

Acts and Omissions

The concept of acts and omissions with reference to informed consent may be relevant. Clough (1977) suggested that there is a difference between an act with the

intention to harm and an omission, which may result in harm, but where the intention was to do good "Thou shalt not kill but needst not strive officiously to keep alive". It can be argued that an individual . e.g. a clinician may not be able to foresee all the results of his actions therefore he cannot be blamed unless he acted without due care and attention. A clinician may feel that by omitting to tell a patient unpleasant information he is acting in her best interest by attempting to preserve her psychological state. This may result in the patients trust being broken when the full situation is known. On the other hand a clinician may act in what he feels are his patients best interest giving her full information to consent to treatment only to find that the result is severe psychiatric morbidity for the patient (Tobias 1992).

e, **ADVOCACY**

Advocacy encapsulates the concept of sharing information, allowing the patient to decide on their own course of action and then enabling the patient to realise that decision by offering the patient whatever support or resources they need to achieve their aim (Wells 1986). Often nurses take up the role of patient advocate (Wells 1986, Bird 1994) when patients face making decisions or exercising choices. Abrams(1978) questioned the notion of nurses being used as patient advocates. Historically nurses have been subservient to their medical colleagues. The bureaucratic structure they were a part of did not encourage, questioning, deviation or advocacy. They were often seen as the hand maidens who carried out medical prescriptions and instructions.

Wells (1986,p24) suggested "rarely if ever , is the role of the nurse considered. Perhaps this is because of a belief held by many of our medical colleagues that a nurse who is fully involved may be unable to remain impartial and unemotive in the care of

sick people. One voice in the veritable wilderness was that of the Cancer Research Campaign working Party in Breast conservation-'ideally, the trained nurse counsellor, or some other suitably qualified person should help obtain informed consent.'" Since Maguire et al (1978, 1980) established that nurses appropriately trained in assessment for psychiatric morbidity could successfully identify patients at risk and make appropriate referrals to a department of psychological medicine, nurses especially clinical nurse specialists in breast care, have been taking a leading role in acting as advocates for patients diagnosed with breast cancer (Maguire et al. 1980, 1988b) This role has been evaluated by the work of Watson, Denton, Baum & Greer (1988), Roberts & Fallowfield (1990) and supported by advisory documents such as the Fforest Report (1986), Cancer Relief Macmillan Fund's Minimum Standards for Breast Care (1994), the British Association of Surgical Oncologists guide-lines on treatment protocols (1994), and the British Breast Group's assessment of specialist cancer centres (1995) all of which have endorsed the supportive role of appropriately trained specialist nurses who are able to participate in information giving, decision making and psychological support.

The United Kingdom Central Council for Nursing, Midwifery and Health Visitors (UKCC) state in their document Exercising Accountability state "the role of patient's advocate is an essential aspect of good professional nursing practice" (UKCC 1989) but it is interesting to note that the UKCC go onto say in the same document that other health care professionals, not only the nurse can also be the patient's advocate. This could be problematic if every discipline feels they are the body acting on the patient's behalf. This also raises another issue. Is advocacy a function which is taken on in any given instance for example; a woman has just been given a diagnosis of

breast cancer and she is being pressed to make a treatment decision, a nurse who is present sees the woman's distress and in this instance acts as an advocate to assist the woman to remedy the situation, or is it an ongoing relationship e.g. just before an individual patient receives a diagnosis of Breast Cancer she is introduced to her Breast Care Nurse who will be available to her at any time, anywhere, and through out her disease continuum?

Porter (1988) argued strongly against nurse advocates. It has been argued that several unwarranted assumptions are inherent in the role: Are nurses capable of abrogating their vested interests as professionals and challenging the vested interests to colleagues. Will society allow the sick true autonomy? Nurses can be seen as professionals in an institutional setting involved as agents of social control assisting doctors. Do nurses have a vested interest in maintaining the exclusive professional power of the establishment on which they depend for employment. If nurses act as patient advocates are they not fostering a relationship in which the patient can develop a dependency? Advocacy could be used as a vehicle for paternalism (Bird 1994) Advocacy may result in schism and conflict with the nurse and patient being seen as colluding. It could be argued nurses are not trained to plead the cause of others and therefore independent advocates or counsellors should be made available to patients.

Advocates need to be articulate, self aware and professional. Advocates require specific knowledge, skills and motivation to facilitate the patient in their quest. They must be able to function within the healthcare system but not be compromised by it (Copp 1926). The advocate must put the clients interests impartially above his own.

He must be emotionally neutral towards his client as far as sex, creed, colour and status are concerned.

Wells (1986, p24) argued "nurses can only have the right to a role in the giving of informed consent if they have sufficient knowledge and emotional equilibrium to express a rational informed opinion." He went on to argue "if nurses became involved in informed consent, as many people believe they should, and participate equally with their colleagues in the role, they must be seen to be less emotional, more knowledgeable and mature in their discussions and opinions, and if they achieve that they may well lay aside the dictum of Mallett that 'she (the nurse) must never ask why, and seldom, if ever ask how'."

Rational for Advocacy

Advocacy is a tangible expression of respect for the notion of patient autonomy. It also recognises the fact that some patients may have diminished autonomy. The nature of relationships within the National Health Service are not equal. It could be suggested the doctor/patient relationship lacks equality hence the need for advocacy to put forward the patients point of view. This is necessary in order to fulfil the duty owed to patients of justice and beneficence. Patients have legal and moral rights, which must be protected. Advocacy is also important because some patients are not aware of their rights as consumers in the National Health Service (Patients Charter 1992).

Output 6

Maslin, A., 1999, 'Clinical Effectiveness and Evidence Based Practice' in

Maslin, A., Powles, T. 1999, Eds. 'Breast Cancer, Sharing the Decisions',

Oxford University Press, Oxford, pp39-44

CHAPTER 3

CLINICAL EFFECTIVENESS and EVIDENCE BASED PRACTICE

Even if an argument is forcefully made for a woman with breast cancer having the right to information which will enable her to exercise her autonomy, if she so wishes, by being involved in the decision making process, how likely will it be that accurate, clinically effective, individualised information will be available for her? This section aims to review the current position in relation to breast cancer.

People living in the 20th century are living with a degree of fear and a vast amount of uncertainty (Read 1995). This applies equally to issues current in society, politics, religion, ethics and health care. Richards, Ramirez, Degner, Fallowfield, Maher and Neuberger (1993) stated “ Marked cultural changes have occurred in Europe and the USA over the past 30 years, with an increasing concern for individual autonomy and the rights of the consumer. Changes in Medical practice have occurred which reflect these broader changes in society. Increasing emphasis is now placed on the provision of information to patients and their participation in decision making about their management.” but how can women facing a diagnosis of breast cancer truly participate when there are so many factors including; a knowledge deficit on the patients part, variations in clinical practice (sometimes evidence based , sometimes not), variations in availability, added to the impact of stress and selective perception on a vulnerable patient (Roper, Winkenwerder et al., 1988, Coates and Simes 1992 Baum 1995, Beaver, Luker, Owens et al. 1996)?

Saunders, Baum and Houghton (1994 p.457) observed that “The practice of medicine has always been ‘experimental’: cures being tried on patients and the results

observed. Traditionally therapeutic regimens were derived from anecdotal experience, and medical innovations were largely a matter of trial and error. Such was the discovery of Ambroise Pare in 1537 of a new dressing for gunshot wounds. Prior to all this all authorities had taught that burning oil should be applied to the wound to counteract the poison. But in his first campaign he was so inundated with gunshot wounds that he was forced to use an alternative 'digestive' made of egg yolks ,oil of roses and turpentine.

That night I could not sleep at my ease...I raised myself early to visit them, when beyond my hope I found those to whom I had applied the digestive medicament felling little pain, their wounds neither swollen nor inflamed and having slept throughout the night. the others whom I had applied the boiling oil were feverish with much pain and swelling."

Baum (1994 p. 23) states "It is indeed a cosy myth that the doctor knows best for every patient, for every disease, a peculiar conspiracy of the public and profession together, has effectively held back the progress of medicine for 100 years, delaying its entry into the scientific era and making it extraordinarily difficult to draw the line of demarcation between orthodox and 'alternative' medicine. Michael Peckham at the time he was NHS Director of Research and Development supports this view he stated: "some interventions which were used with genuine conviction in the past have been shown over time to be ineffective or harmful. (quoted by Moran 1995)"

Kee, 1996, p 958., summarises, "Patients today demand more information about their treatment. Doctors however, seem reluctant to cast aside ingrained habits

of paternalism, believing they can best interpret therapeutic choices for their patients. Whether doctors can be more objective and effective than patients in interpreting the probabilities of medical evidence is open to question. On the other hand, the exercise of choice by patients may itself have a bearing on probabilities of outcome. Involving patients more in making therapeutic choices is justified if doctors can present options in an unbiased and effective manner and if the process improves the outcome of the care delivered.”

Baum 1982, and Schafer,1989, rightly draws attention to the fact that many patients are unaware how many clinicians choose treatments based on their training and personal anecdotal experience. Clinical decisions are not always made based on empirical research but sometimes on 'trial and error'. Schafer (1989, p31) states "Many patients are unaware of the extent to which uncertainty pervades modern medicine". Many patients and lay writers will question the ethics of randomised controlled trials but do not question the ethics of recommending untested treatments. Revealing the uncertainty, which actually exists, can often be as difficult for the patient as for the clinician (Tobias 1992). This difficulty is compounded when the clinician in an effort to discover optimal treatments is involved in clinical trials. In this situation the patient may feel she wishes to challenge his motives. Is the clinician now acting with her best interests at heart or with a research motive in mind (Schafer 1988, Tobias 1992).

Roper, Winkenwerder et al (1988, p1197) stated "Although modern medicine provides great benefits to large numbers of people, medical professionals and clinical researchers have expressed concern about the effectiveness and appropriateness of

many current and emerging medical practices. for example, the evidence substantiating the effectiveness of many such practices are questionable and in many instances entirely lacking...Many physicians lack the skills to interpret and critically evaluate medical literature, and they approach the same clinical problem with different theoretical assumptions contributing to wide variations in practice patterns."

Rawlings (1992, p 32f) summarises a possible scenario when a competent adult visits a physician.

"An individual with a problem consults a physician: Skilful interviewing, examination, and selection of appropriate tests lead to rapid and accurate diagnosis of the problem.

The physician recommends a course of action: Tradition historical experience, pharmacological study and animal experiments have suggested certain approaches; their comparative worth will have been verified clinically by appropriate human trials; and the physician will be aware of results through education, publication and conferences, and thus able to judge what to recommend to the patient and accurately describe the alternatives.

The patient decides: Full, honest, and reliable information, given in the context of a relationship of trust and confidence, allow the patient to choose the most personally suitable treatment plan.

The plan is implemented: An educated motivated, co-operative health care team work with the patient to carry out what has been decided, funds and facilities are available to do this in the way intended."

Rawlings (1992, p33) goes on to say; "It can readily be appreciated that we have a long way to go, to achieve this ideal in the 1990s. What is more vexing, and gives rise to the profoundly difficult questions of human experimentation, is that the validity of most recommended approaches is in dispute. Personal anecdotal experience, published historical results, conjecture based on results in animal or possibly comparable diseases, are the usual reasons for outlining a certain treatment plan (as well as, an unquestioning belief in what was taught in medical school or residency); these justification for therapeutic decisions are grossly inadequate to assess the worth of manoeuvres which will have such an impact on human lives." EBM aims to be a new paradigm for medical practice which "de emphasises intuition, unsystematic clinical experience and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research (EBM Working Group 1992 p 2420). "The term evidence based medicine (EBM) or, more broadly evidence based clinical practice, reflects the aspiration that doctors and other clinical professionals should pursue their work of diagnosis, therapy and care on the basis of procedures which are known, through research evidence to be effective" (Long & Harrison 1996 p1). The phrase, evidence based medicine, attempts to encapsulate the concept of a process of life-long, problem based learning in which caring for ...patients creates the need for evidence about diagnosis prognosis, therapy; and other clinical and health care issues. 'Evidence -Based Medicine' (EBM) has now become a priority topic in the United Kingdom. Stephen Dorrell, then

Secretary of State for Health said “ It is imperative for the UK National Health Service (NHS) to harvest the fruits of scientific and technological advance to the Benefit of patients (1995 p114).

In the EBM process:

- 1) these information needs are turned into answerable questions;
- 2) the best evidence from which to answer, them (whether from clinical examination, the diagnostic laboratory, the published literature or other sources) are tracked down;
- 3) evidence is critically appraise for its validity and usefulness; the results of this appraisal are applied in clinical practice and
- 4) the outcome is evaluated (Sackett & Haynes 1995).

EBM has caused a great deal of discussion within the medical profession. There are some for whom EBM has always been their aim (Baum 1982, 1990, 1995, Baum et al 1988). As previously stated Baum (1982) suggested 'it would shatter the image of a noble and caring profession if the public were aware of how much "medical treatment" could easily be looked upon as uncontrolled experimentation.' Baum (1995) however notes that the responsible doctor “bases his decision first and foremost on the quality of the evidence and that this intervention will be advantageous for the patient.”) Baum 1995 p198) stated “It is possible to construct a hierarchy of approaches to the development of knowledge in medicine. The weakest kind of evidence is anecdotal. This includes anecdotal case reports, and even a report of a series of cases without adequate controls. The strongest evidence comes from the

randomised controlled trial, ideally the confirmed or replicated randomised controlled trial.”

Naylor (1995 p 840) when discussing those who are sceptical about EBM stated “ a backlash is not surprising in view of the inflated expectations of outcomes orientated and evidence-based medicine and the fears of some clinicians that these concepts threaten the art of patient care. Evidence based medicine offers little help in many of the grey zones of practice where the evidence about risk benefit ratios of competing clinical options is incomplete or contradictory.” This is an important issue in breast cancer care (Coates & Simes 1992). Breast cancer is often a chronic unpredictable disease and in spite of consistent research endeavour there remain areas in which there is more than one treatment of choice and those treatments do not carry an absolute guarantee of success thus necessitating an evaluation by the clinician and or patient of the risks and benefits (BASO 1994, BBG 1994, NHS Executive COG 1996).

Rawlings (1992) points out that what may be considered the 'best' treatment in terms of length of life may have unacceptable side effects which would impinge on quality of life. Even if a 'best' treatment was known it is sometimes the case that the results of research are not known by individual practitioners or accepted by them. Another key factor is that the patients priorities and values when considering treatment may vary considerably to the clinicians (Cassileth, Zupkis, & Sutton Smith 1980). This discussion becomes particularly pertinent when one considers the patient with cancer. For many adult cancers, including breast cancer, cure rates are poor. Surgery and treatments offered are often disfiguring, and complex with debilitating side effects.

Those patients who wish to participate in their treatment decisions require clear concise but full information to enable them to make a relevant choice (Fallowfield et al. 1994 b). Women with breast cancer are often facing a future with a chronic disease in which there are few guarantees. This is compounded by the fact that there is legitimate debate re: the management of breast cancer (Baum 1982, Fallowfield et al 1989, Powles & Smith 1991, Rubens 1992, Saunders & Baum 1994, Rijken et al 1995) adding difficulty to the decision making process. Women with breast cancer are in a unique position they face choices and decisions relating to local and systemic therapy which are often complex and uncertain but they and their clinicians do have access to a very comprehensive portfolio of research based evidence on which to base therapeutic decisions (Baum et al 1988, 1990, Powles & Smith 1991, Fisher et al 1989, 1993, 1994, Harris et al 1993) There is concern over how uncertainty is communicated to patients. Goldie (1982 p131) astutely commented "Obviously one would not begin to seek out and display the truth without undertaking to remain with patients whilst they digest assimilated it: To do otherwise would be like performing a skilful surgical operation and then leaving the skin unsecured."

Women with small uncomplicated localised breast cancers do have a choice of surgical treatment option (Fisher et al 1989, Fallowfield et al 1990). Volume 1 Number 2 (1996) of the new Evidence-Based Medicine journal reports from Jacobson, Danforth and Cowan et al. ' Breast-conserving surgery plus radiation therapy was as effective as mastectomy'. This has obviously been known for some time (Fisher et al 1989) but it does draw attention to the fact that women in this group are able to exercise a genuine choice based on evidence. Evidence also shows us that women when offered a choice will not always opt for breast conserving surgery and

that psychiatric morbidity is experienced in both surgical groups (Fallowfield, Baum, M Maguire, 1986, Fallowfield, Hall, Maguire, & Baum 1990 a &b).

Output 7

Maslin, A., 1999,

‘Communication, Psychiatric Morbidity, Access to Information and
Decision Making’ in **Maslin, A., Powles, T. 1999, Eds.** ‘Breast Cancer,
Sharing the Decisions’,

Oxford University Press, Oxford, pp45-68

CHAPTER 4

COMMUNICATION, PSYCHIATRIC MORBIDITY, ACCESS TO INFORMATION AND DECISION MAKING

Considerable research has been carried out in relation to the psychiatric morbidity women with a diagnosis of breast cancer experience (Maguire et al 1980, 1982, 1983, 1985, 1988, 1990, Watson et al 1988). It is known that approximately one in four women with breast cancer will suffer from severe anxiety and or depression requiring psychiatric intervention (Maguire et al 1980, Watson et al. 1988). It is also now known that the communication or lack of it women with breast cancer experience with their clinicians does have a psychological impact and affects the patients ability to adjust (Fallowfield,, Maguire and Baum 1986, 1987, Fallowfield et al 1990 a&b, Fallowfield et al 1994 a &b). This section reviews the impact of communication on psychiatric morbidity and the role choice plays in adjustment to breast cancer diagnosis and treatment.

Maguire and colleagues have looked extensively at the communication and assessment skills clinicians and nurses exhibit (1978, 1980, 1984, 1986, 1990). It is important that clinicians and nurses dealing with patients affected by a cancer diagnosis are able to communicate the information the patient requires as effectively as possible (Maguire & Faulkner 1988). It is also important that that the people involved in information giving and psychological support are able to assess the impact of the information on the patient and also for psychiatric morbidity (Maguire et al 1980, Maguire & Faulkner 1988b, Maguire 1990).

Maguire and colleagues (1980, 1982, 1983, 1984) developed an assessment tool and communication workshops from their extensive research into teaching communication skills (Maguire 1985, 1990). Maguire et al looked at the communication skills of clinicians (1985) and nurses (1980) and found that without appropriate training their skills were deficient. Doctors in the past were often unaware of the deficiency. Although there is now a greater awareness of the psychological and

information needs of cancer patients it would appear the training and supervision of 'cancer counsellors' varies considerably (Roberts & Fallowfield 1990). Roberts (1990, p 33) commenting on a nursing sample surveyed noted that "Only a third ... (33.9%) used a particular counselling scheme or model in their work.. This might reflect the low percentage of respondents with recognised formal counselling/psychotherapy qualifications.....Formal assessment of clients was carried out by only 23.4% of respondents."

Watson, Greer et al. (1984, p2008) noted that denial is used as a coping mechanism by some women diagnosed with breast cancer and that those "who denied the seriousness of a cancer diagnosis experienced significantly less mood disturbance." Maguire agrees that some patients will use sublimation or denial as a coping mechanism and that that mode of action may be appropriate but he also acknowledges that there are some patients who want "more or complete information" (Maguire 1990). Maguire and Faulkner (1988 p 974) suggest "Patients use denial when the truth is too painful to bear. So denial should not be challenged unless it is creating serious problems for the patient or relative. In challenging denial it is important to do so gently so that fragile defences are not disrupted but firmly enough so that any awareness can be explored or developed". The skill lies in the professionals ability to discern the information requirements of the patient and being able to explain the way forward including advantages and disadvantages in such a way that the patient is able to participate to the level they wish(Maguire 1978, Maguire & Faulkner, 1988).

In an unusual small (n40) study by Shapiro, Boggs, Melamed and Graham-Pole (1992) using video taped consultations which noted that the expression and demeanour of the Oncologist i.e. whether he looked worried or not worried when giving affected the patients response and ability to recall clinical information. Patients who saw a worried Oncologist perceived the clinical situation to be worse reported significantly higher levels of anxiety and had significantly higher pulse rates.

Fallowfield, Baum & Maguire (1986) in a study which randomised patients with no strong treatment preference to mastectomy or breast conservation noted anxiety in 33% of those who underwent mastectomy and found 38% of those who

underwent breast conservation had an anxiety state, depressive illness or both. This study though useful did not fully take into account the possible bias that is introduced by including data from women who were willing to be randomised to either breast conservation or mastectomy. Fallowfield et al (1990 p1394) in a follow up study which addressed these issues discussed the impact of patients being allowed choice. They concluded "Whatever the treatment for early breast cancer, good communication skills at the initial "bad news" consultation when diagnosis and management are discussed may well contribute much to future adjustment."

Dr Maureen Roberts, was Clinical Director of the Edinburgh Breast Screening project from 1979 to 1989. Dr Roberts was diagnosed with breast cancer and subsequently died of the disease she said "Communication is all important. Proper truthful accounts of diagnosis, treatment and aftercare must be written and made available everywhere, so that women become well informed and most important, start to take part in the decision making process for themselves (1989)."

If it is accepted that sentient adult women with breast cancer have a right to express their autonomy, if they so wish, by accessing accurate evidence based information relating to their disease and treatment options, communicated effectively and that this may be positive for their future psychological adjustment, how likely is that to be their experience. This section reviews the issues relating to the patients ability to access the information and participate, again if she so wishes, in the shared decision making process.

Goldie commented in 1982 "The question whether or not to tell the patient the truth usually arises in connection with cancer." He suggested that healthcare professionals were often influenced by their own fantasies of what it must be like to have cancer and that they often adopted a policy of avoiding mentioning unpleasant or distressing news for as long as possible. This alleged behaviour on the part of healthcare professionals may still in part be correct but it needs to be counterbalanced with the fact that many patients, in particular breast cancer patients, have adopted a more proactive stance in relation to their own health care and related issues (Kfir &

Slevin 1991, Cancer Relief Macmillan Fund 1994, Hack et al 1994, Maslin 1994, Richards, Ramirez, Degner, Fallowfield, Mahur, Neuberger, 1995, Kee 1996).

Kfir & Slevin (1991) argued that information means control and power. They suggested "Information is a major asset when trying to create a new order and less chaos." (Kfir & Slevin 1991, p 19). This ability to feel in control is a coping mechanism for some patients (Fallowfield et al. 1990). Hack, Degner & Dyck (1994 p280) suggest "Two important ways by which cancer patients gain a sense of control over their illness include a, acquiring information about their illness and its treatment and b, playing a more active role in decision making. Patients feelings of psychological control over their health may also increase if they perceive that their needs for medical information have been satisfied. Conversely, psychological control may be defined as the belief that one can predict what will occur in the environment and that one can modify the environment to produce change which is fundamental to successful adaptation."

This promotion of active participation in decision making must however be balanced against the fact that a patient seeking advice about a suspected cancer is under considerable stress (Hughes 1993, Luker, Beaver, Leinster, Owens, Degner & Sloane 1995). The individual is suddenly faced with a number of very real difficulties, first they must see their family doctor, be referred to a specialist in their field, , then begin to learn a new language relating to their disease and possible treatments, then they must come to terms with their diagnosis, decide whether they are comfortable with the advice of the specialist they have been referred to, decide whether or not to seek a second opinion and then for some make a choice between various treatment options which can put them under considerable stress. The decisions they make at this time may literally have an impact on whether they live or die (Valanis & Rumpler 1985). Maslin (1993) noted that when patients were questioned on what aspects of the information they received were inadequate they often mentioned the fact that at the time of the breast cancer diagnosis they were in a state of shock and therefore could not take in or comprehend much of what the clinician said.

Health care professionals express a variety of views on whether patients should be actively involved or not in decisions relating to their care (Cassileth et al 1980, Wagener & Taylor 1986, Tobias 1988, Baum 1994, Waterworth & Luker 1990, Fallowfield, Hall, Maguire, Baum, A'Hern 1990 a & b, 1994 a & b, Beaver, Luker, Owens, Leinster, Degner 1996, Mort 1996 Curtis and Lacey 1996). Baum (1995) stated "Decision making in medical practice is a complicated algorithm. A therapeutic decision is made as a result of a dialogue between the doctor and the patient. The doctor and the patient approach this decision making through different pathways. The patient has expectations and priorities, some of which may be unrealistic. For instance, he or she may prefer to trade quality of life for length of life or vica versa. The patient has fears. These may be rational or irrational, and patients of mine in the past have been so frightened of surgery that they have refused that advice. Finally, patients, to varying degrees, wish to express autonomy, and autonomy is expressed through involvement in the decision making process. Clinicians on the other hand are weighing up their own scales of merit. There is the quality of the evidence known to them, the availability of the best treatment locally or nationally, there is the influence of their own ethics and subliminal preferences".

Rawlings (1992, p29) stated "the way we conceptualise medical care has been changing; we no longer see the patient only as a passive recipient of medical intervention, but also as a client/partner in a mutual enterprise of seemingly ever-expanding scope." It is this premise that underpins much of the thinking surrounding patient access to information (Maslin 1993, 1994, Saunders et al 1994). There are the ethical/moral reasons why patients should be able to access the information they require but there is also a change in public opinion. Breast cancer patients in particular are demanding their rights as thinking individuals and consumers of healthcare (Richards et al 1995). The Patients' Charter (1992) has made explicit for many patients the fact that they have recognised rights within the National Health Service. Goldie (1982 p128) suggested the moral issue is not simply whether or not to tell cancer patients the truth, but more importantly how to do so. "Time and trouble is needed to understand patients and help them understand their situation."

Clinicians/scientists/nurses are in a difficult position. They must balance sensitively providing adequate explanation with not causing the patient undue worry by providing unsolicited and perhaps frightening information.(Declaration of Helsinki 1964, C.R.C Working Party 1983, Baum 1986). This puts them into the position of having to balance patient rights with healthcare professionals' duties (Schafer 1989, Rawlings 1992, Maslin 1993,1994). Wagener and Taylor (1986) noted that in failed transplant patients they recalled the circumstances of the initial decision in a manner that lessened personal responsibility for that decision. In that way they were able to rationalise to themselves that they had no choice but to take that course of action and therefore they were not personally responsible for it.

Patients with cancer have been found to express different opinions on the quantity/quality of information they would find desirable and on whether they wish to be actively involved in treatment decisions (Ingelfinger 1980, Tobias 1988, Baum & Houghton 1988, Beisecker & Beisecker 1990, Thornton 1992, Maslin 1993,1994). It is common in the clinical oncology situation for a patient to say initially they want to be told all the relevant information regarding their case and then for them to be unable or unwilling to hear (Priestman 1986, Maslin 1993).

Cassileth, Zupkis, Sutton-Smith and March (1980) in a survey of 256 patients with cancer found that at about 10 months post diagnosis 95% of patients wanted to know whether or not they had cancer, "what the treatment would accomplish" and "what the likelihood of cure is". Approximately 80% wanted "as much information as possible" and about 60% felt having that information was absolutely essential.

Strull, Bernard, & Gerald (1984) found when surveying 210 hypertensive outpatients that 41% of patients wanted more information about hypertension. In 29% of cases the clinician overestimated the amount of information the patient wanted. They also note the fact that clinicians thought 78% of their patients wished to participate in decision making when in fact only 53% wished to. They found the fact that a patient chose not to take the initial therapeutic decision did not mean they did not wish to participate in the ongoing evaluation of therapy.

Sutherland, Llewellyn-Thomas, Lockwood et al (1989 p 260) conducted a similar but smaller study (n52) with cancer patients but in their study 77% of the patients said they had participated in decision making to the level they wished. Most of the remaining 23% would have liked a greater opportunity to participate. Although the patients sought information, a majority, 63%, preferred the clinician to make the therapeutic decision for them.

Fallowfield et al. (1986) reported that more than half the women with breast cancer in a UK randomised study felt they had been given inadequate information when the various therapeutic options were discussed.

Blanchard, Labrecque et al (1988) found out of 439 encounters between hospitalised adult cancer patients and their doctors 92% of patients preferred to receive all information whether good or bad and 69% indicated they wanted full participation in their care.

Beisecker & Beisecker (1990 p19) noted in their study with 106 rehabilitation patients looking at information seeking behaviours that patients desired information about a wide range of medical topics but did not engage in many information-seeking behaviours when communicating with doctors. Whilst the patients desired information they regarded the doctors as “the appropriate persons to make medical decisions.” Patients whose conversations with the doctor lasted longer than 19 minutes began to display more information seeking behaviour.

Suominen, 1992, found that out of 109 breast cancer patients, 54% said they should have a significant share in decisions about their treatment and most patients, 64% were dissatisfied with the information they received.

Luker, Leinster, Owens et al. 1993, looking at 150 newly diagnosed women with breast cancer and found 20% wished to actively participate in the decision making about their breast cancer treatment, 28% wished to be involved and share in the decision regarding their future treatment and 52% wished to leave the decision making to their clinicians.

Degner and Dyck, 1994, studied breast cancer patients preferences for involvement in treatment decisions and preferences for information about diagnosis, treatment, side effects and prognosis. They found women who desired an active role in treatment decision making also desired detailed information. This relationship was less clear in passive patients. p135). Maslin, 1993, 1994, Luker et al.,1995, Richards, Ramirez, Degner, Fallowfield, Mahur, Neuberger ,1995, all point out that a desire for information may or may not result in the patient wanting to participate in treatment decision making patients may exercise their autonomy by putting their confidence an trust in a Clinician to make decision on their behalf (Ingelfinger,1980, Degner et al 1992).

Luker, Beaver, Leinster et al.(1995) supported nurses, particularly clinical nurse specialists playing a key role in providing breast cancer patients with useful and appropriate information. In their study of 150 women newly diagnosed with breast cancer and 200 with benign breast disease they found the top three information needs of the women with breast cancer were likelihood of cure, spread of disease and treatment options. Luker et al. (1995) suggested this level of information was not within the scope of the average ward nurse but may well fall within the scope of practice of the specialist breast care nurse.

Bilodeau & Degner, 1996, conducted a study with 74 women recently diagnosed with breast cancer to attempt to describe their preferred and actual roles in treatment decision making. Of the group 57% assumed a passive role in decision making although 43% stated this was their preference. Although 37% preferred a collaborative role only 19% were able to achieve this. Bilodeau & Degner felt women who wish to collaborate in decision making may find difficulty in achieving this aim. They strongly suggested nurses can "assess women's desired roles in treatment decision making and facilitate women achieving their preferred roles."(Bilodeau & Degner 1996, p691)

BREAST CANCER SURVEY - BACUP, Autumn 95

Cancer BACUP (the British Association of Cancer United Patients) conducted a small survey to find out about **Breast Cancer Patients -Users of BACUP Information Service- experience**. The questions were addressed to people with Breast Cancer, 18% of those who contact BACUP Cancer Information Service, for two weeks.

It should be emphasised that **the sample was very small and unrepresentative**. The majority of BACUP Users are referred by Health Professionals and/or are strongly motivated to search for information. Consequently, they cannot represent in any way the whole population of people with breast cancer. Therefore, we can only have some indications of the way individuals-Users of BACUP were treated.

A) Who first told them and where it was.

The vast majority of Breast Cancer Patients, 80% were told by a Consultant Surgeon (Specialist, Registrar), while only 5% were told by their GP.

Person that gave the diagnosis	Percent (%)
Consultant/Surgeon (Inc Registrar)	80
GP	5
Other (Including Unspecified Drs)	15

75% were in an 'appropriate' place, like Room with Privacy or Consultants/Doctor's Office when they were given their diagnosis. However, 13% were told in a ward or at home over the phone.

PLACE they were	Percent (%)
Room with Privacy	41
Consultant's / Doctor's Office	34
Ward / At home over the phone	13
Other (Not Specified)	12

B) How long they spent together.

Many patients, 38%, spent between 15-29 minutes with the Health Professional, whereas 27% spent between 5-14 minutes.

TIME (minutes)	Percent (%)
< 5 minutes	14
5 - 14 minutes	27
15 - 29 minutes	37
30 minutes or more	13
Other	9

C) What information they received when they were first told.

Almost half, 47%, of Breast Cancer Patients received what they believed to be satisfactory information when they were given their original diagnosis. 58%, received at least some information. A very high percentage, 42% did not receive any information at all.

INFORMATION GIVEN	Percent (%)
No Information at all	42
Some Information (Not Specified)	11
Yes, they had Information	47

Of those that had information and specified what information they had exactly (47%), 70% had information about their cancer, treatment and surgery issues. A lower proportion, 20%, were given BACUP Booklets/Information and only 13% received information for Counselling Services.

SPECIFIC INFORMATION	Percent (%)
Cancer (Including Site Specific, Treatment & Surgery Information)	70
Counselling Services	13
Booklets / Leaflets (Not Specified)	10
BACUP Booklets / Information	

D) What information they would have found useful to receive when they were first told.

Not surprisingly, many people with Breast Cancer (67%) required more information than what actually received. Nevertheless, 17% of Users were happy with the received information and did not require anything else, while 16% couldn't think or didn't know what information they would have found useful at the time of diagnosis or at the time of survey questioning.

ADDITIONAL INFORMATION	Percent (%)
Yes, they would have liked to receive more information	67
Couldn't think / Didn't know	16
No, they did not require any additional information	17

Of those (67%) that required additional information, 37% would have liked information about support groups and especially contacts with other patients. 26% would have liked to know more about their cancer (types, causes, meaning etc.). Treatment, Emotional Support and written information were among the commonest requests.

SPECIFIC USEFUL INFORMATION	Percent (%)
Support Groups (inc Patient to Patient)	37
Breast Cancer Specific Information	26
Treatment (exc Prognosis & Surgery)	18
Prognosis	12
Surgery	12
Emotional Support/Reassurance	19
Booklets / Leaflets (Not Specified)	19
BACUP Booklets / Leaflets	9
Other	9

E) Comments

It can be seen from the above that most of the Breast Cancer patients **were treated well and received information at the time of the original diagnosis**. The majority were told by a Consultant Surgeon in an appropriate place and they spent 15 - 29 minutes with him/her. A high proportion received satisfactory information, as well. Moreover, **comparing with previous BACUP survey**, they seemed to be better informed and treated than other cancer patients.

Breast cancer patients quoted:

'The surgeon was quite concerned about impact of news on both me and my husband. He offered us a cup of tea before we left in order to help us collect our thoughts!'

'Everyone had been as helpful as they could be'.

'I have seen Breast Care Nurse since and I feel well informed and supported'.

'Very good service. If anything too much information. However, I feel I was lucky to get referred to a breast cancer centre. I feel it was a bit of a lottery fortunately I got the winning ticket.'

Nonetheless, **the given information was not sufficient** for the majority of them (67%). What was given to them was mainly verbal, general information about their cancer and treatment options (70%) and in some cases booklets/leaflets (30%). Not a lot information was given about Counselling/Support Services.

What people (67%) would have liked to receive was written information, contacts/details of Support Groups, more information about breast cancer, treatment and emotional support.

People commented:

'Initially it was very difficult. I needed to be told this happens to lots of people and they get through it. It would have been helpful to have information on Support Groups and BACUP.'

'I wanted to know more details about what I had got, what was going to happen next, what the treatment might be.'

'I would have liked to have met someone who had had a mastectomy in outpatients. I would have liked to be given information what having cancer meant.'

'How I was going to cope with it? I felt as if I could have done with a bit of extra support. Somehow down the line'.

Written information appears to be preferable:

'I would like to be given information booklets. Brings it to you that you are not the only one. You can read booklets again and again'.

'I would have liked to read some background information about the choices I was given, i.e. surgery and radiotherapy'.

Even if people were **in 'shock'** when they were given the diagnosis, they would request some additional information **later on**:

'I was in 'shock'. I didn't think about what would have been useful to ask. I would have need to know about causes.'

'I was so shocked as I was expecting it not to be cancer. I am not sure what I wanted exactly at the moment. Telephone numbers of where to phone for information and support booklets/leaflets might be helpful.'

'I really needed something written. I would have welcomed some booklets and leaflets so that I could have read them afterwards when the shock had worn off.'

Despite the generally perceived good treatment of Breast Cancer Patients, mistreatment and communication problems still exist:

'Felt let down because specialist 'guaranteed' that the lump was not malignant - but then it turned out that it was.'

'I lost confidence in breast care nurse immediately. When we were left alone, I asked her if there is anything that can be done. She said, 'there is no cure'.'

'I felt unsupported after discharge. Delayed contact from health professionals - no communication.'

'I was treated like a number, insensitively handled when I first told (mammogram, needle biopsy). However, later they were very good.'

The most extreme cases:

'The Surgeon half turned away from me and said 'I'm sorry, it was malignant.' I was not given any information. I got more support from other women in same situation.'

'It was a terrible experience. The Surgeon that did the operation just came up to the bed in the ward with his understudies at visiting time. He said, 'it was a nasty lump'. I just flipped out, got dressed and run out of the hospital.'

'Nobody told me I had cancer. I was told that if I woke up after the operation and had a drip it would be bad news!'

Nonetheless, the way that people with breast cancer are treated seems to be improving by time as Health Professional and people in general become aware of different issues of breast cancer. A person that had a recurrence after 10 years, felt the information and support was much better this time. However, as the above individuals experience showed, information and treatment of cancer patients needs further improvement.

M. Boudioni, BSc, MSc, BACUP Research Officer, Autumn 95.

BACUP CANCER INFORMATION SERVICE
APRIL 96 / MARCH 97
BREAST CANCER ENQUIRIES
(27.9% of the total 40,925 enquiries)

GEOGRAPHIC (UNITED KINGDOM) DISTRIBUTION
(excluding unknown location enquirers)

Region	Percent (%)
YORKSHIRE	3.7
EAST MIDLANDS	7.3
EAST ANGLIA	5.5
GREATER LONDON	4.0
SOUTH EAST (ex LONDON)	15.6
SOUTH WEST	28.8
WEST MIDLANDS	10.5
NORTH WEST	7.8
SCOTLAND	6.7
WALES	5.7
OTHER	3.2
TOTAL	100.0
UNKNOWN	
TOTAL	

BACUP CANCER INFORMATION SERVICE
APRIL 96 / MARCH 97
BREAST CANCER ENQUIRIES
(27.9% of the total 40, 925 enquiries)

TYPE OF ENQUIRER

TYPE OF ENQUIRER	Percent (%)
Diagnosed Patients	59.1
Friends/Rel. of Diagn. Patients	28.5
Undiagn. Persons/Friends/Rel.	6.6
Health Professionals	2.4
Students	1.5
General Public	0.7
Others/Unspecified	1.0
TOTAL	100.0

Note:

Friends/Relatives of Diagnosed Patients include:

Friends/Rel. of Diagn. Patients	28.0
Friends/Rel. of Deceased Pts	0.5
TOTAL	28.5

Undiagnosed Persons/Friends/Relatives include:

Undiagnosed Persons	4.9
Friends/Rel. of Undiagn. Persons	1.7
TOTAL	6.6

Health Professionals include:

Nurses	1.9
Other Health Professionals	0.5
TOTAL	2.4

Others/Unspecified include:

Organisations/Support Groups	0.1
Other non-health professionals	0.5
Unknown	0.3
TOTAL	1.0

**BACUP CANCER INFORMATION SERVICE
 APRIL 96 / MARCH 97
 BREAST CANCER ENQUIRIES
 RELATIVES AND FRIENDS OF DIAGNOSED PATIENTS ONLY
 (28.5% of all breast enquirers)**

SUBJECT OF ENQUIRY - GROUPS

SUBJECT OF ENQUIRY	Percent (%)
Administrative	4.4
Publications	47.0
Prev/Screen/Risk Factors	8.0
General Treatment Enquiries	26.7
Specific Therapy Enquiries	41.3
Site Specific Information	35.4
Other Medical Enquiries	38.5
Emotional Support	44.9
Support Services	11.5
Other Support Enquiries	30.7

NOTE: It should be mentioned that the nurses can code up to 6 Subjects of Enquiry for every enquirer.

The above percentages represent the number of relatives/friends of breast cancer patients who asked about one or more of the particular subjects belonging to the group, no matter if other subjects were raised. For example, 47% of all relatives/friends (100%) requested Publications, while 41.3% of all relatives/friends needed information for one or more specific therapies.

It should be underlined that the total of enquirers and the total of enquiries are two distinctly different numbers. As the enquirers ask many questions and the nurses can code up to 6 subjects, the number of enquiries is inevitably higher than the number of people.

If group statistics are quoted, it is advisable to refer to subjects included in every group for clarification. See 'subject of enquiry-analytical'.

**BACUP CANCER INFORMATION SERVICE
 APRIL 96 / MARCH 97
 BREAST CANCER ENQUIRIES
 RELATIVES AND FRIENDS OF DIAGNOSED PATIENTS ONLY
 (28.5% of all breast enquirers)**

SUBJECT OF ENQUIRY - ANALYTICAL (new groups)

SUBJECT OF ENQUIRY	Percent (%)
Administrative Enquiries	4.4
Publications	47.0
Prev/Screen/Risk Factors	
Breast screening	2.6
Cervical screening	0.0
Other Screening	0.3
Risk Factors	5.2
Warning Symptoms	1.6
Treatment Enquiries	
General Treatment	5.2
Treatment Side Effects	15.3
Drugs Queries	1.4
Research / Clinical Trials	4.0
Treatment Centres / Drs	4.7
Specific Therapy Enquiries	
Auto / allo BMT & stemcell transplant	0.5
Chemotherapy	18.8
Complementary / Alternative Therapies	3.1
Hormonal Therapy	12.0
Immunotherapy	0.2
Radiotherapy	16.6
Surgery	9.2
Other Treatment	1.0
Site Specific Information	35.4

NOTE: see NOTES on the next page

SUBJECT OF ENQUIRY - ANALYTICAL (new groups)

SUBJECT OF ENQUIRY	Percent (%)
Other Medical Enquiries	
Clarification of Information Received	13.9
Death & Dying	2.8
Diagnostic Procedure	2.3
Diet & Nutrition	2.6
Follow-Up	0.5
Pain Control	3.1
Prognosis	12.7
Recurrence	5.2
Second Opinion	1.6
Symptom Control	4.2
Emotional Support	
Bereavement	0.7
Emotional Support/Reassurance	41.6
Narratives / Catharsis	2.6
Support Services	
Community Care	3.8
Counselling Services	3.7
Support Groups	5.4
Other Support Enquiries	
Health Prof. Communications	11.7
Pers / Fam / Friends Communications	16.4
Sexuality / Sexual Problems	0.3
Complaint about Health Care Received	1.7
Financial Concerns	3.7
Practical Support	2.3
Other Subject of Enquiry	0.9

NOTE: Risk factors include Heredity / Genetics (4.4%) and other.

Community care includes general, Macmillan enquiries and other.

Practical Support includes Getting Equipment & Protheses / Wigs.

Financial Concerns include General Insurance, Holiday/Travel Insurance, Benefits, etc.

**BACUP CANCER INFORMATION SERVICE
 APRIL 96 / MARCH 97
 BREAST CANCER ENQUIRIES
 RELATIVES AND FRIENDS OF DIAGNOSED PATIENTS ONLY
 (28.5% of all breast enquirers)**

SUBJECT OF ENQUIRY - THE COMMONEST ENQUIRIES

THE COMMONEST ENQUIRIES	Percent (%)
Publications	47.0
Emotional Support	41.6
Site Specific Information	35.4
Chemotherapy	18.8
Radiotherapy	16.6
Pers/Fam/Friends Comm.	16.4
Treatment Side Effects	15.3
Information Clarification	13.9
Prognosis	12.7
Hormonal Therapy	12.0
Health Prof. Comm.	11.7
Surgery	9.2
Support Groups	5.4
Recurrence	5.2
General Treatment	5.2
Risk Factors	5.2
Treatment Centres/Drs	4.7

NOTE: It should be mentioned that the nurses can code up to 6 Subjects of Enquiry for every enquirer.

The percentages represent the proportion of relatives/friends of breast cancer patients who asked about a particular subject, no matter if other subjects were raised. Therefore the total is not 100%.

Finally, it should be underlined that the total of enquirers-people and the total of enquiries-questions are two distinctly different numbers. As the enquirers ask about different subjects, the number of enquiries is inevitably higher than the number of people.

**BACUP CANCER INFORMATION SERVICE
 APRIL 96 / MARCH 97
 BREAST CANCER ENQUIRIES
 DIAGNOSED PATIENTS ONLY (59.1% of all breast enquirers)**

SUBJECT OF ENQUIRY - THE COMMONEST ENQUIRIES

THE COMMONEST ENQUIRIES	Percent (%)
Emotional Support	45.8
Publications	44.6
Site Specific Information	32.0
Treatment Side Effects	31.5
Chemotherapy	22.8
Hormonal Therapy	20.7
Information Clarification	17.5
Radiotherapy	15.6
Surgery	15.1
Health Prof. Comm.	12.9
Recurrence	9.6
Prognosis	6.1
Pers/Fam/Friends Comm.	6.0
Symptom Control	4.8

NOTE: It should be mentioned that the nurses can code up to 6 Subjects of Enquiry for every enquirer.

The percentages represent the proportion of breast cancer patients who asked about a particular subject, no matter if other subjects were raised. Therefore the total is not 100%.

Finally, it should be underlined that the total of enquirers-people and the total of enquiries-questions are two distinctly different numbers. As the enquirers ask about different subjects, the number of enquiries is inevitably higher than the number of people.

**BACUP CANCER INFORMATION SERVICE
 APRIL 96 / MARCH 97
 BREAST CANCER ENQUIRIES
 DIAGNOSED PATIENTS ONLY (59.1% of all breast enquirers)**

SUBJECT OF ENQUIRY - GROUPS

SUBJECT OF ENQUIRY	Percent (%)
Administrative	1.9
Publications	44.6
Prev/Screen/Risk Factors	5.1
General Treatment Enquiries	37.9
Specific Therapy Enquiries	57.6
Site Specific Information	32.0
Other Medical Enquiries	39.9
Emotional Support	48.5
Support Services	5.5
Other Support Enquiries	24.3

NOTE: It should be mentioned that the nurses can code up to 6 Subjects of Enquiry for every enquirer.

The above percentages represent the number of breast cancer patients who asked about one or more of the particular subjects belonging to the group, no matter if other subjects were raised.

For example, 44.6% of all patients with breast cancer (100%) requested publications, while 57.6% of all patients needed information for one or more specific therapies.

It should be underlined that the total of enquirers and the total of enquiries are two distinctly different numbers. As the enquirers ask many questions and the nurses can code up to 6 subjects, the number of enquiries is inevitably higher than the number of people.

If group statistics are quoted, it is advisable to refer to subjects included in every group for clarification. See 'subject of enquiry-analytical'.

**BACUP CANCER INFORMATION SERVICE
 APRIL 96 / MARCH 97
 BREAST CANCER ENQUIRIES
 DIAGNOSED PATIENTS ONLY (59.1% of all breast enquirers)**

SUBJECT OF ENQUIRY - ANALYTICAL (new groups)

SUBJECT OF ENQUIRY	Percent (%)
Administrative Enquiries	1.9
Publications	44.6
Prev/Screen/Risk Factors	
Breast screening	0.8
Cervical screening	0.2
Other Screening	0.3
Risk Factors	2.7
Warning Symptoms	1.5
Treatment Enquiries	
General Treatment	2.2
Treatment Side Effects	31.5
Drugs Queries	0.9
Research / Clinical Trials	2.8
Treatment Centres \ Drs	3.6
Specific Therapy Enquiries	
Auto / allo BMT & stemcell transplant	0.7
Chemotherapy	22.8
Complementary / Alternative Therapies	3.2
Hormonal Therapy	20.7
Immunotherapy	0.1
Radiotherapy	15.6
Surgery	15.1
Other Treatment	0.5
Site Specific Information	32.0

NOTE: See NOTES on the next page

SUBJECT OF ENQUIRY - ANALYTICAL (new groups)

SUBJECT OF ENQUIRY	Percent (%)
Other Medical Enquiries	
Clarification of Information Received	17.5
Death & Dying	0.5
Diagnostic Procedure	3.6
Diet & Nutrition	3.6
Follow-Up	2.4
Pain Control	2.3
Prognosis	6.1
Recurrence	9.6
Second Opinion	2.1
Symptom Control	4.8
Emotional Support	
Bereavement	0.1
Emotional Support/Reassurance	45.8
Narratives / Catharsis	2.4
Support Services	
Community Care	0.6
Counselling Services	1.2
Support Groups	4.0
Other Support Enquiries	
Health Prof. Communications	12.9
Pers / Fam / Friends Communications	6.0
Sexuality / Sexual Problems	1.8
Complaint about Health Care Received	1.9
Financial Concerns	4.2
Practical Support	2.1
Other Subject of Enquiry	1.2

NOTE 1: Risk factors include Heredity / Genetics (1%) and other.
 Practical Support includes Getting Equipment & Prostheses / Wigs.
 Financial Concerns include General Insurance, Holiday/Travel Insurance, Benefits, Mortgages etc.

NOTE 2: It should be mentioned that the nurses can code up to 6 Subjects of Enquiry for every enquirer.

The percentages represent the proportion of breast cancer patients who asked about a particular subject, no matter if other subjects were raised. Therefore the total is not 100%.

Finally, it should be underlined that the total of enquirers-people and the total of enquiries-questions are two distinctly different numbers. As the enquirers ask about different subjects, the number of enquiries is inevitably higher than the number of people.

As outlined above in some studies the majority surveyed wished to participate in the decision making process (Cassileth, Zupkis, Sutton Smith et al. 1980, Blanchard, Labrecque, Ruckdeshel et al 1988, Degner, Russell 1988, Brandt 1991.), whilst in others the patients expressed the view that they would prefer their clinicians to take the decisions (Ingelfinger 1980, Sutherland, Llewellyn-Thomas, Lockwood et al. 1989, Degner & Sloane 1992, Bilodeau & Degner 1996).

In summary lack of information is often cited in patient satisfaction surveys as a significant complaint (Locker & Dunt, 1978, Rothert, Padonu, Holmes-Rovner 1994, Maslin 1994.) It has been suggested (Tyron & Leonard 1965, Greer et al 1979, Kendall & Watson 1981) that giving surgical patients information in advance results in an improved post-operative recovery. Richards et al (1993) state “involving patients in the decision making process could have both advantages and disadvantages for them. Proponents of offering choice may hope that this will lead to higher levels of patient satisfaction with care and improved acceptance of treatment. It might also lessen psychiatric morbidity and improve quality of life. against this, offering choice could place an undue burden of responsibility on patients. Revealing uncertainty about “best treatment” could lead to a loss of confidence in the doctor. Provision of complex information required to make a valid choice may lead to confusion and could challenge a psychological response of denial/avoidance. Choice of treatment which subsequently proves unsuccessful might induce feelings of self blame and regret in the patient”. Studies addressing psychiatric morbidity in breast cancer patients have indicated that it is not necessarily the type of operation that is the sole cause of anxiety or depression in these women. Fear of recurrence and death are high on the agenda for many women and this will have an impact on the choice made (Fallowfield et al 1986, 1990)

Not wishing to actively take the decision about the final choice of treatment as previously stated may not necessarily mean a total lack of desire for information. Cassileth et al (1980) make the point that only approximately 60% of patients

expressed a preference to participate in decisions regarding medical care and treatment, compared with more than 95% who wanted detailed information. Sutherland et al. (1989) suggest the results of this study indicated that patients "may actively seek information to satisfy an as yet unidentified aspect of psychological autonomy that does not necessarily include participation in decision making." Fallowfield et al (1986, 1990 a &b) likewise found that a desire for well communicated information may not necessarily lead to a patient wishing to take sole responsibility for treatment decisions.

Gray (1990) suggests once the word cancer is mentioned to a patient they often do not hear the rest of the conversation. Patients can and do change their minds regarding their desire to access information over a period of time (Priestman 1986). Patients may experience many conflicting emotions including numbness, disbelief, anger, fear, hope and despair (Buckman 1986, Priestman 1986,). This sequence of emotions can make information giving generally, or decision making specifically, difficult at the time of diagnosis. Many patients find it difficult to comprehend what is being said and many find it difficult to remember what they have been told (Watson 1988, Hogbin & Fallowfield 1989, Maslin 1993,).

Goldie (1982, p132) pointed out that staff often by putting themselves in the shoes of their patients misunderstand the patients actual thoughts and feelings. This results in the patient not being given the opportunity to express their view because staff feel they already know it and therefore don't ask the patient. Goldie also stated "Sometimes the hospital or part of it can become like a totalitarian state, with a limitation on the subject's freedom to think and act independently."

Reynolds, Sachs, Davis and Hall (1981 p227) suggest that "physicians and nursing staff see a woman as a patient, a person and a statistic, the patient often has a difficult time understanding what is happening to her and why." The patient may wonder what is uppermost in the clinicians mind when treatment options are suggested. They go on to suggest information is generally lacking for patients and their families-no matter how good a job the physician and hospital staff are doing in trying to communicate important information (Maslin 1994). For some patients

information gathering becomes a coping mechanism. Information for this group of people enables them to have some control over their disease and its treatment. Information supplies them with options and options may lead to encouraging possibilities (Kfir & Slevin 1991 p22-30). Fallowfield et al (1994 b, p203) discussing their 1990 study stated " One of the primary findings was that although there were fewer cases of anxiety and depression in the group of women treated by surgeons who offered 'choice' wherever possible, choice was not the determining factor. consulting style, in particular offering satisfactory information about treatment options was crucial to long term adjustment." Fallowfield, Hall, Maguire, Baum & A'hern (1994 a, p448) reporting their 3 year follow up data of their 1990 study (the Psychological Outcomes of Different Treatment Policies in Women with Early breast Cancer Outside a Clinical Trial) stated "23 of the 62 women who were offered choice found it difficult to make a decision; eight refused to choose. Women were asked how they felt about having been asked to choose their operation. Twenty-six expressed positive reactions, 13 were unable to say, and 10 were unenthusiastic. Five women, four of whom had chosen breast conservation, expressed doubts about their original decision; two eventually underwent mastectomy, one because of recurrence of the cancer and the other because severe problems after radiotherapy. The remaining 48 patients, nine of whom subsequently developed recurrence, did not regret their choice."

Fallowfield et al. (1994 b, p202) discussed the impact offering choice had on psychiatric morbidity in this group. Their results confirmed Maguire's (1980) assertion that there is a "significant minority of women who experienced unremitting psychiatric morbidity , irrespective of surgeon group or actual surgery performed." Another important issue was " Pre-operatively, women completed the Speilberger Anxiety Trait questionnaire. The mean Speilberger score for women with breast cancer aged between 50 and 69 is 31.79. All the women offered choice who made the decision for themselves, had higher than normal anxiety trait scores. For those who experienced no difficulty in deciding, this mean was 35.2 ($p<0.01$). For those who experienced some or considerable difficulty, the mean was 36.6 ($p<0.05$). However, for those who were unable or unwilling to choose, the mean was 29.3 which was not significantly different from the population mean (Fallowfield et al. 1994 b, p204)." At

three years 14% of those women able to choose their treatment option were anxious and 17% were depressed. On the other hand of the women not offered choice 21% were anxious and 23% were depressed. Fallowfield et al (1994 b) noted that at three years women who were treated by surgeons who offered choice wherever possible benefited in terms of their incidence of psychiatric morbidity when compared to the women who treated by the surgeon who main treatment choice was mastectomy. There was no significant difference in psychiatric morbidity between the choice group and the breast conservation group.

Fallowfield et al (1994 b p 206) concluded “. Women with breast cancer seem to benefit form the provision of clear information about treatment and, if appropriate, reasons why, the doctor would recommend one treatment over another. If suitable, understandable information is provided, time to think and maybe to discuss the implications either with the doctor or an adequately trained specialist nurse, then an offer to take part in decision making if women so wish may significantly affect good adjustment.”

Output 8

Maslin, A., 1999, 'Approaches to Shared Decision Making'

in Maslin, A., Powles, T. 1999, Eds.

'Breast Cancer, Sharing the Decisions',

Oxford University Press, Oxford, pp69-98

CHAPTER 5

APPROACHES TO SHARED DECISION MAKING

The evidence appears to support the case for a sentient adult women with breast cancer having a right to express her autonomy, if she so wishes, by accessing accurate evidence based information relating to her disease and treatment options and that this information should be communicated effectively to her. But how can a woman with breast cancer access the information and participate, again if she so wishes, in the shared decision making process? This section reviews the common and a selection of the less common methods available for the sharing of information with patients.

i., Person to Person Verbal Information

It is widely recognised that communication is one of the most important aspects of patient care (Fallowfield et al 1986,1987, 1990 a&b 1994 a&b, Maguire et al 1980, 1983, 1986, 1988b&c, 1990, Roberts et al 1990), and one where surveys of patient experience have revealed areas of considerable dissatisfaction (Cartwright 1964, Rapheal 1969, Parkin 1976, Reynolds 1978, Priestman 1986, Buckman 1986, Blum & Blum 1991). Ley (1988) reported a median dissatisfaction rate with medical communication of 38%. Blum & Blum (1991) demonstrated similar findings in their study looking at patient-team communications. They found 25% of callers to a community based agency identified patient-physician communications as their primary concern. Fallowfield and Baum (1989) stated " We have important data emerging

from studies suggesting that the way in which the surgeon conducts the 'bad news' consultation i.e. informing the patient of the diagnosis and treatment options, can have a major impact on short and long term psychological outcome." Fallowfield and Baum (1989) argued strongly that the 'bad news interviews' were crucial in the patient/clinician relationship and that an appropriately trained nurse counsellor in partnership with a department of psychological medicine could also facilitate in a reduction in a breast cancer patient's psychiatric morbidity (Maguire 1978, Maguire 1982, Watson, Denton, Baum, & Greer 1988).

Problems arising from poor communication are not solely confined to the medical profession. Macleod-Clarke (1983) and Wilkinson (1992) likewise demonstrated nurses often engage in brief, infrequent communication interactions which are often task orientated. If there is dissatisfaction with communication and the exchange of information how can any patient give Informed Consent? Hughes (1993 p 623) conducted a study examining the relationship between information about breast cancer treatment options and patients choices of treatment. The group studied were women facing either a wide local excision followed by radiotherapy or a mastectomy. The amount of information provided for each patient was recorded on an observer check list. The information was primarily shared verbally. Follow up telephone calls were conducted six to eight weeks after the surgery. Hughes states "The results indicate that subjects choice of treatment was unrelated to the amount of information they received during their clinic visit. Manner of presentation also did not influence treatment selection. However treatment selection was related to the amount of information they received prior to their clinic visit ($p < 0.01$). The results also indicate that patients recall of information about treatments and associated risks is exceedingly

poor.” Almost 50% of the women who chose wide local excision could not recall characteristics of their treatment and associated risks and this rose to 66% in the mastectomy group. This finding is of obvious importance when considering the information given at the time of diagnosis. Another interesting finding was that women who opted for a mastectomy received significantly more information about their operation and breast cancer treatment prior to their clinic visits from informal sources like friends and family (Hughes 1993). It is obvious that this information may or may not be accurate and this needs to be borne in mind by health care professionals.

Fallowfield et al. (1987) noted that taking a friend or relative along to listen with the patient when visiting the clinician. Replying to Apolone and colleagues in the BMJ (1990 p 1394) Fallowfield confirmed that “women treated by surgeons who offered “choice” whenever possible fared better in terms of psychiatric morbidity than women in other surgeon groups. This was true even when women could not be permitted choice for technical reasons. This implies that those surgeons who were prepared to allow women to participate in the decision making process whenever possible differed in some qualitative way from those who tended to make the treatment decision for their patients. We could suggest that the surgeons who offered choice were perhaps more skilled in the art of communication, including the provision of good information and psychological support.”

The evidence clearly shows that verbal information effectively communicated to a patient with breast cancer can have a significant impact on patient satisfaction and their ability to adjust to their diagnosis and treatment. Difficulties with communicating information verbally surround on the part of the professional, at times, lack of

knowledge, lack of expertise and lack of time and on the part of the patient, at times, a lack of general understanding or an inability to understand due to the impact of stress and selective perception (Greer 1979, Watson, Greer et al 1984, Greer et al 1990).

ii.,Use of literature

Ellis, Hopkin, Leitch & Crofton (1980) demonstrated that the addition of written information to the provision of verbal information improved patient understanding and recall. Webb (1987) discussed the range of topics and the variety of ways written information is available to patients within the cancer setting. Webb expresses the view that good quality written material with appropriate illustrations can be a powerful medium for facilitating patient education and understanding. Webb states “a permanent record or hard copy of factual information allows reinforcement of material when the patient and family want it.” One problem with the written word is that often the level of literacy required by the reader is too high (Boyd & Feldman 1984, Redman, 1988, Swanson, Forest, Ledbetter et al 1990, Meade, Diekman, Thornhill, 1992). Although the effectiveness of the written word may be enhanced if it is prepared with the reading age of the user specifically in mind (Meade, McKinney, & Barnas 1994). Luker & Caress (1988, p712) pointed out that nurses are rarely trained in the “breadth and depth of knowledge necessary to teach patients who by view of their illness may have special learning difficulties.” Maslin, Powles, Buam et al (1993) noted that in a sample of 200 patients at high risk of developing breast cancer or a confirmed diagnosis of breast cancer 75% received or remember receiving written material on entering a clinical trial and 99% of that group claim to have read it. When this same sample of patients expressed written comments on the information

they received they wanted access to more explicit information particularly in relation to side effects of treatments and drugs.

Chapman, Elstein & Kostbade Hughes (1995) reported a study they conducted examining the effects of materials for providing patients with information on breast cancer on patients and its treatment options on individuals choice of treatment options. They used undergraduate students as surrogate patients and assessed their baseline knowledge on the disease and its treatment options. They also ascertained the individuals initial preferences for treatment from wide local excision followed by radiotherapy, mastectomy followed by reconstruction or a mastectomy followed by use of a breast prosthesis. This was done both prior to and after reading a booklet or watching an interactive videotape of the relevant information. Treatment choices were not affected by reading the booklet but a preference shift was noted after watching the videotape towards breast conserving surgery. This study is a useful indicator but the use of surrogate patients makes the reliability of its findings in relation to breast cancer patients difficult to ascertain.

One difficulty with literature is that it caters for a group of patients and is not always able to meet the needs of patients who are outside the norm. For example hospital literature aimed at women with breast cancer may take general examples and scenarios but may not be able to meet the needs of a patient with a condition which is less common i.e. inflammatory breast cancer or Pagets disease. Another difficulty with written information which is obtained in a library or straight off the internet is that it may not be directly applicable to the patient and therefore the opposite problem is experienced where the patient accesses copious information some of which may not

relate to them. In view of this it may be useful to adopt information sharing methods which are tailored to the patient (Hogbin & Fallowfield 1989) e.g. the use of audio tapes.

iii.,Use of Tape Recorders

Use of tape recorders for reinforcement of information on hernia repair was used by Baskerville, Heddle & Jarrett (1985). They aimed to give and record appropriate information in a relaxed setting with the patients and then provided the patients with a copy of the recording to take home. Baskerville et al. (1985) reported 90% of the patients found the tape recording adequate and accurate. They noted the voice of the surgeon appeared to give the audio recording a greater sense of authority than written material.

Hogbin and Fallowfield (1989) studied the effectiveness of using a tape recorder during cancer patients 'bad news' interviews. In total they gave 46 patients audio recordings of their interview with the clinician when the 'bad news' and possible treatment options were discussed. Hogbin and Fallowfield aimed to discover 1, if it was practical to record the consultation in an ordinary outpatient department, 2, what differences if any did this make to the consultation and the way information was communicated and finally how useful was this process to the patients with cancer. Of the 46 patients 39 listened to the tape recording and of that 39, 38 listened to it with a friend or relative. All 39 patients found the tape recording helpful and 15 stated it

contained information they had forgotten. Of the 39 patients 8 of the patients did feel the tape or part of it upset them but 31 said it did not.

Hogbin and Fallowfield (1989 p 332) use a number of patient quotes to illustrate the usefulness of the tapes these included;

“ ‘ the tape was a wonderful idea I was able to play it several times to my very large family.’

‘This (the tape) was a tremendous help as it is impossible to recall everything said when one is in a state of shock.’ “

Knowles, (1992) reported a randomised study of 34 patients with advanced cancer half of whom were randomised to have their consultation tape recorded and half not. Their aim was to see if the use of an audio tape increased information retention and reduced anxiety and depression levels. This study was small and therefore the results were only indicators. Patients who had the tape-recording appeared to have a decrease in their mean anxiety scores after one week from 7.1 to 3.1 (HAD, Zigmond and Snaith 1983) and a substantial increase in information recall at a second interview. The control group however showed only a marginal improvement in information recall and retained a mean anxiety score of 6.1. Patients did however express largely positive feelings and confirmed the view that the tapes were helpful not only for the patient but the immediate and extended family.

The use of audio tapes would appear on balance to have had a largely favourable response and helps to address issues relating to the stress a patient

experiences which may affect their ability to hear and understand a diagnosis/treatment options particularly during a bad news interview.

iv.,Use of Videos

A variety of linear videos have been made. Videotapes have been found to be as effective as other forms of instruction and more effective than printed materials alone (Gagliano, 1988, Nielson Sheppard, 1988, Uzark, Rosenthal, Behrendt, Becket 1985, Tongue 1991). Uzark, et al (1985) found the use of videos for parents of children with congenital heart defects resulted in improved parental understanding and as a result the families were more willing to comply with recommendations for care.

Meade, McKinney & Barnas did compare the effectiveness of written information and videotaped information in patients with limited literacy who had a diagnosis of cancer of the colon. The results showed an increase in knowledge and understanding in both groups but only short term memory recall was evaluated. The authors suggested the fact that the literature was prepared specifically with the needs of the person with limited literacy in mind this may have made the literature more effective.

Tongue 1991, conducted a study of a video based information system (VISIP) for general practice waiting room areas to assess its value to patients. He found that it was possible to produce at low cost an information system for patient waiting areas but he found staff and patients expressed a variety of views as to what it would be most helpful for the system to concentrate on. Tongue felt health promotion material merited consideration. Webb (1987) suggested time in outpatients could be

used effectively for cancer patients by the introduction of self directed educational programmes. Videos currently available on breast cancer treatment options vary between those specifically designed for the patient those developed as a teaching tool for professionals for example; Cleese, Buckman and Garden 'Breast Cancer' (1993). These videos have not been subject to evaluation in a clinical trial. If an individual patient has access or the ability to purchase they can see material which is not specifically prepared for them.

Videos are useful in countries like the UK. where access to a video recorder is fairly commonplace. The videos can be borrowed at little cost and the patient can view the material in the surroundings of their choice. Difficulties may arise if the patient has questions which cannot be answered immediately or if the material although accurate is not appropriate to their own situation for example treatments may be discussed which are not an appropriate option for the individual.

v.,Use of Computers

Computer assisted learning (CAL) for patients is a new but rapidly developing field. CAL does appear to be helpful in patient education (Fisher, Johnson, Porter, Bleich, Slack 1977, Deardorff 1986). As far back as 1977 Fisher et al. demonstrated that even the elderly found the technology acceptable. Deardoff (1986) found that CAL was rated more highly than written material. An important feature of CAL is that the patient is free to cover the material in their own time, to repeat the information and in many cases to do this without the fear of taking up too much of the professionals time(Deardoff 1986). With the availability of cd and laser disc systems the information can be given verbally as well as visually which is helpful to those who are

deaf or blind. The use of touch control screens enable those unfamiliar with keyboards to use the systems rapidly. Luker and Caress (1988, p716) rightly state that the usefulness of these systems is largely dependent on the quality of the software in interaction with the user.

Comprehensive Health Enhancement Support System (Chess)

CHESS was developed as a user friendly interactive computer based system designed to provide information and support to women facing a breast cancer diagnosis. This system was developed by a group at the University of Wisconsin, Madison and has been piloted (Gustafson, Wise, McTavish et al. 1993 & McTavish, Gustafson, Owens et al. 1994). The system will soon be available for general use (Mort et al. 1995). The "services include answers to common questions, a database of articles and brochures, a tutorial that explains social services.....personal stories and an on-line discussion group (Mort et al 1995 p7).

Bedside decision board for adjuvant therapy decisions.

This is a tool which was developed in Ontario to help ascertain patients preferences for adjuvant chemotherapy (Levine, Gafni, Markham & MacFarlane 1992). The tool is a decision board which provides patients with probabilities of recurrence and quality of life outcomes associated with chemotherapy. The aim of Levine et als.(1992) study was to develop an instrument to help clinicians inform patients with breast cancer of risk and benefits of adjuvant chemotherapy as demonstrated by clinical trials and help the patient decide whether to accept or reject a treatment option. A pilot was conducted amongst healthy volunteers to determine their preferences and to assess for reliability and validity.. Although this was useful it is known that

surrogate patients/control patients views do frequently differ to those of the patient directly involved (Slevin et al 1990, Maslin 1993,) The decision board was been found to be acceptable and helpful to 37 newly presenting high risk patients with node negative breast cancer (Levine et al 1992).

The Shared Decision Making Programme (SDP) /Interactive Video Disc System (IVD)

McNeil, Parker, Sox and Tversky (1982,p1259) stated "there is a growing appreciation in the general public and medical profession of the need to incorporate patient preferences into medical decision making. To achieve this goal, the physician must provide the patient with the data about possible outcomes of the available therapies and the patient must be able to comprehend and use the data."

In a 1991 American Medical Association survey 69% of the respondents claimed they were losing faith in Doctors and only 42% stated their doctors does an adequate job of explaining disease and treatment (Willson 1992) . This is not surprising given that it is estimated that by the American National Board of Medical Practitioners that doctors on average spend less than seven minutes talking to patients and this figure has fallen from eleven in 1975 (Willson 1992.)

Mort (1996) drew attention to the fact that in some instances (Mort quoted Hormone Replacement Therapy (HRT) as an example) there was widespread variation in prescribing patterns. Mort acknowledges there will be some expected variation but what was unexpected was the systematic variations in prescribing which appeared to be systematic and linked to geographic region, physician gender and other non-clinical

factors. With this known variation it is reasonable that some patients may wish to know why there is a variation in practice and may wish to participate in the decision to evaluate what therapy if any is offered.

Mulley et al (1990) hypothesised that active efforts to involve patients in decisions made about their care should improve outcomes by better matching treatments with patient values and needs. In an attempt to address this quantity and quality issue with regard to the patients access to information the Foundation for Informed Medical Decision Making, a non-profit foundation developed and produced initially four interactive multimedia programmes (Kasper, Mulley, Wennberg 1992, Mulley, 1990a, 1990b, 1992, Wennberg 1992b, 1992c, Wagner, Barrett, Barry et al. 1995) dealing with benign prostate disease, hypertension, lower back pain and early breast cancer. These aimed to allow individual patients to explore the details of benign prostate disease, low back pain, hypertension and early stage breast cancer.

The programmes are a mixture of documentary style video clips, still shots, diagrams and text. The programs are ported to a DOS-based play-back system, a Dell 486 equipped with a Sony GVM 1315 TS Touch Screen, and a Sony LDP 1450 Videodisc player. To create the programmes the developers consulted with doctors and patients focus groups to ascertain the questions which are important to patients.

The Interactive Video (IVD), Shared Decision-Making Program (SDP) "is a video program presented in an interactive format using an video disc player, a modified microcomputer, a video monitor, and a printer. It is designed for use in the health care provider setting. Information is given about a given medical condition is provided

along with descriptions of the benefits and harms associated with the relevant treatment alternatives” (Kasper et al 1993, p183).

Barry, Floyd, Fowler, Mulley, Henderson and Wennberg (1995) conducted a study to evaluate an IVD/SDP for men with benign prostate disease, hypertension. The study was a prospective cohort study conducted in three hospital based urology clinics. Data from 373 men were suitable for analysis. The patients rated the programme for length, clarity, balance and value of the programme. The patients (77%) were very positive and 16% were generally positive about the programmes usefulness. Patients rated the programme as generally clear, informative and balanced. The results suggested that patients can be helped to participate in treatment decisions and support a randomised trial of the shared decision making programme.

The Kings Fund Centre for Development (England) have supported pilot studies looking at the systems usefulness for patients. Data is available for patients with benign prostate disease, hypertension and breast cancer (Shepperd, Coulter & Farmer 1995, Maslin, Baum, A’Hern, Secker Walker & Prouse 1998).

Shepperd et al (1995) conducted a descriptive cohort study piloting interactive videos in general practices to help to inform patients regarding treatment choices for mild hypertension and benign prostatic hypertrophy. Fifty-four patients with mild hypertension and twenty nine with benign prostatic hypertrophy were recruited from eight general practices in Oxfordshire. The patients views of the video, treatment preference, level of involvement in treatment decision and satisfaction with decision making process were assessed as well as the GPs view on subsequent consultations.

The patients and GPs were favourable in their responses with 71% of patients saying it definitely helped with their treatment decision and GPs indicated in 82% of cases they found the IVD helpful. The results of this study provided support to the thinking that a randomised controlled study to evaluate the impact of the IVD on the doctor-patient relationship, on subsequent treatment decisions, on health outcomes and patient well being.

Naylor (1995) when discussing evidence based medicine (EBM) points out that EBM "offers little help in many grey zones of practice where the evidence about risk benefit ratios of competing clinical options is incomplete or contradictory". The aim of an Interactive Video System is to facilitate shared decision making, in these grey areas for those patients who would wish it, by providing a computerised database of established evidence based "knowledge" which will help to meet the information needs of patients and allow them to become involved in the decision making process (Kasper, Mulley, & Wennberg, 1992). The patient's participation and value system are integral to the operation of the system.

Kasper, Mulley and Wennberg (1992, p183) suggest "The shared decision and the process by which it is reached offer the best hope for improving patient satisfaction, increasing feelings of professionalism among providers, and promoting treatment choice on the basis of patient's values." Vahl Davis (1992) states "informed consent implies that the information given has been received and understood, that it will be given without bias, and that the patient will have a real choice, whether it is to treat or not to treat, whether it is this treatment or that which should be used, whether to have an operation or not." The interactive video disc system it is claimed offers a

unique opportunity to attempt to provide information with limited bias and to provide real choice.

Mort (1996) states the interactive video disc/shared decision making programme "is not designed to replace the physician in the decision making process. On the contrary, it complements the traditional physician /patient encounter. In practice physicians identify eligible patients and advise them to use the programme." She points out that the information received assists some patients by giving them a working vocabulary which facilitates their encounters with their physicians enabling more productive consultations.

The Breast Cancer SDP/IVD

A poorly informed breast cancer patient is more likely to be an anxious patient (Fallowfield, Baum and Maguire, 1986). In a study looking at 101 breast cancer patients who had been randomised to either mastectomy or breast conservation were asked about the adequacy of the information they received from their doctors. Over half the patients were not satisfied with the information they received. As previously discussed Maslin (1993), surveyed breast cancer patients satisfaction with the process they experienced when giving consent to join a clinical trial especially in relation to information and support. Over 90% of the patient surveyed wanted access to specific written and verbal information including risks/benefits and a comprehensive account of known side effects.

Fallowfield, Baum and Maguire (1987,p686) suggested the "benefits of being well informed appear to outweigh the anxiety provoked by uncertainty and unrealistic

fears...clinicians are somewhat guarded about providing prognostic information for cancer patients and this often communicates itself to the patient as something serious. Patients themselves often felt inhibited about seeking information from doctors and thus invest much time in worrying." Hack Degner & Dyck (1994 p 279) summed up the situation stating "To enable cancer patients to contribute to the process of selecting their treatments, it may be necessary for them to have a sufficient amount of illness-treatment related knowledge. For example if women with T1 N0 M0 breast tumours are to choose between a modified radical mastectomy and breast conserving surgery, they may require information about the probability of success and side effects associated with each treatment alternative." There are a number of useful ways to provide information to patients but how can we provide information to those breast cancer patients who wish it which is accurate, empathetic, unique to them and consistent?

The interactive system provides research based information on local and systemic treatment and also explores areas of uncertainty and variations in practice. The breast cancer IVD/SDP provides the patient with research based evidence which is directly applicable to their own situation. They are able in the adjuvant therapy section to access general information about a hypothetical patients risks of recurrence and mortality but they are also able to access their own personal risks of recurrence and mortality figures. The patient is advised this information may not apply in their case it reflects the statistics which would apply to a group of individuals in their situation. The information is presented verbally, visually and diagrammatically and includes figures for relative risk reduction, absolute risk reduction, difference in event free survival, and the number needed to treat to achieve benefit.

The first available shared decision making programme (SDP) for patients with cancer was produced in 1994 and was aimed at women with early breast cancer Kasper, Mulley & Wennberg (1992), Maslin et al ?? 1998. The programme summarises treatment options with results for each option based on efficacy. The results as indicated above include odds for relapse, and survival.

The interactive component to the system in the breast Cancer IVD is expressed in two ways;

- 1, the patients own details e.g. age, tumour size, lymph node status defines the content of the first part of the interactive video disc.

- 2, the patient is able to interact with the system by agreeing to proceed, have a break or stop. In the second part of the system a learn more section is available and the patient is able to interact with the content of this section at will e.g. choosing material to watch, going over previous material, accessing new material etc.

The IVD is different to a standard linear video tape in that it provides information which is unique to each patient. The information content of the IVD is tailored to each patient according to the personal details which are keyed in. The interactivity of the system means patients can go forwards or backwards in the system. They can review material or they can opt out if they wish. The system also has programmed pauses to allow patients to take a break if required.

The Breast Cancer interactive video system database aims to provide:

- 1, Information in the management of individual patients with early breast cancer based on the current overview of randomised controlled trials.

2, To offer information on current areas of debate concerning the management of breast cancer and a rationale for treatments on offer.

3, To address issues relating to benefits and disadvantages of treatments based on the impact of a treatment on quality of life balanced against the possibility of extending life expectancy.

4, To address areas of current controversy and uncertainty.

5, To recognise that individual patients will have legitimate personal views, values and preferences which may influence their choice of local or systemic treatment.

Mort et al (1995 p5) state “When women with early stage breast cancer who are suitable candidates for either surgical option (wide local excision followed by radiotherapy or mastectomy +/- reconstruction) learn that their survival outcome is the same in either case, a broad range of outcomes become important to consider.....Although many physicians and patients would agree that the most important outcome for women with early-stage breast cancer is survival, it is less likely that physicians and patients would agree in the relative importance of outcomes that relate more to the patients quality of life (Slevin et al. 1988). One woman may feel strongly conserving the physical appearance or sensation of her breast is extremely important. Another woman may feel that removing the involved breast and reducing her chance of dealing with an in-breast ipsilateral recurrence and subsequent mastectomy is more important than conserving her breast. It bears emphasising that having a choice is not the same as having to make a decision.”

The patient should after using the interactive video system and standard informational care from their clinicians and clinical nurse specialist (Mort, Esserman, Tripathy, Hillner, Houghton, Bunker, Baum 1995);

- 1, Be able to make an informed treatment choice.
- 2, Have a rationale for their chosen treatment.
- 3, Understand the benefits, trade offs and impact on quality of life which may occur as a result of their choice.
- 4, Be in possession of a hard copy of the information they have accessed which is personalised.

As discussed under Use of literature; Chapman, Elstein & Kostbade Hughes (1995) reported a study they conducted examining the effects of materials including the breast cancer IVD for providing patients with information on breast cancer and its treatment options. They used undergraduate students as surrogate patients and assessed their baseline knowledge on the disease and its treatment options. They also ascertained the individuals initial preferences for treatment from wide local excision followed by radiotherapy, mastectomy followed by reconstruction or a mastectomy followed by use of a breast prosthesis. This was done both prior to and after reading a booklet or watching an interactive videodisc (IVD), shared decision making programme (SDP) of the relevant information. Post test scores of the students knowledge base were significantly higher in both groups but in the IVD group the students whose background was psychology had better scores after watching the IVD. The authors suggest this result may be due to some added teaching value of a video format. Treatment choices were not affected by reading the booklet but a preference shift was noted after watching the videodisc towards breast conserving surgery . It appears the students found the personal story of individual women interviewed on the

IVD influenced their decisions. Chapman et al. (1995) suggest this difference may be due to the additional features the video had to offer such as interviews with other patients and more realistic images of treatment options. Chapman et al. also concede that their results are at odds with other studies e.g. Hughes (1993, 1995). One significant reason their results may vary with other studies is the fact that surrogate patients were used. These students are obviously not facing a life threatening cancer diagnosis and therefore may be more able to learn and retain information. They are not suffering from shock or denial (Watson, Greer, Blake et al. 1984, Hogbin & Fallowfield 1989).

Maslin, Baum, A'Hern, Secker Walker & Prouse ??1998, piloted and evaluated the shared decision making programme (SDP) described above for women with early breast cancer looking at surgical and adjuvant treatment options using the personalised, computerised interactive laser disc system (IVD). The study aimed to determine the acceptability of an interactive video system, in addition to the standard informational care and support provided by the clinicians and clinical nurse specialist, as a means of providing information about the risks and benefits of treatment choices- surgery and subsequent adjuvant chemotherapy. An experimental randomised study design (n100) was chosen.

The main outcome measures included questionnaires to ascertain the acceptability of the IVD, an assessment of health status, the SF36, the Hospital Anxiety and Depression (HAD) scale and after nine months repeat retesting with the SF36 and HAD in addition to a further questionnaire aimed to elicit the patient's satisfaction with their treatment choice at nine months post diagnosis.

One hundred patients were recruited. At 9 months 94% of questionnaires were returned. The HAD Scale overall summary scores, for both groups, indicated a significant fall in anxiety at 9 months $p < 0.001$ but there was no real change in the depression scores in either group which were low. The SF 36 Questionnaire demonstrated nil of significant note. The IVD system was very highly evaluated. When asked if the patient would recommend the IVD to someone they knew with a diagnosis of breast cancer 90 % said yes. Overall there was a high degree of satisfaction in both groups. There was no statistically significant difference in outcomes or satisfaction in either arm. The study did appear to support the significance of effective communication by the Clinician and Clinical Nurse Specialist (CNS) in Breast Care.

It could be suggested that the patients in this study were a biased sample because many of these patients had proactively elected to come to this centre over other more local services. Many of these women actively therefore sought information and were willing to travel to obtain it. The reasons for this may be due to the fact that this study was conducted in a specialist centre (Maslin 1993). It may therefore be the case that these patients either were patients who wished to actively participate in decision making or the patients wished to support the specialist centre in improving information and support for breast cancer patients.

The reasons given by some women for not wishing to participate in this study varied. It was interesting to note that some women felt that they would prefer factual information and support to be provided by friends and family who have had personal

experience of breast cancer supporting the findings of Bilodeau & Degner, 1996. This choice may be seen by the woman as an expression of their autonomy and may enhance a sense of control (Kfir & Slevin 1991) but this position could cause difficulties in relation to treatment decisions as it is quite unlikely a friend or relative will not have sufficient accurate information to disseminate to the patient and they may or may not be aware of current treatment advances.

Another point of interest was the fact that a few elderly patients expressed the view that they did not want to see anything visual when approached about entering the study even when assured by the clinical nurse specialist that they would have the ability to control the programme or stop viewing at any time. These patients expressed the view that they would leave all decisions to the hospital and they just wanted their breast cancer treatment 'sorted out' as quickly as possible. Although this view was in the minority it represented the view of 33.3% who refused to participate (Bilodeau & Degner 1996).

The length of the IVD programmes had been debated extensively by the professionals who viewed the IVD's prior to the study commencing. To the professional who has a fairly extensive knowledge of breast cancer and the various treatment options the IVD can seem protracted and slow taking from as much as half an hour to view at minimum, an hour on average and at times up to two hours. Patients do not appear perceive the IVD in the same way as professionals as indicated by 82 % of the sample stating they found it just about right in length. The reason for this difference in perception between the professional and the patient may be that whilst this information is well known to the professional it is for many patients new

information. For the patients the fact is that in their case the topics being dealt with can explore the possibility of preserving or losing a breast or in the case of the adjuvant therapy IVD the possibility of maximising quantity and/or quality of life. The impact of these possibilities cannot fully be conceived of by the personally uninvolved professional (Kfir & Slevin 1991).

Participants largely appeared to be absorbed by the IVD as evidenced by 96% stating they found the material interesting or very interesting. As stated the patients did not appear to find the IVD lengthy but they themselves were conscious not of their time but the Clinical Nurse Specialists (CNS) time. Patient's often commented that they were very content to sit and view the IVD for as long as it took but they did not want to take up too much of the CNS's time. The Clinical Nurses Specialists in this study reassured the patients that they were free to view as much or as little as they wished. They were also free to return to review the material if they wished at any time.

It has been suggested that the IVD could save the Clinicians time (Rice 1992, Wennberg 1992, Mulley 1994,) Could the IVD be used to reduce the amount of time patients spend with health care professionals? The answer could be yes if it was used to replace rather than assist the multidisciplinary team in the provision of information? It is a fact that health care professionals do only have a limited amount of time to allocate to patients and it may be that facilitating more efficient use of this time should be a priority. Although a reduction in time spent specifically with the clinician, may be possible, in this study the use of the IVD did increase the time spent by the CNS with the patient. The reason for this was, the fact that, the patients required a full

...
explanation of the study and the IVD, as well as all the usual care and support from the CNS, Clinician, and the Multidisciplinary Team. The overall time therefore spent with the multidisciplinary team particularly the clinical nurse specialist was increased by the time taken explaining the system, the actual time the IVD was being viewed and also by any questions/discussion which followed as a direct result. The majority of patients as discussed spent at least an hour viewing the IVD material in addition to the pre and post viewing conversations. The majority of patients viewed the first section dealing with the basic information a patient would need to make a decision and the majority then chose to view part of the learn more section although the number of additional choices selected in the learn more section varied. As a result of having viewed the IVD information the patient was in a stronger position to ask more detailed questions than the average patient and therefore additional time was given to address these questions by the Clinical Nurse Specialist (CNS).

Participants in this study as previously outlined had the full support of a CNS and were not left to view the IVD unattended in case of an adverse reaction to the material viewed. The principle investigator had been concerned that this might occur particularly as the patients viewing the adjuvant therapy IVD had the facility to view their own personal risks of recurrence and mortality statistics. It was felt by the principle investigator to be unethical to provide this level of information to patients without professional support immediately available. This concern however was unfounded. The patients viewing the risks of recurrence and mortality figures did not seem disturbed by this facility. Not all patients elected to look at their own possible risks of recurrence etc. and this decision was respected. It may be however that the presence of the CNS was a calming factor and therefore the patients felt secure when

electing to view such sensitive material and that was the reason for the uneventful viewing.

At the outset of the study it had been thought by the investigators that the patients may find the material contained in the IVD to be at too high and specific a level. This does not appear to have been the case with 96 % finding it easy or very easy to understand. Another area which the investigators thought might pose a problem was the use of detailed graphs and statistics but 92% did not raise this as a problem when specifically asked.

Comments from participants on the IVD indicated that;

i. the IVD had given them information that was new i.e. “I didn’t realise there was a possibility of breast shrinkage after radiotherapy”. “The IVD says that radiotherapy is going to kill the rest of the cancer cells so operations obviously don’t get all the cancer.” “I didn’t realise it was possible to get a recurrence in the scar line.”

ii. the IVD met general information needs i.e. “It caters for all types of people and gives the facts very clearly.”

iii. the IVD provided practical assistance in coping i.e. “The section on hair loss was very up front and helpful in facing the situation.” “Seeing the scars were frightening it just released my fear of surgery.” “It was good to see someone cry on the video because we all do.”

iv. the IVD provided some psychological benefit i.e. “It was good to see women of the same age. I did not feel so isolated.” “Of course one is apprehensive but the future is always an unknown whether one is ill or not. I appreciated the time and care the unit gave to patients. Discussion certainly gives peace of mind.”

v. the IVD was used by some patients to consider risks and weigh up treatment options i.e. “I appreciated the section on recurrence statistics and adjuvant therapy.”

vi. for some the IVD confirmed their own views on treatment and choice i.e. “The video validated the information I had already gathered, it reassured me I had understood what the consultant had said. Having real women talking about their experiences and how they came to their decisions was helpful. You felt you could identify with them.” “Catering for such a wide variety of patients is very difficult and therefore it is impossible to get a video just right. I felt it was helpful but in view of my knowledge of the subject (because of my family history) it was a little elementary.” “The IVD reinforced the information I already had, it did not change the emphasis of what I already knew. I needed to absorb a great deal of information at a time when I was not really mentally suited.”

vii. the IVD was generally helpful i.e. “My husband and I found it helpful but would not have wanted to see it in isolation without a breast care nurse present.” “I found it generally most helpful and informative.” “I thought the IVD was most helpful in asking and answering the questions that I needed to know.”

This results of this study are similar to Maslin (1993) 'A survey of the opinions of women of a breast unit on the issues of giving informed consent to joining a clinical trial' in that when asked if there was anything else the patient would have included in the IVD content patients comments focused strongly on the provision of additional information rather than any suggestion of the removal of information e.g. Some of the patients would have liked more information on practical issues i.e. bathing, on treatment related issues i.e. tamoxifen and radiotherapy, side effects of all treatments, potential problems i.e. more on chest wall recurrence, more on the views of all concerned the women and their relatives. As in Maslin (1993) the patients wanted access to this information as a right not a privilege which they could chose to exercise if they wished.

Comments which related to the actual technology were few. The women did not find the technology difficult. To the viewer it was simply a television screen with touch screen control providing personalised information on their disease. One facility the patients found particularly useful was the print out they received at the end of their viewing session which summarised the information they received.

The last three questions were useful indicators as to how useful the IVD's really are. The IVD did provide information which gave 72 % of the women a clearer understanding of their breast cancer and treatment options. The majority 66% likewise felt the IVD had been useful and possibly the most important indicator 90% stated they would recommend it to someone they knew who had a diagnosis of breast cancer. The recommendation of a service to a friend or relative is one of the highest forms of commendation for a product or service because individuals may tolerate imperfect

service for themselves but they usually require a higher standard of care for relatives or friends. The fact that a patient would recommend the IVD to someone they knew with breast cancer is a strong indicator of the rating they give the system. As discussed earlier (Naylor, 1995) evidence based medicine “offers little help in many grey zones of practice where the evidence about risk benefit ratios of competing clinical options is incomplete or contradictory”. The Interactive Video System appears to facilitate shared decision making, in these grey areas for those patients who would wish it, by providing a computerised database of established evidence based “knowledge” which helps to meet the information needs of patients and allow them to become involved in the decision making process if they so wish (Kasper, Mulley, & Wennberg, 1992).

At Nine months post treatment:

It was interesting to note that relatively few of the patients changed their minds about whether or not to have mastectomy or wide local excision 11% or adjuvant therapy 13% based on the information they saw on the IVD. The reason for this could be:

1. The patients had received sufficient information to make a decision from their existing interactions with the Clinician, Clinical Nurse Specialist and Multidisciplinary Team.

2. The patients may have already formed a fixed view based on their own existing knowledge or after sharing and acquiring information from others i.e. friends and family.

3. The patients were not influenced by the data they viewed.

The results on who made the treatment decision reflected the view of the patients that they participated but in collaboration with the Clinician and the Breast Care Nurse. The largest single group were those who felt the decision was collaborative between themselves the Clinician and the Breast Care Nurse (44%). Only 11% of the patients felt they had taken the treatment decision on their own followed by 16% who felt the decision was made between themselves and the Clinician. The Clinician alone accounted for 22% of the decisions. The results confirm those of previous studies which indicate that although patients may wish to access information they may not wish to take sole responsibility for the decision (Beisecker & Beisecker 1990, Luker et al. 1995, Bilodeau & Degner 1996). It would also appear the clinician as sole arbitrator of treatment decisions is largely past. The fact that only 22% of the sample stated the clinician alone made the decision may reflect a number of things either;

- 1, The Clinician was responding to the patients request to decide on their behalf thereby the patient although not demonstrating autonomy by making the decision personally, demonstrated autonomy by delegating their autonomy to their clinician (Ingelfinger 1980) or

- 2, It may be that the Clinician was behaving in a paternalistic fashion (Brock & Wartman 1990)

- 3, It maybe that the patient did participate but the stress of the situation has negated that participation in their mind (Brock & Wartman 1990)

As previously outlined Maguire et al (1978, 1980) established that nurses appropriately trained in assessment for psychiatric morbidity could successfully identify patients at risk and make appropriate referrals to a department of psychological medicine, nurses especially clinical nurse specialists in breast care, have been taking a leading role in acting as advocates for patients diagnosed with breast cancer (Maguire et al. 1980, 1988b, NHSE COG 1996) The role has developed and continues to be widely endorsed (the Fforest Report,1986, Watson et al.,1988, Roberts & Fallowfield,1990, Cancer Relief Macmillan Fund's Minimum Standards for Breast Care,1994, the British Association of Surgical Oncologists guide-lines on treatment protocols, 1994, the British Breast Group's assessment of specialist cancer centres,1995, and the NHSE COG on Breast Cancer 1996, all of which have endorsed the supportive role of appropriately trained specialist nurses who are able to participate in information giving, decision making and psychological support. The patients in this study explicitly and implicitly looked to the CNS as a source of information and support. Although it may be true to say the CNS is not totally impartial she would appear to act as an advocate on occasions (Wells, 1986) and this role and function is endorsed by the patients. She is also seen to be part of the team facilitating informed consent (CRC, 1983).

This study does demonstrate quite strongly the supportive role of the CNS in Breast Care. Overall the patients in both groups of the study were satisfied with the tools used in information giving. Although the sources of information used varied in each arm of the study the continuing support both in terms of information and psychological support of the CNS remained. Working together with the clinician it could be suggested that this support rather than the tools used was of primary

importance. Luker et al. (1995) suggested detailed clinical information was not within the scope of the average ward nurse but may well fall within the scope of practice of the specialist breast care nurse. This study would appear to support that position. The fact that the CNS was seen by 50% of the patients as being involved in sharing in the decision making process gives an indication of the strength of her input.

Overall the IVD was evaluated very highly but the IVD could be seen as being expensive in a number of ways. There is the initial capital purchase, the need for regular software updates, the need for a dedicated room during viewing of the programme and the associated manpower costs. The results of this study have indicated that viewing the IVD did not result in a significant increase in satisfaction or improvement in the intervention groups anxiety and depression scores over the group who received standard care as both arms of the study were comparable.

It could be suggested the comprehensive, individual support the patient received from the Clinician, the CNS and the multidisciplinary team was the a key factor in satisfaction and adjustment rather than the specific method of information sharing used. If this is the case and if cost is a major issue for carers provided the appropriate support from the clinician, clinical nurse specialist and members of the multidisciplinary team is available to the patient other less expensive forms technical information support could be used to aid the provision of more detailed information. It could be suggested, literature, cards, other computer software or a straight linear video dealing with specific scenarios could be just as effective as aids to information giving.

The IVD has the ability to store and provide consistent protocol based information at a uniformly high rate which would be difficult for a clinician or nurse given the influence of the stresses of a working week to match. The professional has the ability to gauge a patients' mood and assess patient requirements which the machine cannot do (Maguire et al 1980, 1983, Watson et al 1988). It would be interesting to evaluate how the information given by the clinician and clinical nurse specialist varies as the week progresses and how other factors e.g. time, stress, personal factors affect the quantity and quality of information given to patients. This issue may be important when considering the debate on informed consent Baum 1986, Baum & Houghton 1988, Williams 1992. With the IVD professionals can demonstrate that a certain level of specific information was presented to the patient and this was reinforced verbally by the CNS and in writing by the summary print out. The professional still has the problem of knowing exactly what impact stress and selective perception is having on the patient and therefore can never be sure exactly how much information the patient has absorbed. This however is balanced by the fact that in an imperfect world where no method of information giving will be entirely correct for every patient this system provides an useful vehicle for facilitating the informed consent process not just for information in which risks and benefits must be assessed, but also for very technical information or in clinical trials (Williams 1992). The system could be useful to those conducting clinical trials by providing high quality, evidence based, personalised information which outlines the nature of clinical trials, the specifics of the trial, the advantages and the disadvantages of participation (Schafer 1989).

One important issue relates to the updating of software. Breast cancer research is constantly updating the information available and it will be important that any system or software has the capacity to incorporate new information at an affordable level. What is known and accepted today may need updating within a relatively short period. One solution could be an annual fee which covers software updates which subscribers to the system could support. Although this study does not address the subject of the multitude of computer/CD systems available it may be that in view of the fact that computer technology is advancing at such a rapid rate the principles used in the production and use of the IVD may be achieved more easily and less expensively today.

There is substantial research to support the view that good communication is important in patient adjustment to a cancer diagnosis (Maguire, 1978, Buckman 1986, Fallowfield et al 1986), the key players in the area of breast cancer appears to be the clinician (Fallowfield et al 1990 a & b, 1994 a & b) and the breast care nurse (Maguire et al 1978, 1980, 1983). It would appear many patients do want access to good quality information on their disease, treatment options and side effects (Thornton 1992, Maslin 1993), and some patients though not all may wish to participate in the decision making process (Bilodeau & Degner 1996). This study demonstrated that the IVD is highly evaluated by those who used it as tool to assist decision making. Those using the IVD system did not appear to suffer any adverse psychological affects and found the system simple and easy to use. Equally this study showed that patients in the standard care group were very satisfied with their level of information. Does this mean providers of health care should opt for the simpler methods of reinforcing information

giving provided the backbone of support and information is provided by healthcare professional

SDP/IVDs are not only about patient choice they could also act as a valuable resource in the standardising of treatment protocols, promoting evidence based practice, and potentially helping to collect valuable clinical/research data and provide a measure for quality assurance (Kasper et al 1992, Mulley 1994, Breast Cancer COG 1996). It may be that these additional functions could provide a rationale for the expense incurred by the provision of these resources. The system could facilitate protocol based practice but would this be acceptable to the majority of clinicians? It would be interesting to discover how many hospital based consultants would support the introduction of such systems more widely. Can clinicians be induced to change their practice in line with the patient's expressed preference as result of using the SDP? In this study with supportive clinicians the answer was yes but this was equally true in the standard care group with the same consultants. Subjective experience seems to suggest enthusiasts for SDP/IVDs are quality assurance officers, patient information groups, or nurses, the very people who often lack the authority or resources to make tangible change in the health care system.

Is there then an added value in the use of IVD/SDPs in terms of data collection, quality assurance and medical audit over time? This is a hypothesis which would need to be tested but with compliance and co-operation in the use of the system it could be suggested the system could provide a useful tool. It is possible that the IVD could act as a tool in helping to safeguard the multidisciplinary team from litigation because of its very specific and uniform delivery of information. As previously discussed viewing

the SDP ensures a quantifiable amount of information has been provided for the patient. It cannot ensure the information has been received but it can be used to substantiate the fact that certain information was covered. This could be useful particularly in difficult situations like patients giving consent to participation in clinical trials.

This study did determine that providing information to women with early breast cancer using an interactive system did not significantly reduce the anxiety and depression associated with its diagnosis and treatment. Both the control and intervention groups within this study experienced a reduction in anxiety and depression at nine months but this reduction could not be attributed to the IVD.

The study also determined that providing information using an interactive video system, to women about treatment choices did not significantly increase their satisfaction with the choice they made. Both groups were largely satisfied with their choices and there was no statistically significant increase in the satisfaction expressed by the IVD group over the controls. The skill appears to lie in the professionals ability to discern the information requirements of the patient and being able to explain the way forward including advantages and disadvantages in such a way that the patient is able to participate to the level they wish (Maguire 1978, Maguire & Faulkner, 1988). The interactive video disc system however does offer a unique opportunity to attempt to provide information with limited bias to patients and to provide real choice.

The study does appear to support the significance of effective communication by the Clinician and Clinical Nurse Specialist (CNS) in Breast Care. The control

group demonstrated equally high levels of satisfaction with their quantity and quality of information. It may be that if the IVD had been evaluated in a centre where the clinician was not open to dialogue with patients and where the services of a CNS was not available the results between the two groups could have been quite different.

The study also ascertained that the use of the IVD technology is acceptable to the women. The majority of the women who used the IVD were comfortable with the touch control screen and with the visual display unit. The data from this study is helpful in that it demonstrates that the use of an IVD with explicit but empathetic information does not appear to be harmful to those women who choose to view it. This fact does not exclude the possibility that some patients choose to exercise their rights by delegating them to their clinician and this too is a valid treatment choice (Ingelfinger 1980, Maslin 1993, 1994, Baum 1994, Fallowfield, Hall, Maguire, Baum 1990).

The IVD appears to be a valuable tool but as detailed above a relatively expensive one. It may well be as technology moves on the IVD will be superseded but at present for those patients who desire it the IVD provides breast cancer information the content and quality of which is at a consistently high predetermined level. The patient is also in the unique position of being able to view detailed personalised information and have their personal risks and benefits of treatment options clearly and empathetically explained. It is difficult to put a price on the value of this to patients.

Webb (1987) when discussing information and patient education for cancer patients quotes a patient who said “there are no simple solutions for the problems of all people with cancer, but there are options we can explore, approaches we can try and steps we can take to help ourselves....Please give us the power and sense of control over our lives that knowledge can bring“ As discussed earlier Maureen Roberts, Clinical Director of the Edinburgh Breast Screening project, 1979 to 1989, who succumbed to breast cancer said “Communication is all important. Proper truthful accounts of diagnosis, treatment and aftercare must be written and made available everywhere, so that women become well informed and most important, start to take part in the decision making process for themselves (1989).”

Appendix A from Outputs 3, 4, 5, 6, 7, 8,

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