The development of a model of follow-up care for adult patients with inflammatory bowel disease

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in the Faculty of Medical and Human Sciences

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List of associated publications and presentations from the thesis

Kemp K, Griffiths J, Lovell K. Understanding the health and social care needs of people living with IBD: A meta-synthesis of the evidence. *World J Gastroenterol* 2012; 18(43): 6240-6249
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Kemp, K, Griffiths J, Campbell, S, Lovell K 'A Qualitative exploration of inflammatory bowel disease patient attitudes towards self management and new modes of care delivery' Gut. July 2012; 61 (2) *poster presentation*

Kemp K, Griffiths J, Lovell K (2012)' An exploration of the health and social needs of people living with inflammatory bowel disease: a metasynthesis' JCC Vol 6, Suppl 1, S119 ***Highly commended award*** */oral presentation*

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Abstract

Introduction Inflammatory bowel disease (IBD), Crohn’s Disease and ulcerative colitis, are long term conditions which follow a relapsing and remitting pattern. The rising incidence of IBD in adults and children has implications for the lifelong burden of disease and the provision of specialist services. Patients are predominantly managed by secondary care and follow a traditional, scheduled follow-up cycle, which is unsustainable and unsatisfactory. Patients with IBD should have access to specialist care which is delivered according to their values and needs. However few studies have examined patients’ views of follow-up care. There is also concern in the UK that services for patients with long term conditions are not orgnised to promote independence with silo working in primary and secondary care.These may be brought together formally through the development of models of care. Utilization of current out-patient spaces to regularly review stable patients is inappropriate and is challenged by commissioners.The question remains as to what models of follow-up are we able to offer patients which are acceptable and what is the role of the general practitioner (GP) and primary care within this. The aim of this study was to develop an integrated, acceptable, model of follow-up care for patients with IBD.

Methods The study follows the development phase of the MRC Framework for complex interventions. A best evidence synthesis was undertaken to identify the follow-up care models in IBD. A meta-synthesis of the health and social care needs of patients with IBD was conducted to explore the impact of living with IBD. Qualitative interviews with 24 IBD patients (18 patients had CD, and 6 UC, age range 27-72 years, disease duration range 2 – 40yr) and 20 GPs purposively selected from across NW England were carried out. Patients were asked about their experience, values and preference of follow-up care. The GPs were questioned about their current and potential role in IBD. Analysis was undertaken using Framework Analysis. The best evidence synthesis, meta-synthesis and interviews were synthesised by an expert panel, Consultant Gastroenterologist, patient, GP, IBD Nurse, to develop the model of follow-up care.

Results There were similarities and commonalities between the patient and general practitioner interviews. Patients did not want to be seen when well, GPs wanted more involvement in care and there is scope for an IBD outreach nurse at the interface of primary/secondary care. Discharging quiescent patients into enhanced GP care, to ensure equitable treatment, was acceptable to all, as was the concept of ‘virtual’ clinics. Patients would initiate self referral within the ‘virtual’ arm whilst patients under GP care would be referred back into secondary care as a rapid referral <7days and not using a new patient tariff. Complex IBD patients would remain under secondary care. A stratified model of follow-up care was developed.

Conclusion This study provides an acceptable integrated model of follow-up for patients with IBD. It takes into account the growing incidence of IBD and UK policy to reduce inappropriate follow-up. It emphasises role of self management, the integration of primary and secondary care, placing the patient closer to home whilst allowing secondary care to concentrate on complex patient management.

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Deborah Ward for proof reading the final thesis.

Dedication

The thesis is dedicated to my husband Paul and children Robert and Thomas. It's been a long journey and they have loved me unconditionally throughout, and to my mum and dad who care for my children more than I could possibly ask for.

The Author

I qualified as a Registered General Nurse in 1988 and spent a number of years as a nurse in intensive care, completing my Bachelor of Nursing (Hons) degree in 1997. In 1998 I left intensive care to take up a specialist nurse role in gastroenterology, concentrating on nutrition. I completed an MPhil at the University of Manchester in 2001, ‘A clinical and cost effectiveness analysis of a nutrition support team’. Following this I concentrated more in the area of inflammatory bowel disease, completing lower gastrointestinal endoscopy / flexi-sigmoidoscopy at Hull University.

In 2008 I was appointed a part time lecturer at The University of Manchester and maintained my role as part time Inflammatory Bowel Disease Nurse Practitioner. In 2009 I was successfully awarded one of the first National Institute of Health Research Clinical Academic Training awards for Nurses, Midwives and Allied Health Professionals and commenced this study in 2010.

Abbreviations

Inflammatory Bowel Disease	IBD
Crohn’s Disease	CD
Ulcerative Colitis	UC
General Practitioner	GP
Primary Care Research Network	PCRN
Quality of Life	QoL
National Institute of Health Research	NIHR
Extra Intestinal Manifestations	EIMs
Quality Outcomes Framework	QOF
Clinical Commissioning Groups	CCGs
Long Term Conditions	LTCs
Quality Innovation Productivity Prevention	QIPP
Medical Research Council	MRC
Computer Assisted Qualitative Data Analysis Software	CAQDAS

Chapter 1

Introduction

The overall aim of the thesis was to develop a patient centred model of follow-up care for inflammatory bowel disease (IBD).

IBD is a chronic inflammatory disease of the gastrointestinal tract and is divided into two subgroups, Crohn’s Disease (CD) and Ulcerative Colitis (UC). It is characterised by periods of remission and relapse. Bowel movements may occur up to 20 times per day with associated faecal urgency and incontinence. It is estimated that there are up to 240,000 people living with IBD in the UK, with a cost in excess of £254 million per annum (Bassi, Dodd et al. 2004). The increasing prevalence of IBD has now led it to be recognised as a long term condition. There is no cure for IBD and in most cases, the disease requires a lifetime of care.

IBD is a challenging disease for the healthcare service in terms of its treatment, diagnosis and prognosis, assessment of disease activity and severity, as well as outcome of treatments (Dignass, Van Asshce et al. 2010; Dignass, Lindsay et al. 2012). As a chronic long term condition it has been recognised that these patients should have access to specialised care although the recent national IBD Audit highlighted major discrepancies in how care across the UK (Royal College of Physicians 2010).

The current structure of health-care provision differs from hospital to hospital and often depends on whether there is an IBD team in place dedicated to the care of these patients. In the current system, even with the presence of an IBD team, patients are compelled to attend hospital for their follow-up care. Factors such as the type of medical treatment they receive, the type of haematological monitoring required and the level of support from primary care, in addition to pattern of disease, all influence the follow up care a patient requires or receives.

Follow-up care for patients living with IBD is governed by organisational issues, such as outpatient clinic appointment availability, bed pressures and the availability of specialist team input. Conventional follow-up care for this group of patients is unsatisfactory and unsustainable. The follow-up tariff for face-to-face follow-up appointments is expensive to both patients and commissioners, is an inefficient use of facilities and is an unproductive way to manage a long term condition such as IBD. Yet, ironically, it is the present tariff system, payment by results, which acts as a barrier to the development of innovative models of follow-up care management.

A separation exists between primary and secondary care in terms of IBD management. The current model of care is reactive and secondary care based, with little or no integration with primary care. Evidence that IBD care is best provided by specialists is acknowledged (Rubin, Uluscu et al. 2012) but this is in the very acute, complex patient. The patient experiencing quiescent disease follows the same pattern of follow-up care to that of the complex active patient; care is provided by secondary care in a traditional follow-up scheduled way.

There are no models of follow-up care for patients with IBD, which take into account the fluctuating nature of the disease and its chronicity, and there is no evidence for the mobility of care between primary and secondary care in this disease area. No studies, to date, have involved IBD patients in the process of defining the type of organization or service delivery they would like to receive and no studies have explored the views of GPs on how they want to, or are willing to be involved in, IBD care.

As an IBD Nurse Specialist, my interest in a model of follow-up care led directly from clinical experience. Observing over-booked clinics, patients waiting hours to be reviewed, and well patients seen routinely and repeatedly, led the author to believe that other avenues of follow-up care had to be explored. The opportunity to undertake this research came at a time of NHS overhaul in England with the implementation of the White Paper ‘Equity and excellence – liberating the NHS’ (DH 2010), which recommended restructuring of GP care and long term conditions. This presented an ideal opportunity to review IBD follow-up care.

1.1 Aim of the study

The aim of the study was to develop a best evidence model of follow-up care that is acceptable to patients with inflammatory bowel disease.

1.2 Objectives of the study

There are five objectives to the study.

Stage one objective

To identify the evidence base of models of follow-up care for patients with IBD by a best evidence synthesis of the literature.

Stage two objectives

To understand the health and social needs of patients living with IBD through meta- synthesis methodology.

Stage three objectives

To explore patient preferences for follow-up care delivery, by whom, when and where through qualitative interviews.

Stage four objectives

To examine the current role of the GP, their preferences for follow-up care and their involvement in IBD care through qualitative interviews.

Stage five objectives

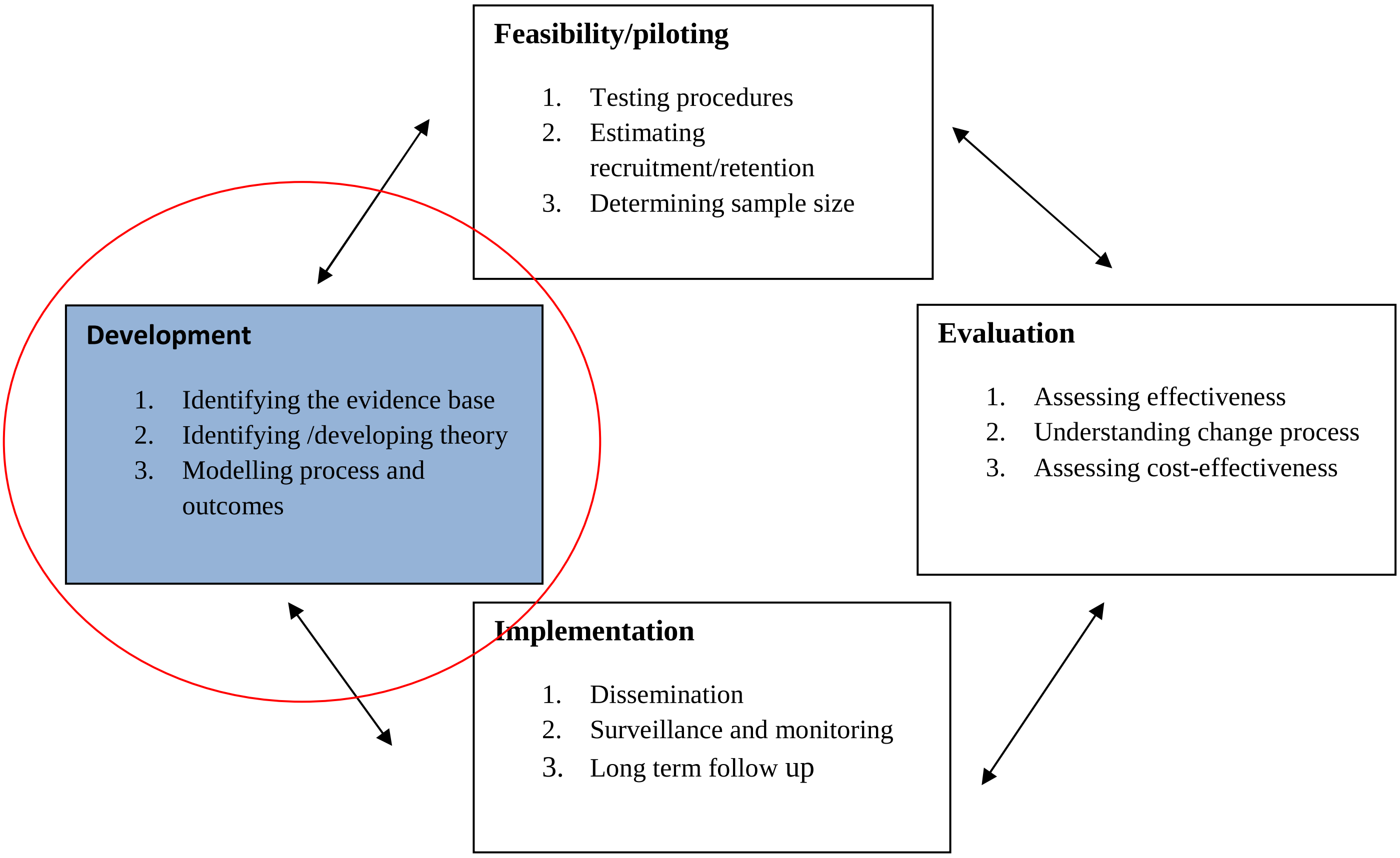
To identify the range of pathways and model follow-up care derived from the best evidence review, meta-synthesis study, patient and the GP interviews by synthesising the data to develop an acceptable model of follow-up care using the Medical Research Council (MRC) Framework for the development of complex interventions (Campbell, Murray et al. 2007).

1.3 MRC Framework for the development of complex interventions

This project focused on follow-up care of patients with IBD with the overall aim of developing a new model of follow-up care for patients. The MRC framework follows a staged approach to the development of complex interventions: preclinical or theoretical; modelling; exploratory or pilot trial; definitive randomised controlled trial; and implementation (Craig, Dieppe et al. 2008). The stepwise approach concentrates on the development phase, establishing the evidence and providing a coherent theoretical basis for the intervention within the context of the setting (Campbell, Murray et al. 2007).

The modelling phase is achieved by identifying the main ingredients of the intervention using exploratory qualitative methods, in this case interviews, to sufficiently understand the problem and how the intervention will result in improvements for patients and the healthcare organisation (Campbell, Murray et al. 2007). This study concentrates specifically upon the development phase, identifying the evidence base for the model of care, developing the theory and modelling of the intervention by qualitative interviews of patients and GPs and synthesising the evidence with a Consultant Gastroenterologist, GP and a patient (see Figure 2).

Figure 1: Key elements of the development and evaluation process MRC (Craig, Dieppe et al 2008, pg 8)



This project will provide a unique insight into patients' perceptions of how follow-up care should be planned and delivered. It will provide a clear and practical understanding of follow- up care delivery and identify patient preferences for the service. This will lead to the development of an acceptable, and evidenced based protocol, of follow-up care that can be evaluated. An understanding of patients' views and needs will enable a model of care delivery to be developed which is driven from the user perspective and therefore patient centred. The design of an intervention depends on understanding the underlying problem and context (Campbell, Fitzpatrick et al. 2000) and the rigorous approach to data analysis.

The thesis is presented in the alternative format. It describes four studies which conclude the theoretical phase of the complex intervention, the development of a model of follow-up care for patients with inflammatory bowel disease (IBD). The thesis is structured as follows: Chapter one introduces the rationale for the study; Chapter two provides an outline of IBD in the form of a topic review; Chapter three provides expansion of the methods used in each phase of the study and the rationale for using each approach; Chapter four is a best evidence synthesis of models of follow-up in IBD; Chapters five to eight present the studies undertaken within the thesis, labelled papers 1-4. Chapter nine will conclude with a discussion, summary and limitation of the studies, implications for the care and management of patients with IBD and recommendations for future research.

The thesis will present the following four papers:

Paper 1 Kemp K, Griffiths J, Lovell K, Understanding the health and Social needs of people living with inflammatory bowel disease: a meta-synthesis.

Published in **World Journal of Gastroenterology**; 2012, 18 (43) pg 6420-6429.

Doi:10.3748/wjg.v18.i43.6240

Paper 2 Kemp K, Griffiths J, Campbell S, Lovell K, An exploration of the follow-up up needs of patients with inflammatory bowel disease.

Journal of Crohns and Colitis, Vol 7, issue 8, e386

Paper 3 Kemp K, Griffiths J, O'Malley J, Lovell K, General practitioners' perspectives of inflammatory bowel disease management in primary care.

Submitted

Paper 4 Kemp K, Griffiths J, Lovell K, Developing a model of follow-up care for patients with inflammatory bowel disease using the MRC framework for the development of complex interventions: a description of the modelling phase

Prepared for submission.

These studies are presented in the format for publication.

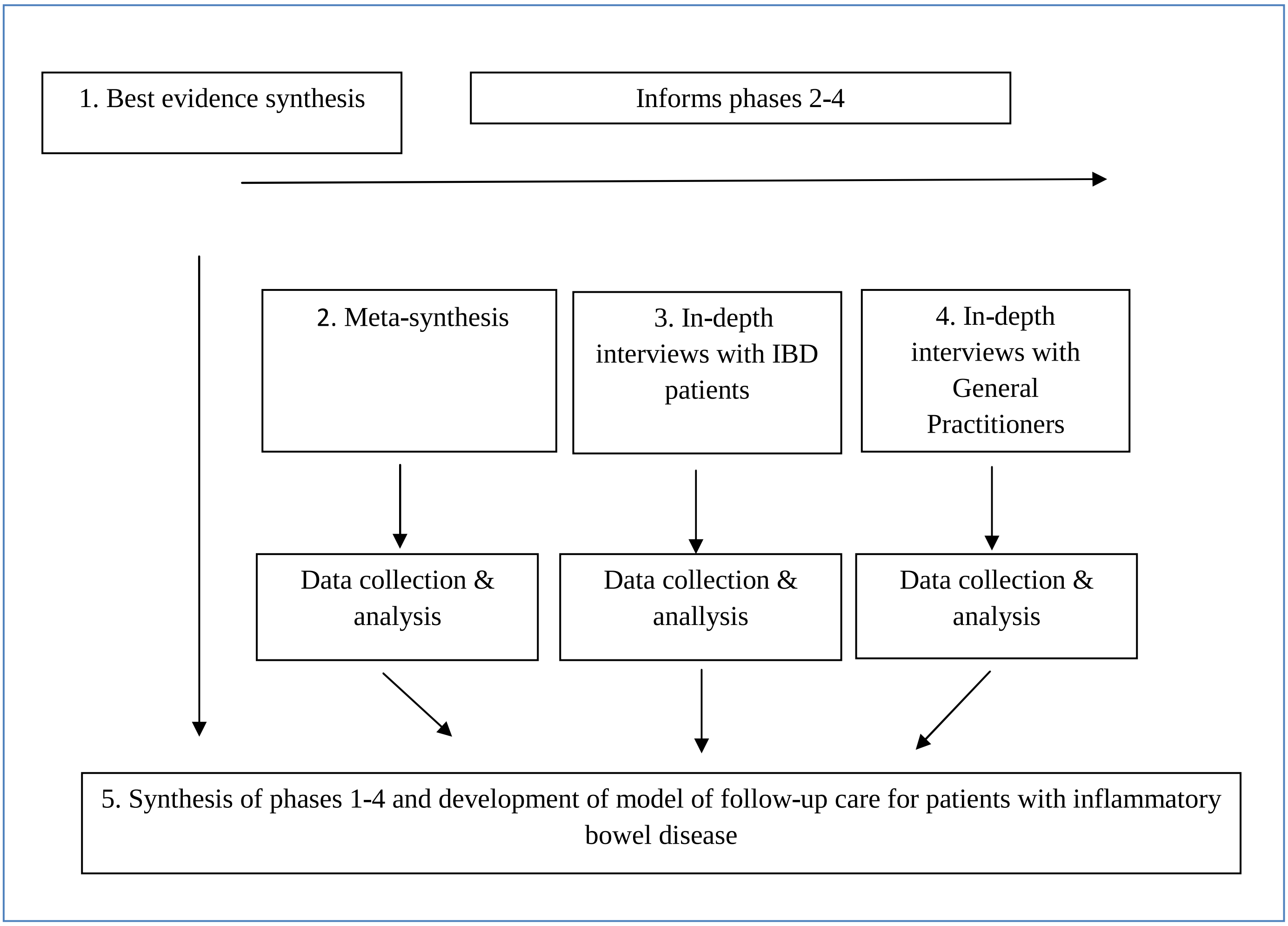
Paper 1 describes a meta-synthesis of the qualitative evidence of the impact of living with IBD. The aim of this paper was to understand the health and social care needs of people living with IBD, to support personalised, tailored care using meta-ethnographic methodology. The findings from this study were used to inform the interviews with patients and GPs and the modelling process.

Paper 2 explores the perspectives of patients with IBD, identifying their needs of follow-up care. The aim of this paper was to explore patients' experience, needs and preferences of follow-up care.

Paper 3 describes the interviews with GPs. The aim of this paper was explore GP perspectives of IBD care, their role and responsibilities and to identify how IBD care in a primary care setting could be facilitated.

Paper 4 describes the processes undertaken to develop the intervention with emphasis on the description of the modelling phase of the MRC framework in which a stratified follow-up care model for patients with IBD was developed. This paper describes the benefits of concentrating on the development phase of the MRC complex interventions framework and how the model was developed.

Figure 2: Framework for the development of model of follow-up care for patients with IBD



Chapter 2

Background Review

This chapter provides the background of the thesis and presents the current literature related to inflammatory bowel disease (IBD) follow-up. The chapter will provide an overview of Crohn's Disease and ulcerative colitis, their epidemiology, the burden of disease, organisation of gastrointestinal services. It will also describe policies relating to the management of long term conditions in the UK.

Inflammatory Bowel Disease

Inflammatory bowel Disease (IBD)

IBD is a chronic bowel disease comprising of two main diseases, Crohn's Disease (CD) and ulcerative colitis (UC).

2.1 Ulcerative colitis (UC)

UC is an inflammatory condition causing continuous mucosal inflammation and ulceration of the colon. The inflammation extends proximally, uninterrupted, from the rectum and may encompass the entire large bowel. The disease follows a relapsing and remitting pattern, with 'remitting' defined as a complete resolution of symptoms and mucosal healing and 'relapse' defined as a flare of symptoms that includes rectal bleeding, increase in stool frequency and the presence of abnormal colonic mucosa (Stang, Travis et al. 2008).

The main clinical features of UC are diarrhoea, usually with blood and pus present, up to or greater than 15 times per day, abdominal pain, severe fatigue, and urgency to defeacate and tenesmus (feeling of incomplete evacuation of the bowel). Approximately 50% of patients with UC will relapse in any year and 30% will require surgery with a colectomy (removal of the large bowel) and formation of a stoma (Langholz, Munkholm et al. 1994; Winther, Jess et al. 2003; Jess, Riis et al. 2007). Patients with UC have a normal life expectancy, however those diagnosed <50 years of age with extensive colitis have increased mortality within the first two years of diagnosis which is directly related to post-operative complications (Winther, Jess et al. 2003).

Evidence suggests that patients with UC have an added risk of developing colorectal carcinoma (CRC) (Clevers 2006). The relationship between UC and CRC has been studied extensively and a thirty year surveillance analysis showed that this risk is 2.5% after 20 years of disease duration, rising to 7% after 30 years and 10.8% at 40 years (Rutter, Saunders et al. 2006). There has been a steady downward trend in the risk of developiong CRC in UC and this is likely to be related to better inflammatory control by pharmacotherapy. Several studies propose that mortality for patients with UC and CRC is higher than that of the general population, as the carcinoma is more histologically aggressive (van Heerden and Beart 1980; Aarnio, Mustonen et al. 1998). Recent evidence suggests that a diagnosis of chronic UC is an independent risk factor for poor prognosis, irrelevant of the cancer stage (Jensen, Larsen et al. 2006).

2.2 Crohn's Disease (CD)

CD is characterised by patchy, transmural inflammation which can affect any part of the gastrointestinal tract, as opposed to UC which is continuous and affects only the large bowel. The main clinical symptoms in CD are: diarrhoea; abdominal pain; weight loss; anaemia; severe fatigue and lethargy. CD presents as deep ulcers within the mucosa and follows a different pattern to that of UC. CD may be fistulating (an abnormal tract between two epithelial surfaces, such as bowel to vagina, or a tract from one organ to the skin surface) or stricturing (narrowing of the lumen). Approximately one third of patients with CD develop complicated disease associated with fistulas, fissures and strictures (Friedman and Blumberg 2005). The cumulative mortality of patients with CD is twice that of the population with death predominantly related to sepsis, pulmonary embolism, immunsuppressive medical treatment and complications of surgery (Ekbom, Helmick et al. 1992; Jess, Winther et al. 2002). Patients with CD follow a chronic active pattern as opposed to a straight forward relapsing remitting course with up to 50% requiring surgery in the first ten years (Rampton and Shanahan 2010).

2.3 Extraintestinal Manifestations

IBD is complicated by extraintestinal manifestations (EIMs) with up to 40% of patients affected by them (Ricart, Panaccione et al. 2004). Almost any organ of the body can be affected but the most common EIMs affect the joints, skin, eyes and hepatobiliary system and are directly related to the activity of the disease in the bowel: in general, if the disease is active, the likelihood of EIMs is increased. However, whilst some EIMs are disease activity related, large numbers such as ankylosing spondylitis, are independent of this.

2.4 Treatment

IBD is a long term condition with no known cure. There is a wide range of medical interventions for both CD and UC aimed at symptom reduction by controlling the inflammatory process, and more recently the achievement of 'mucosal healing' (Froslie 2007; Schnitzler 2009). Mucosal healing has been defined as the complete abscence of any ulceration, lesion or obvious inflammation along the gastrointestinal tract. It is suggested that complete mucosal healing can lead to improved outcomes and reduce the risk of complications of the disease (Ghosh and Lacucci 2010). The key objectives of treament are to increase the time the patient is in remission, avoid complications and establish an acceptable quality of life.

Medical therapy for IBD follows a step up approach, with corticosteroids being one of the first drugs of choice for inducing remission (Truelove and Witts 1954). Treatments which aim to maintain remission for both UC and CD combine immunsuppressive drugs, such as azathioprine and methotrexate, and the biologic drugs, anti Tumour Necrosis Factor alphas. Medical therapy is evolving rapidly, targeting both the immunologic cascade and the role of phenotyping, whilst balancing the risks of some of the adverse effects of these drugs with the benefit they have on the disease.

2.5 Epidemiology

There are approximately 240,000 people living with IBD in the UK. The prevalance of CD is 145 per 100,000, the prevalence of UC of 243 per 100,000. In a UK population of 60 million this equates to 87,000 people living with CD and 146,000 people living with UC (Rubin 2000). A recent systematic review reports that these figure are rising, with Europe having the highest prevalence compared to North America, Asia and the Middle East (Molodecky, Soon et al. 2012). Molodecky (2012) found that the prevalence of UC in Europe is 505 per 100,000 persons and CD 322 per 100,000 persons.

Importantly, the incidence of CD in children has increased three fold from 1960 in the UK (Barton 1989; Sawczenko, Sandhu et al. 2001; Henderson, Hansen et al. 2010). This is mirrored both in Europe (Perminow, Brackmann et al. 2009) and North America (Benchimol, Guttmann et al. 2009). This continuing rise has clear implications for the substantial lifelong burden of this disease and the provision of specialists services.

2.6 Aetiology of IBD

IBD shows phenotypic signs of autoimmunity problems, similar to rheumatoid arthritis, but the pathology is far from clear. They are complex chronic inflammatory conditions with altered lymphocyte/ immunological responses to host antigens. It is widely accepted that it results from a dysregulated immune response involving a complex interaction between environmental and genetic factors (Pastorelli, Vecchi et al. 2008). The genetic exploration of IBD is an area of continued growth, with the identification of the first gene in 2001, NOD2 or CARD15 (Hugot, Chamaillard et al. 2001; Ogura, Bonen et al. 2001). Genetic factors appear to play a more important role in CD than in UC. Both CD and UC are more common in women than men, with peak incidence ages 10 and 19 years and then again at age 50, thereby identifying IBD as one of the most significant chronic illnesses of childhood and adolescence (Moses, Moore et al. 1998). There have been more than 30 genes cited with CD and approximately 18 in UC but their overall contribution to developing IBD remain very low, identifying IBD as a polygenic disorder.

The environmental hypothesis is based on the observation that Asian and Jewish people living in in the UK and USA are more likely to be affected by IBD than those living in Israel (Rampton and Shanahan 2010). A large volume of studies have been published about smoking and its relationship with IBD and it is recognised as an important factor with smokers having almost twice the risk of developing CD (Calkins 1989). Whilst smoking plays a protective role in UC, the reverse occurs in CD resulting in more aggressive disease (Calkins 1989; Johnson, Cosnes et al. 2005). There is a relationship between stress and exacerbations of IBD (Bitton, Sewitch et al. 2003; Mardini, Kip et al. 2004) but stresss as a causal factor of IBD remains insubstantiated (Porcelli, Leoci et al. 1996).

2.7 Burden of Disease

The results of the European Federation of Crohn's and Ulcerative Colitis Association's (EFCCA) patient survey (Ghosh 2007) reported that quality of life (QoL) did not form an important role for the healthcare practitioner when considering care for patients with CD and UC, despite the plethora of studies highlighting this as fundamental to their care. The patient may appear well and coping but the disease may be having a tremendous negative effect on the patient's social and emotional life.

Recently EFFCA has completed a comprehensive 24 country European wide survey which aimed to obtain a multinational perspective of the impact of living with IBD (Wilson, Lonnfors et al. 2012). Participation in this was by self-selection and may bias the results and views not truly representative of the IBD population in Europe. However, the IMPACT survey, which had nearly 5000 responses, offers an insight into the affect of IBD from diagnosis to living with quiescent disease. Diagnosis took longer than five years in 18% of the respondents, with 64% presenting to emergency care with symptoms of IBD *prior* to the diagnosis. This emphasises the difficulty in diagnosing IBD and the need for education in Primary Care and their European counterparts. IBD impacts on the individual's daily life, education and employment. The survey found that at any one time, half of the respondents were *not* in remission.

One of the most prevalent concerns of patients with IBD is fatigue (Drossman, Leserman et al. 1991; de Rooy, Toner et al. 2001). Fatigue, lethargy and lack of energy have a profound impact on the patient’s lifestyle, affecting their ability to work and socialise, confirming the disability associated with IBD (Mallett, Bingley et al. 1978) . The IMPACT survey (Wilson, Lonnfors et al. 2012) reported 96% of individuals with IBD felt tired, weak and worn out during a flare up and yet 83% still reported feeling like this during remission. Unemployment and sick leave are more common in IBD patients compared to the general population (Bernstein, Kraut et al. 2001; Bernklev, Jahnsen et al. 2006). IMPACT stated that 74% of individuals required time off work during the previous year with 25% of individuals receiving complaints from their employers because of sick leave, and 21% suffering discrimination in the workplace (Wilson, Lonnfors et al. 2012).

Mallett, Bingley et al (1978) identified four main symptoms which condense the burden of this disease: bowel frequency, urgency of defecation, abdominal or rectal pain and lassitude. The unpredictable nature of the disease, the fear and humiliation surrounding incontinence, feeling dirty, isolation and living in fear (Dudley-Brown 1996; Casati, Toner et al. 2000; Hall 2005) have a devastating impact on the individual both physically and psychologically. The incidence of anxiety and depression is higher in patients with IBD compared to control populations (Walker 2008) with the disease still impacting on the individual’s psychological status even when in remission (Lix 2008).

The cost of caring for patients with IBD in the UK is estimated to be in excess of £254 million per annum (Bassi, Dodd et al. 2004). This cost includes routine follow up appointments in secondary care, of which IBD patients account for 13% of all gastroenterology outpatient clinics appointments in the UK. Figures suggest that outpatient clinic follow up appointments account for up to one third of the total cost of IBD care (Bassi, Dodd et al. 2004; Kappelman, Rifas-Shiman et al. 2008; Mowat, Cole et al. 2011).The peak age of onset for IBD is between ages 15 to 30, even occuring outside of this age range, the economic burden of IBD is corresondingly high due to this age group, often leaving them unable to work and contribute to the economy

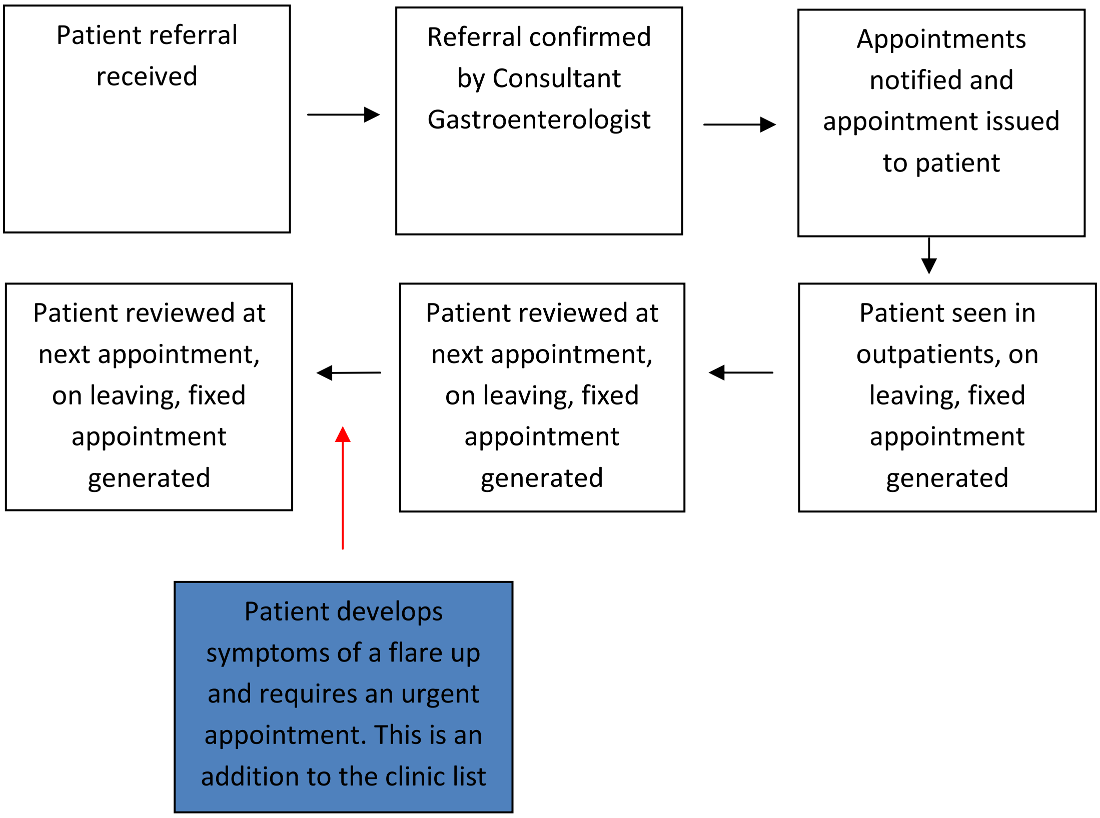
2.8 Organisation and structure of gastroenterology outpatient services

The organisation and structure of any outpatients department, including gastroenterology, is based on a payment by results system; payments that are generated according to activity. This was introduced to the NHS in an attempt to improve the efficiency and quality of services offered and as an incentive to do more work, such as reducing waiting lists and cancer targets (Featherstone, Whittham et al. 2010). Basically, the hospitals were paid more for the work they did, including the number of patients seen in an out-patient capacity. This structure of this payment system meant that whilst hospitals were paid a fee for a service, GPs were not and so hospitals increased the range of services provided to increase their income (Corrigan and Mitchell 2011). Introduced in 2004, GPs were rewarded with a different incentivised method, the Quality and Outcomes Framework (QoF).

The principle of payment by results for the secondary care sector meant that patients which would normally have been discharged back to primary care, or shared care, remained in the traditional out- patient setting to income generate, each follow up visit accorded a set tariff. It is these financial incentives which hinder the integration of primary and secondary care coming together to support the IBD patient (Goodwin 2012).

Patients with suspected or confirmed IBD are referred to the consultant gastroenterologist in secondary care (IBD Standards Group. 2009), the referral is accepted and an appointment is generated and sent out to the patient. After the first consultation, this cycle is repeated. The patient attends outpatients and on leaving, another scheduled face to face appointment is generated. This system was originally developed as a ‘fail safe’ system but due to the vastly different waiting times for individual patients, it was later updated to a ‘partial booking’ system (DH 2000). When the patient experiences symptoms of a flare up and is unable to manage, the patient then contacts the service and an urgent appointment is usually offered, even if the patient had been reviewed in clinic the week before.

Figure 3: Fixed appointment system – follow up routine patients. Adapted from DH (2000), ‘Step by step guide to improving outpatient services’.



National figures show that up to 67% of patients with a flare up are usually reviewed in clinic within seven days (Royal College of Physicians 2010). However, these patients are added to an already burgeoning clinic list. If the clinic template list is overbooked, a fixed list of, for example, 10 patients may be overbooked to accommodate 15 patients within the same time period, with the consequence of lengthened clinic waiting times. Attempts to provide and protect vacant outpatient slots are usually very difficult given the pressures to meet the two week cancer pathway (patients with symptoms suggestive of cancer must be seen within two weeks) and the 18 week diagnosis target (patients must be been reviewed, diagnosed and treatment commenced by week 18 after referral to secondary care) (DH 2000; DH 2010). In addition, a new tariff called ‘new to follow up ratio’. Some NHS Trusts have set this as 1:1, this means that for every follow-up patient reviewed, one new referral patient must also be seen, potentially having a dramatic effect on the availability of appointments to review follow- up patients with a long term condition such as IBD. Aspects of gastroenterology services are struggling to meet these targets with patients reporting waiting times as one of their main concerns (Williams, Roberts et al. 2007).

Follow-up care for IBD differs from that of many other healthcare situations; follow-up is a long term process and may involve the acute follow-up of a surgical procedure, the initiation of new therapy or follow-up of the patient's well being and the ways in which they are coping with their illness in general. The nature of the symptoms suffered by patients, reflecting the complexity of the disease, dictate that the follow-up facilities required are beyond those normally provided for outpatients (Carter 2004). Despite initiatives to optimize the quality of outpatient care for patients with IBD, by establishing specialist clinics, problems with access remain prevalent (Mawdsley, Irving et al. 2006).

Follow-up care for patients with IBD must be viewed in the context of other long term conditions and government healthcare policy.

2.9 Follow-up care in other long term conditions

Patients with other long terms conditions often face a more consistent progressive deterioration of their symptoms, unlike IBD, which follows an unpredictable remitting and relapsing pattern with the associated development of refractory problems. The patient may be very well at the start of the day, become progressively unwell by the evening, unwell for a period of time and then be well once again with few symptoms. It is this pattern of disease behaviour which makes it difficult to compare with other diseases with a progressive deterioration.

Patient satisfaction with follow-up care is influenced by expectations and preferences (Carr-Hill 1992) and there is now evidence that hospital follow-up appointments do not appear to improve readmission rates or survival in general medical patients (Grafft 2010). Using rheumatoid arthritis as a comparative disease, a six year RCT was undertaken which tested a patient–initiated review system (Hewlett, Kirwan et al. 2005). The study, which included a patient help line, patient education sessions and a two year ‘pending’ appointment which acted as a safety net, found the two groups were comparable in relation to clinical and psychological well being and the intervention group requested fewer appointments and found direct access more acceptable.

‘Virtual paper clinics’ have been explored as a way of improving delivery of outpatients in colorectal services (Porrett and Lunniss 2004) and concluded that paper clinic follow-up is an effective and feasible follow up alternative to the traditional follow-up scheduled appointment.

IBD is a complex disease and exploring the evidence related to follow up care in other disease areas may assist in the development of model of follow up care in this group of patients. See table 1 for examples of models of care in other long term conditions

Study reference	**Study type**	**Content of intervention**	**Outcomes**	**Patient involvement in study design, development**
‘Managing chronic kidney disease in primary care: a quality improvement study’ (Thomas and Loud 2012)	Quality improvement methodology	Implementation of care bundle, 4 practical activities: (1) ask patient whether they want to take part in self management programme (2) measure and document proteinuria, prescribe appropriate medication (3) document B/P and treat according to NICE targets (4) document cardiovascular risk.	Most practices recorded 100% reliability after 3-4 months. April 2012 the care bundle had been applied to over 700 consultations and >500 patients had received the self-management pack.	The ENABLE project had patient representation from the Patient and Service User Advisory Group, a group of patients with kidney disease. Their role was to develop and inform the project alongside the clinicians, and they made significant suggestions and input, in particular the self-management aspect of the care bundle.
Randomised controlled trial of specialist nurse in heart failure’ (Blue, Lang et al. 2001)‘	RCT	Patients randomised to intervention or usual care. Intervention consisted of: planned home visits; telephone contact as needed; patient education; self-monitoring and liaison with social workers and other healthcare professionals.	81 patients randomised into usual care and 84 into nurse intervention. Death rates were similar in both groups, length of hospital stay was reduced in the intervention group with more patients commenced on ACE inhibitors. Readmission to hospital for all causes were reduced in the intervention group compared to usual care.	Not specified
‘Early discharge with ongoing follow-up support may reduce hospital admissions in COPD’. (Lawlor, Kealy et al. 2009) ‘	Retrospective review	Patients within the inclusion criteria discharged with follow-up home visit by nurse or physiotherapist for 14 days, telephone contact as needed, rapid follow-up clinic available as needed. Scheduled follow-up at 6 weeks and 3 months. Comparisons were made with 12 and 6 months before early discharge and 6 and 12 months post early discharge.	6 month and 12 months post early discharge, emergency department presentations reduced by 48% and 40% respectively, hospital admissions reduced by 51% and 42% at 6 and 12 month post early discharge. The patients in the self managed group had greater reductions in both hospital admissions and emergency department presentations.	Not specified

‘Development of a district wide teledermatology service’. (Lawton, English et al. 2004)	Implementation and evaluation study	4 PCTS and a Secondary Care dermatology dept developed a district-wide teledermatology service led by nurses and a GP with special interest. The service was developed to diagnose, treat and manage patients in a primary care setting to achieve a reduction in waiting times, improve patient access, improve GP satisfaction, ensure a consistent approach to dermatology referrals, increase dermatology skills of health professionals and manage the demons more effectively.	Sustained drop in patient waiting times from 20 to 13 weeks, GP and patient satisfaction was high, greater patient involvement in decisions making.	Not specified
‘Clinical effectiveness of a collaborative care for depression in UK primary care (CADET): cluster randomised controlled trial’. (Richards, Hill et al. 2013)	RCT	Primary care practices were randomised to collaborative care or usual care with patients meeting inclusion criteria randomised into the intervention or control group. The collaborative care was delivered by a team of care managers, supervised by mental health experts. Care managers had 6 to 12 contacts with participants over 14 weeks followed by telephone contacts thereafter. Care further consisted of antidepressants drug management, behavioural activation, and symptom assessment.	Collaborative care improves depression immediately after treatment compared to usual care and persists up to 12 month follow-up care. Collaborative care is preferred by patients over usual care.	Not specified although a public and patient advocate is listed as author.

2.10 Integrating IBD care

IBD care is predominantly administered by secondary care services and is increasingly regarded as a ‘super-speciality’ within gastroenterology (Irving 2012). However the drive to offer patient choice and treat patients closer to home, commissioning services by GP consortia and clinical commissioning groups (CCGs) (DH 2010), the reduction in inappropriate follow-up care appointments outlined in the Ten High Impact Changes (Institute for Innovation and Improvement 2007a), is changing the landscape of long term conditions care, shifting the care from secondary services back into the primary care domain.

Much work has been carried out evaluating outreach clinics in primary care in the UK with no difference in health outcomes but at a higher cost compared to hospital based clinics (Powell 2002), CCGs must therefore weigh up the costs of outreach clinics compared to the advantages. Similarly, evaluation studies of general practitioners (GPs) with special interests have also been undertaken. One study of a GP with a special interest in dermatology concluded that the outreach service was more accessible compared to traditional outpatient care and was preferred by the patients (Salisbury, Noble et al. 2005).

Integrating primary and secondary care can be established in four different ways: (1) the transfer of services directly into primary care where by the same service is offered but by primary care practitioners; (2) the relocation of specialist hospital clinics into primary care, where by the same specialists from secondary care move their clinics into the community setting; (3) joint working between secondary and primary care whereby there is an agreement to share care with an identified division of responsibilities between the two; and (4) professional behaviour change where referrals into secondary from primary care are managed differently ranging from educating the practitioner to financial incentives that reward no referral. A scoping review of the evidence (Sibbald, McDonald et al. 2007) found that the transfer of hospital services to primary care and interventions that change behaviour reduced secondary care outpatient attendance but risked the reduction in quality of care. Relocating specialists into primary care improved joint working, and shared care and tele-medicine improved access to care without a reduction in quality. It remains questionable as to whether any of these initiatives will reduce costs to the NHS (Sibbald, McDonald et al. 2007).

There is no evidence evaluating the shift of IBD care into primary care or IBD specialist outreach clinics. In the past GPs have been reluctant to take on the full management of patients with IBD (Moody, Mann et al. 1993). However, although only in abstract form with no patient diagnosis details, one study reported that community based out-reach gastroenterology clinics moved on-going outpatient management into primary care and was more effective at discharging patients, but this did not reduce the number of patients seen in secondary care clinics (Strettle, Abdulrehman et al. 2012).

2.11 Long Term Conditions Policy

The DH (2012) defines a long term condition (LTC) as a condition that cannot, at present, be cured but is controlled by medication and/ or other treatment/ therapies. There are 15.4 million people living with a LTC in England. People with LTCs account for 80% of all GP appointments (Institute for Innovation and Improvement 2007a), account for 70% of all in-patients bed days and 70% of the total health care spend in England is attributed to caring for this group of people (DH 2012). The majority of people over 65 years have two or more LTC, whilst the majority of people over the age of 75 years have three or more LTCs. The prediction is for a 252% rise in the number of over 65 year olds by 2050 and a 60% increase in the number of people with multiple LTCs by 2016 (DH 2012).

The challenge of meeting the demands of caring for people with LTCs has led to many reports and initiatives. The Institute for Innovation and Improvement, formerly the NHS Modernisation Agency, developed ten high impact changes which included avoiding unnecessary follow-ups for patients, providing necessary follow-ups in the right care setting and applying a systematic approach to care for people with LTCs (Institute for Innovation and Improvement 2007a). Concentrating on primary care, they issued a directive for high impact practice teams which covered the promotion of self management, improvement of care for patients by redesigning roles in general practice and through systematic patient feedback (Institute for Innovation and Improvement 2007b). Whilst these key impact changes may affect quality of care they also reflect potential cost reductions.

A key principle of The NHS White Paper ‘Equity and Excellence – Liberating the NHS’ (DH 2010) is that patients must have more control over the care they receive. Based on this, the LTC strategy is currently being revised and will reflect the Quality Innovation Productivity Prevention (QIPP) agenda, which is also trialling an annual risk adjusted capitation budget to overcome the barriers of payment by results incentives (DH 2012). Whilst the QIPP agenda supports the maximisation of self care and shared decision making, the new LTC strategy will support rare conditions or minority groups. It will aim to develop services which are based on the individual’s biological, psychosocial and social needs, it will address attitudes and behaviours of professionals and the lack of understanding and education of those delivering care for people with LTCs (DH 2012). The overall aim of all of these measures is for patients to experience a service which is flexible and responsive to their needs as opposed to one which fits around the needs of the service.

2.12 Summary

In summary, the fixed nature of outpatients means that appointments are made months ahead, leading to a service which is inflexible, unresponsive and unable to match care with demand. A study exploring the problem of access, its direct impact on patient care and related outcomes such as cost and morbidity, have to be carried out (Williams, Roberts et al. 2007).

The current traditional follow-up care model is reactive to crisis, secondary care based and is not fit for purpose, placing emphasis on the needs of the service as opposed to the needs of the patient. There are no models of follow-up care for patients with IBD, which take into account the fluctuating nature of the disease and its chronicity, and there is no evidence of the mobility of care between primary and secondary care. There is an absence of studies which have explored users’ views of an acceptable service, primary care’s (GPs) role in the management of these patients or maximising the potential role of the IBD Nurse Specialist.

There is an urgent need for new and innovative models of follow-up to be investigated which are effective, patient centred, acceptable for those receiving care, the patients, and those delivering care, the healthcare professional, and cost effective. The best evidence synthesis, Chapter four, (Slavin 1986; Slavin 1987; Slavin 1995) presents a critical appraisal of the evidence of models of follow-up care, how they work, content and patient acceptability.

Chapter 3

Methodology

The MRC Framework for the development of complex interventions was used to design this study. The purpose of the chapter is to expand the details of the methodology described in papers 1, 2, 3 and 4. The chapter begins with an outline of the overall aims of the study followed by a description of the MRC framework, a synopsis of the methodology, and the rationale for the methodological approach chosen.

3.1 Aim of the study

The overall aim of this study was to develop an evidence based intervention of follow-up care for patients with inflammatory bowel disease, which is acceptable to patients and healthcare professionals.

3.1.2 Objectives of the study

Stage one objective

To identify the evidence base of models of follow-up care for patients with IBD by a best evidence review of the literature.

Stage two objectives

To understand the health and social needs of patients living with IBD through meta- synthesis methodology.

Stage three objectives

To explore patient needs and preferences for follow up care delivery, by whom, when and where through qualitative interviews.

Stage four objectives

To examine the current role of the GP, their preferences for improved follow up care and their involvement in IBD care by through qualitative interviews.

Stage five objectives

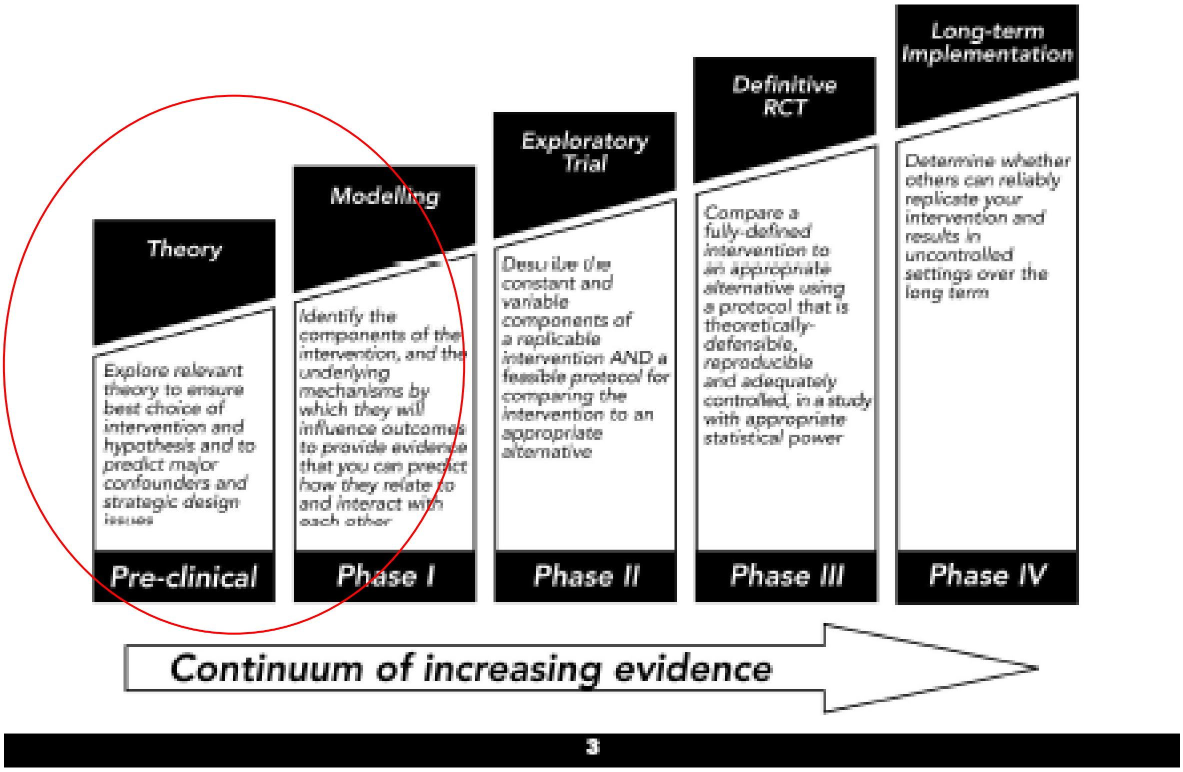
To synthesise the data from stages 1-4 into an acceptable model of follow-up care.

3.2 The MRC Framework for the development of complex intervention

When questions are posed about the effectiveness of healthcare, the randomised controlled trial (RCT) is recognised as the ‘gold standard’ (Sackett, Rosenberg et al. 1996; Muir Gray 1997) and is usually placed at the top of the hierarchy of evidence (Harbour 2001). However, when used to evaluate complex interventions, such as changing behaviour or healthcare delivery, the RCT has been criticised as it only explores the effectiveness of the intervention (Blackwood 2006) which is insufficient in health care research. For example a RCT cannot explain why the trial of an often expensive intervention failed (Bradley, Wiles et al. 1999; Thompson, Coronado et al. 2003). It is recognised that other factors may influence the effectiveness of an intervention such as, who delivered it, or practitioner behaviour, their expertise and skills (Blackwood, O'Halloran et al. 2010).

To address the development, evaluation and the limitations of complex interventions, the Medical Research Council (MRC) developed guidance for healthcare professionals (Campbell, Fitzpatrick et al. 2000). Aimed at targeting interventions made up of varying interconnecting parts, the MRC developed a stepwise approach to their development and evaluation, (see Figure 6: MRC Framework for complex interventions (2000).

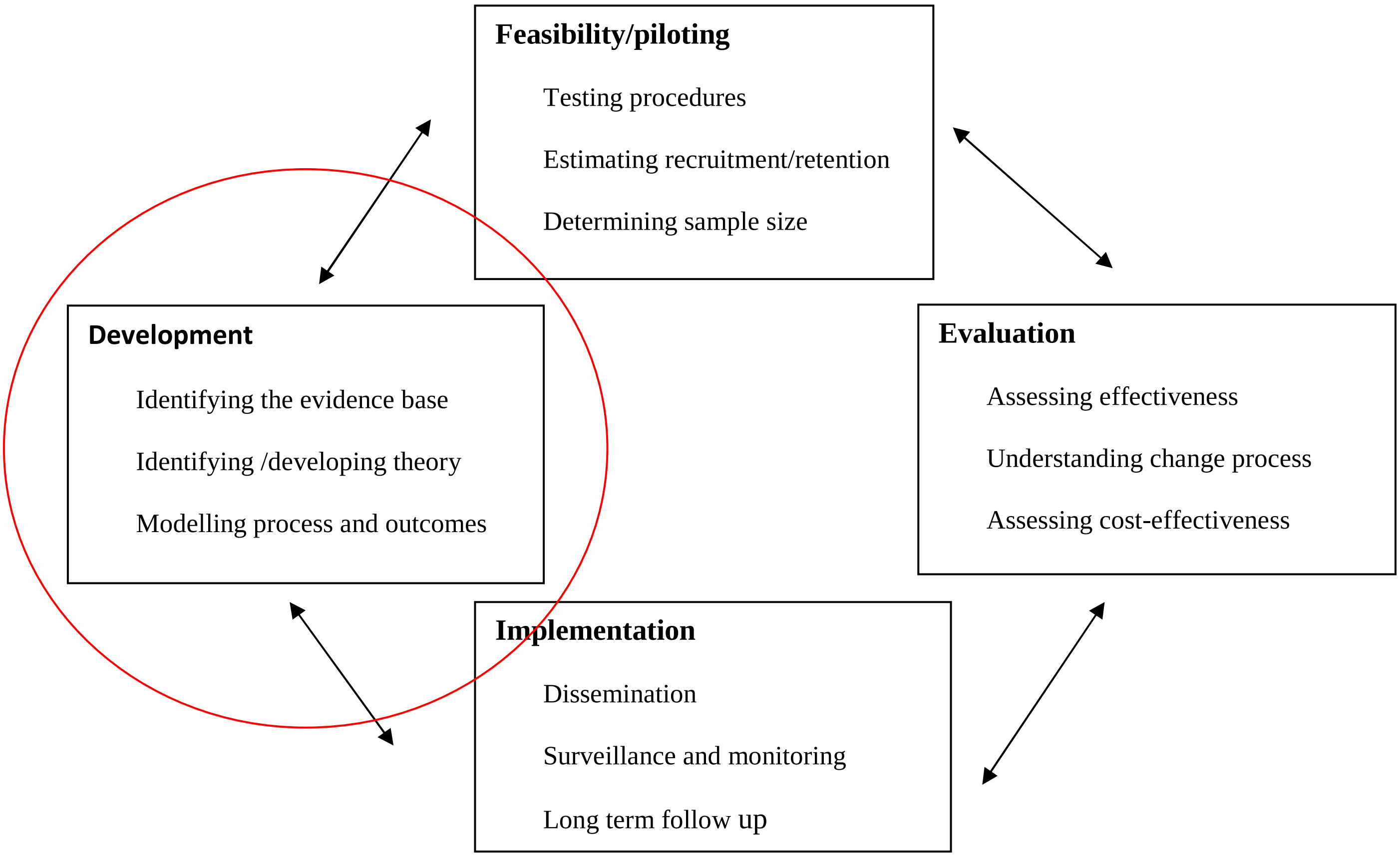
Figure 4: MRC Framework for complex interventions (Campbell, Fitzpatrick et al 2000)



The MRC guidance was updated in 2008 (Campbell, Murray et al. 2007; Craig, Dieppe et al. 2008) to overcome its linear approach and use primarily in drug development (see Figure 7: Key elements of the development and evaluation process MRC). The updated model was cyclical rather than linear, with greater emphasis placed on the early development phase of the model (Craig, Dieppe et al. 2008). The Pre-clinical theoretical stage and the phase 1 modelling stage were re-named the Development Phase.

Campbell, Fitzpatrick et al (2000) describes complex interventions as a model built from a number of components, which can act both independently and interdependently. The dimensions of a complex intervention include the number of interactions between components within both the experimental and control groups; number and degree of difficulty of behaviours required to either deliver or receive the intervention; the number of groups or organisations involved; the types of outcome measures; and the level of flexibility or tailoring of the intervention allowed (Craig, Dieppe et al. 2008).

Figure 5: Key elements of the development and evaluation process MRC (Craig, Dieppe et al, 2008)



The first stage of the development phase is the identification of evidence of what is already known, followed by identification and development of appropriate theory. The aim of the development phase of the framework is to build on existing evidence and theory to develop theoretical understanding of the process of change and to augment this with further research, such as interviews with the intended population or those involved with the delivery of the intervention. The characteristics of the population to be studied, the prevalence and incidence of the disease, how factors change over time and the influencing forces, are crucial contextual elements when designing a complex intervention (Campbell, Murray et al. 2007).

Conceptual modelling (Campbell, Murray et al. 2007; Craig, Dieppe et al. 2008) refines the intervention and maps out the pathway from the intervention to the required outcome. The individual components are identified and evaluated concentrating on how they fit together. Qualitative testing through focus groups, surveys or case studies can be used to define these components (Campbell, Fitzpatrick et al. 2000). The contribution of qualitative methods in both the development of the intervention and modelling phase, combined with quantitative methods, has been demonstrated in previous studies (Bradley, Wiles et al. 1999; Blackwood 2006; Corrigan, Cupples et al. 2006).

The next section will explain the methods in greater detail and justify the methods described in papers 1-4. The specific procedures for the studies are detailed in the papers and will not be repeated here.

3.2.1 Identifying the evidence based for MRC Framework

The approach to identifying the evidence base was two-fold. The literature was searched to identify which models of follow-up care for IBD had been developed and used. This took the form of a 'best evidenced synthesis' (Slavin 1986) (see Chapter 4). However, the review only highlighted what the models were and did not explore IBD patients' needs which were critical to the development of the intervention. For this reason, a meta-synthesis (Noblit and Hare 1998) was also undertaken (see Paper 1 pg 115).

There are many approaches to reviewing and synthesising evidence and these include the traditional clinical review (Vetter 2003; Griffiths 2005), the systematic review (Khan, Kunz et al. 2004), the realist review (Pawson, Greenhalgh et al. 2005) and the best evidence synthesis (Slavin 1986). It has been suggested that all reviews are retrospective, observational reviews and subject to error, but the application of scientific methods distinguish them from other types of reviews (Cook, Mulrow et al. 1997).

The following section provides an overview of these types of literature review and provides a rationale for why a best evidence synthesis and meta-synthesis were undertaken.

3.3.3 Clinical review

The traditional narrative or clinical review is a less formal approach to reviewing literature and is defined as an attempt by an 'expert' in the area to review all of the literature on a defined topic (Vetter 2003; Griffiths 2005). Both qualitative and quantitative data may be reviewed (Dixon-Woods, Agarwal et al. 2005). The strategy is broad and the search strategy usually follows the process of journal runs and citation and author searches to identify all studies related to the topic.

However, the strength of the clinical review, that it is undertaken by an ’expert’ in the subject area may be offset by the fact that the ‘expert’ may be biased by their existing knowledge (Slavin 1995; Vetter 2003). The clinical review has been criticised for the way it searches, collates and generates inferences, suggesting that the author’s personal view may drive the process (Khan, Kunz et al. 2004) and its emphasis on using easily available studies (Slavin 1995). In addition, empirical evidence using expert opinion has been found to be unreliable and unrepresentative of evidence of effectiveness (Antman, Lau J et al. 1992).

3.2.3 Systematic Review

Systematic reviews:

‘identify, evaluate and summarise the findings of all relevant individual studies, combining the results of several studies gives a more reliable and precise estimate of an interventions effectiveness than one study alone’ (Centre for Reviews and Dissemination 2008), pg V.

The systematic review provides a rigorous, transparent and replicable analysis of the primary evidence base (Greenhalgh 1997). The question is usually quite focused and is based upon the Participants, Intervention, Comparison and Outcomes (PICO) (Khan, Kunz et al. 2004). Taking the systematic review a step further, meta-analysis has the ability to provide a powerful, precise convincing conclusion to the effectiveness of treatments (Cook, Mulrow et al. 1997).

However some argue that systematic reviews privilege research over practice based knowledge and concentrate entirely on RCT evidence (Hammersley 2005). The RCT and systematic review do not explain how the treatment can be translated into practice.

3.2.4 Realist Review

The realist review was developed to help make sense of evidence of complex interventions. The approach is relatively new and not yet fully established and seeks to:

“Unpack the relationships between context, mechanism and outcome” (Greenhalgh, Wong et al. 2011) pg 116.

The realist synthesis of literature incorporates different types of evidence and provides an explanation of how complex interventions work (Pawson and Tilley 1997; Pawson, Greenhalgh et al. 2005; Pawson 2006). The intention of using a realist synthesis approach to literature is to ascertain how, whether and why a complex intervention works to enable the implementation of the intervention (Pawson 2006).

3.2.5 Best Evidence Synthesis

The best evidence synthesis was developed as an alternative to the traditional narrative review and the meta-analysis (Slavin 1986). It allows for the inclusion of small studies, audits and abstracts.

The best evidence synthesis method reviews individual forms of evidence in addition to RCTs. It incorporates different types of study design, size and quality. It is essential that the reviewer locate every study ever conducted that meets predefined criteria (Slavin 1995). The approach emphasises the systematic search process but broadens the inclusion of study designs. The best evidence synthesis not only justifies how the reviewer came to the conclusions but also how they can be interpreted clinically (Letzel 1995).

The area of interest in the best evidence review was follow-up care in IBD with the aim of incorporating RCTs and other types of study designs, size, published and unpublished, in abstract form and including qualitative studies. 19 papers were identified for the synthesis, 6 in abstract form. Only 6 were RCTs. A narrowly focused systematic review using these 6 RCTs alone would have not have presented as complete a representation of follow-up care that the best evidence synthesis achieved (Griffiths 2005).

Figure 8 pg 79 and Tables 3-8 pg 77, show the search strategy, search terms used, excluded and included studies.

3.2.6 Meta-synthesis

As recommended by the MRC guidelines for the development of complex interventions, a systematic review of the topic should be undertaken to identify the evidence base (Craig, Dieppe et al. 2008). The MRC propose that questions are asked about the intervention and these include whether there is a sound theoretical basis and has this theory been used systematically to develop the intervention. The impact of any new intervention will depend on what evidence provision already exists and in what context (Craig, Dieppe et al. 2008).

Systematic reviews are accepted as the cornerstone of evidence based practice (Dixon-Woods, Booths et al. 2007) and are based on reviews of effectiveness and of ‘what works’. However there is now a move toward addressing the wider questions, such as why there is a particular problem and how it has come about, to provide answers for the policy makers (Mays, Pope et al. 2005).

The past decade has seen a proliferation of combined qualitative studies with an emphasis on their contribution to health care. As the number of qualitative studies has risen, so has the interest in integrating or aggregating these studies to inform health policy (Sandelowski, Docherty et al. 1997; Dixon-Woods and Fitzpatrick 2001; Paterson, Thorne et al. 2001; Mays, Pope et al. 2005). This has led to the emergence of qualitative meta-synthesis, which is a set of techniques for the integration and interpretation of qualitative research (Sandelowski and Barroso 2007).

The meta-synthesis has been described as research of research (Paterson, Thorne et al. 2001) and a systematic review of qualitative research (Booth 2001). Noblit (2004) states that it is neither an aggregation, nor a review or collation of studies but seeks to “go beyond single accounts to reveal the analogies between the accounts” (Noblit and Hare 1998), pg 13.

There is ongoing controversy surrounding the legitimacy and feasibility of synthesising qualitative studies which have used different methods (Barbour 1998). The resulting synthesis of the separate qualitative studies has been described as destroying the integrity of the individual studies (Sandelowski, Docherty et al. 1997). Yet the goal of meta-synthesis is interpretive and not aggregative (Noblit and Hare 1998) with the ability to promote greater understanding in a particular area (Mays, Pope et al. 2005).

There is growing consensus that the needs, preferences and experiences of patients should be explored when developing and evaluating new health services and one way of doing this is by bringing together, synthesising, research form a range of qualitative studies (NHS 2010).

An in depth understanding of the patient’s health and social care needs and impact of the disease derived from a meta-synthesis could help to understand the complex and multidimensional experience of IBD. This was required before any further activity in the development of the model of follow up could take place. The meta-synthesis can be found in Paper 1, pg115.

The approach used in the meta-synthesis was a meta-ethnographic line of argument synthesis (Noblit and Hare 1998). The meta-ethnographic approach “senses” the diverse content of the qualitative studies and translates them into one another (Noblit and Hare 1998) pg 13. The line of argument synthesis is an interpretive synthesis and takes the synthesis a step further. The synthesis of all of the studies, their similarities and differences, themes, and language, are compared and contrasted repeatedly and the findings are then placed into a “new interpretive context” (Noblit and Hare 1998) pg 62.

The meta-synthesis was carried out in four stages: a search strategy to locate qualitative research studies; inclusion/exclusion of studies; quality appraisal; and synthesis and development of a line of argument (Noblit and Hare 1998).

3.2.7 Searching qualitative studies

Despite the increasing importance of the contribution of qualitative research within healthcare, searching for qualitative studies remains problematic (Dixon-Woods and Fitzpatrick 2001). Some databases do not index qualitative work and are therefore of limited value (Evans 2002; Barroso, Gollop et al. 2003).

It has been suggested that using search filters, or optimal search strategies, may facilitate a more thorough database search (Haynes, Wilczynski et al. 1994). Search filters for RCTs are established (Higgins and (Eds) 2005) but are only just emerging for qualitative research studies (Grant 2004).

To augment any electronic search, more traditional methods of searching were adopted for the meta-synthesis (Lefebvre, Manheimer et al. 2008). Berry picking (Bates 1989) includes foot note tracking, citation searching, journal runs and author searching and these techniques, in addition to a search filter, were incorporated into the search strategy to overcome the recognised problems associated with searching for qualitative research (Evans 2002). (see tables 8-12 pg, 136 for studies included in the meta-synthesis, excluded studies and reasons for exclusion).

3.2.8 Quality appraisal of qualitative studies

The debate continues about the most appropriate criteria for appraising qualitative research and whether quality criteria should exist at all for qualitative research (Dixon-Woods, Shaw et al. 2004). It has been pointed out that this approach may even stifle the creativity of qualitative research (Dixon-Woods, Shaw et al. 2004). Critical appraisal tools differ in the criteria used for qualitative studies.

A range of critical appraisal tools were searched to determine which one was the most appropriate for this meta-synthesis (Blaxter 1996; Walsh and Downe 2006). The tool used to appraise the research papers was the Critical Appraisal Skills Programme (CASP) tool developed by the Public Health Resource Unit (CASP 1999). This tool was chosen for its validity when appraising qualitative research for rigour, credibility and relevance. The researcher and academic supervisors appraised all of the studies using CASP separately and then the researcher combined these into one amalgamated CASP table.

The included studies were compared and contrasted repeatedly by the researcher and academic supervisors to identify common themes and concepts (Noblit and Hare 1998). The studies were taken together to develop a line of argument. Noblit and Hare (1994) define the line of argument as a type of interpretive synthesis with a two step approach:

‘A meta-ethnographic synthesis of the studies and a clinical inference about the “whole” organisation, culture’ (Noblit and Hare 1994), pg 64.

It is evident from the best evidence synthesis and meta-synthesis that there is a paucity of evidence relating to patients’ follow-up care needs, preferences and also the real impact of living with IBD.

The following section provides a brief overview of qualitative research and an expansion of the research methods undertaken in papers 2, 3 and 4.

3.3 Qualitative methods

IBD patient preferences of care may be measured quantitatively (Baars, Markus et al. 2010), as can patient experience (Black and Jenkinson 2009) using a range of instruments but the results are limited as they fail to capture the real phenomenon of the impact IBD may have on patients. Qualitative methods are better suited to uncover the patients' real experience of illness, interactions with healthcare professionals and services (Barbour 2000) and to hear directly from patients, in their own language, what is important to them (Sofaer and Firminger 2005). Methodologies focusing on patients' needs, preferences and experience favour a more in-depth subjective approach, adopting methods such as interviews, focus group interviews or observation to extract the nuances of follow-up care (Jun, Peterson et al. 1998; Attree 2001). These types of approaches are effective at drawing out the patients' experiences, needs, and preferences of care and why these are important to them.

Interpretivism emerged against the backdrop of positivism and qualitative research is, in the main, associated with this philosophy. Interpretivism emphasises and values the human aspects of knowing about the world, the role of the investigator within the research, and phenomena are considered through the eyes of the people in their environment (Weaver and Olson 2006). Qualitative research is concerned with the subjective world with the aim of understanding and exploring peoples' beliefs, behaviours and cultures (Mason 2002; Centre for Reviews and Dissemination 2008). These beliefs are reflected in the methods of qualitative research and are evident in Ethnography, Phenomenology, and Grounded Theory and by the use of observation and interviews (Creswell 2007). However it has been proposed that aligning qualitative research to a particular philosophy is not necessary and that quantitative or qualitative methods should be viewed as alternative tools used for different tasks, each being used to answer a question (Paley and Lilford 2011).

Qualitative research has been recognised as fundamental when attempting to understand individual experiences of health-related treatment decision making (Charles 1997; Paley and Lilford 2011). Campbell et al (2007) emphasised that context is especially important when developing complex interventions, which includes the health service system, the characteristics of the population the intervention is aimed at, and how a problem is caused and sustained. The behaviour of the population must also be considered and how people interact with each other. Adopting a qualitative design within this study allowed exploration of opportunities for follow-up care, identified patients' needs and values and also barriers which could potentially have lead to the wrong choice of intervention (Campbell, Fitzpatrick et al. 2000; Corrigan, Cupples et al. 2006; Campbell, Murray et al. 2007; Lewin, Glenton et al. 2009).

A range of methodological approaches may be used to underpin the theoretical approach, such as Narrative Research, Phenomenology, Grounded Theory and Ethnography. Many researchers ‘borrow’ ideas and stages from the different approaches. For example, Narrative Research consists of focusing on one or two individual’s life stories, and gathering data from those stories. One example of its use in IBD is the auto-ethnographic account of chronic IBD used by Defenbaugh (2008) to describe ‘meandering through’ medical tests during the illness.

Phenomenology is similar to Narrative Research. While Narrative Research seeks the story or experience of an individual, Phenomenology seeks the ‘lived experience’ of a group of individuals (van Manen 1990). Phenomenology is both a philosophy and a methodology with the aim of reducing individual experiences of a single phenomenon to describe the whole ‘essence’ of that phenomenon, to “grasp the very nature of the thing” van Manen (1990), pg177. This approach has been used in a number of studies to explore the lived experience of IBD (Dudley-Brown 1996; Daniel 2001; Lynch and Spence 2007).

Grounded Theory takes Narrative Research and Phenomenology a step further by generating a theory (Strauss and Corbin 1990). Similar to Phenomenology, Grounded Theory seeks to interview participants who have experience of a single event or process. It is an inductive method of theory developed in the 1960s by Glaser and Strauss (1967) and developed to explore staffs management of dying patients. To generate links between the theory of sociology and research (Glaser and Strauss 1967) the process of data collection to theory follows a rigorous, systematic approach to theory development.

Grounded Theory goes beyond descriptions and aims to generate or discover theory which is described as:

> “A set of well developed categories that are systematically interrelated through statements of relationship to form a theoretical framework that explains some phenomenon” (Hage 1972) pg 34.

The generated theory explains the what, how, when, where and why of the phenomena (Corbin and Strauss 2008) and there are examples of Grounded Theory in IBD (Hall 2005; Pihl-Lesnovska, Hjortswang et al. 2010).

Grounded theory may use interviews, observation, written reports or audiovisual materials to generate theory (Creswell 2007) and information is gathered to generate theoretical saturation: the point at which no further new categories emerge.

Consideration was given to the methodological approaches to be used within this study. The aim of the study was to develop a model of follow-up care for patients with IBD. It did not seek to explore the lived experience of IBD, generate theory or a 'story'. The study did however draw on some of the principles of these methodological approaches as will become clear in the chapter. The following sections describe the theory and the application of the stages conducted to develop the model of follow-up care.

3.4 Sampling and recruitment in qualitative research

Qualitative research uses non-probability sampling: individuals are deliberately selected for their features or characteristics and are not statistically representative (Ritchie, Lewis et al. 2003). A range of sampling methods may be used in qualitative research. Purposive sampling or selective sampling involves selecting individual participants from a range of sites so that they can purposefully inform an understanding of the research problem (Creswell 2007). Categories such as age, gender, disease status, marital status and role in the organisation under study, may all be used to identify participants (Coyne 1997). Sampling in qualitative research is therefore deliberately 'biased', although Ritchie (2003) argues that deliberate choices made do not suggest bias but rather an objective approach to enable the sample to stand up to scrutiny.

Convenience sampling is the least rigorous method of sampling and employs the principles of selecting the most accessible participants. It is the least costly of all sampling techniques in terms of time and effort but may also produce poor quality data which may not fully explore the issue and may lack intellectual credibility (Marshall 1996).

Snowball sampling or chain referral sampling, is a technique whereby participants who have already been interviewed use their social networks to refer more participants to the researcher. This technique is particularly useful to reach difficult groups that are not easily accessible, such as drug addicts (Howitt and Cramer 2005). However it may not lead to full exploration of an issue as participants tend to refer friends who share similar views or experiences (King and Horrocks 2010).

Theoretical sampling is associated with Grounded Theory (Charmaz 2006). Participants are sought who may further inform particular issues which emerge from the data by following the analytical trail (Corbin and Strauss 2008). As new concepts emerge from the data a new sample is sought to explore and elaborate on the concept further (Marshall 1996).

Qualitative studies of IBD have used purposive sampling and this may be due to the complex nature of IBD, the many subgroups of disease behaviour, steroid-dependent or steroid refractory, and previous surgery to identify a range of participants (Daniel 2001; Hall 2005; Lynch and Spence 2007; Cooper, Collier et al. 2010).

Sample sizes are usually small in qualitative research (Cooper, Collier et al. 2010; Mason 2010) with some studies exploring IBD using samples as low as five (Daniel 2001), which reflects the rich information obtained. Qualitative research is not concerned with hypothesis statements (Crouch and McKenzie 2006) and it is ‘saturation’ which generally determines the sample size in qualitative research (Mason 2010). Saturation is a concept derived from Grounded Theory and is defined as the point whereby no new information is obtained in relation to themes or the emergence of new themes (Glaser and Strauss 1967). Increasing the sample size no longer contributes data as the participants repeat what has been reported by previous participants (Ritchie, Lewis et al. 2003).

3.4.1 Sampling and recruitment of participants to studies

Recruitment in qualitative research aims to recruit participants who can give the greatest insight to the research subject. Sampling and recruitment is discussed here to expand on the brief descriptions of recruitment in papers 2 and 3. The sampling approach used in the patient and GP interview study was purposive sampling (Patton 1990).

3.4.2 Sampling and recruitment of patients

The justification for purposive sampling was to sample patients based on their age, disease duration, disease characteristics and severity to allow for an effective and detailed exploration and understanding (Ritchie, Lewis et al. 2003). This assisted with establishing whether patterns of healthcare changed throughout the duration of the disease and identified other factors that contributed to preference of care delivery. This approach to sampling identified that patient attitudes to self-management changed as they required more knowledge about their illness and bodily response to their disease. For example, patients diagnosed with IBD within three years did not wish to self-manage.

Patients were recruited from the gastroenterology out-patient department of a large University Foundation Hospital Trust in the North West of England, prior to their out-patient appointment. Similar to other studies of IBD patients (Dudley-Brown 1996; Cooper, Collier et al. 2010), the patients were identified from the clinic listing and posted out an invitation to participate with a patient information sheet and consent form a week prior to their appointment. Patients contacted the researcher directly by telephone to arrange an interview or approached a member of the IBD team at their clinic appointment to agree to be contacted directly by the researcher. All patients invited consented to participate in the study.

3.4.3 Sampling and recruitment of GPs

The study was funded by the National Institute of Health Research (NIHR) and was adopted by the Greater Manchester Comprehensive Local Research Network (CLRN). As the study had a Primary Care component, it was also adopted by the Primary Care Research Network (PCRN). One of the aims of the CLRNs is to provide researchers with the practical support they need to make clinical studies happen in the NHS. GPs often report a lack of time and incentive as reasons not to engage in research (Salmon, Peters et al. 2007; Hummers-Pradier, Scheidt-Nave et al. 2008). Support from the PCRN provided a unique opportunity to interview GPs regarding IBD during a time of unprecedented upheaval within the NHS restructuring process (DH 2010). This had a major impact upon the ease of sampling and recruitment of the GPs, Paper 3, pg 170.

The PCRN invited 65 GPs across the North West to participate in the study. The descriptions of the population of GPs who did not participate or reasons why, are limitations recognised within the study and discussed in the Paper 3. 25 GPs contacted the PCRN and their details passed onto the researcher. Once the GPs had agreed to participate they were contacted directly by the researcher and sent an information sheet, study protocol, and consent form. GPs, like the patients, were purposively selected to focus on the particular characteristics of the population. The GPs were self-selected and 20 GPs were purposively sampled from large and small practices, rural and inner city, deprived and affluent areas.

3.5 Data collection methods.

A range of data collection methods were considered to develop the theory underpinning the intervention; interviews, focus group interviews and observation methods. Observation as a methodological approach has a lot to offer in qualitative research. As a tool it enables the generation of data about the process of decision making in its naturally occurring context (Silverman 2005) but it does have its drawbacks. Actions of the participants may be misinterpreted by the observer (Corbin and Strauss 2008) and being observed may impact on the actions of those being observed, known as the 'Hawthorne' effect (Pope, Ziebland et al. 2000). To counteract these problems, it is usual for researchers to combine observation with interviews. It was decided however that observation was not an appropriate approach for identifying patients' needs and preferences of follow-up care, nor the current and potential role of GPs. This was because researchers cannot observe what someone is thinking, but only interpret their actions. The overarching aim was to understand patient needs and preferences of follow–up care which required the use of interviews (Beaver, Latif et al. 2010)

Focus group interviews were considered. These are gaining popularity in health care research and have been defined as group discussions organised to explore a specific set of aims (Kitzinger 1994). The distinctive feature of focus group methodology is the group dynamics

(Rabiee 2004) and it is this which differentiates focus group from any other data generation tool (Vaughn, Schumm et al. 1996).

Focus groups were rejected however, because the aim of the study was to understand individual patient's needs and preferences for follow-up care delivery, by whom, when and where, relevant to their personal context. Whilst a focus group would have stimulated group discussion regarding patient needs and preferences, the in-depth individual and personal experiences of patients would have been difficult to explore in any depth. It was not the purpose of this study to shape and change patient perspectives through group interaction or observe their social background (Richie and Lewis 2003) but to understand how the individual perceived their own follow-up care needs. Even within a structured focus group personal information from an individual can be difficult to draw out and isolate, not least because of their reluctance to disclose personal information in front of a group of strangers, in this case the issue of incontinence may well have arose. The findings from the meta-synthesis reinforced the decision not to use focus group interviews. The humiliation and impact of incontinence was the main finding from this paper (see Paper 1, pg 115) and I felt that discussing issues such as this within a mixed group would be unfair to the patients and detrimental to the aims of the study.

Focus groups were also not considered the most appropriate approach for interviewing GPs. This is because a strong collective view from GPs in a large inner city practice may not be relevant to smaller practices. The focus of the interviews was to gather individual data reflecting the perceptions of GPs from different geographical areas and sized practices. Pragmatically, it was also extremely difficult to organise GPs into a focus group given their workload pressures (Delaney 2007; Salmon, Peters et al. 2007; Hummers-Pradier, Scheidt-Nave et al. 2008).

For these reasons semi-structured individual interviews were considered the most appropriate method. The next section builds upon papers 2 and 3 and explains further why semi-structured interviews were the chosen methodological approach, how the participants were sampled and recruited and how the interviews were conducted.

Table 2: Application of interviews and focus groups (taken from Ritchie and Lewis, 2003, Qualitative Research Practice, pg 60).

	Interviews	**Focus groups**
Nature of data	For generating personal accounts. To understand the personal context. For exploring issues in depth and detail.	For generating data which is shaped by group interaction, refined and reflected. To display a social context- exploring how people talk about an issue. For creative thinking and solutions. To display and discuss differences within the group.
Subject matter	To understand complex processes and issues e.g. motivations, decisions, impacts and outcomes. To explore private subjects or those involving social norms. For sensitive issues.	To tackle abstract and conceptual subjects. Where enabling or projective techniques are to be used, or in difficult or technical subjects where information is provided. For issues which would be illuminated by the display of social norms. For some sensitive issues, with careful group composition and handling.
Study population	For participants who are likely to be less willing or able to travel. Where the study population is geographically dispersed. Where the population is highly diverse. Where there are issues of power or status. Where people have communication difficulties	Where participants are likely to be willing and able to travel to attend a group discussion. Where the population is geographically clustered. Where there is some shared background or relationship to the research topic. For participants who are unlikely to be inhibited by group setting.

3.5.1 Semi-structured Interviews

The individual interview is one of the most commonly used methodological approaches in social science (Miczo 2003; Nunkoosing 2005). The qualitative interview is defined by its flexible and open ended approach, its ability to focus on individual experiences as opposed to general beliefs and opinion and the relationship between the interviewer and interviewee (King and Horrocks 2010). Ritchie (2003) suggests that the interview is the most appropriate method when:

‘It is important to get the perspectives heard within the context of personal history or experience (Ritchie 2007, pg 58).

Interviews are generally described as in-depth, unstructured or semi-structured but it has been argued that all interviews require a degree of structure to meet the aims (Britten 2000).

King and Horrocks (2010) propose that there are ways to conduct an interview, and ways not to. The aim is to avoid leading questions, over complex and multiple questions, judgemental responses and a failure to listen or pickup on non-verbal clues. Complex experiences may be probed and clarification surrounding processes may be concentrated on during the interview.

Yet the ability of the interview to uncover personal experience has been criticised (Atkinson and Silverman 1997). Despite its many advantages over other methodological approaches, during interviews stories are narrated that are constructed in the moment of the interview: people choose what to reveal and what not to reveal (Charmaz 1995) and choose the aspect of their lives they are most interested in telling (Nunkoosing 2005). The asymmetrical power distribution between the interviewer/interviewee, the power swinging backwards and forwards as the interviewer, in a position of authority seeks knowledge, and the interviewee as a privileged ‘knower’ has been identified in studies which impact upon the interview process (Nunkoosing 2005; Karnieli-Miller, Strier et al. 2009). Some have questioned whether it is possible to have a non-hierarchical position during an interview and this must be taken into account during analysis (Glesne and Peshkin 1992). This was addressed during the interviews with patients and GPs and is discussed later in the sections detailing rigour and reflexivity.

3.5.2 Patient interviews (see Paper 3)

Individual interviews were considered the most appropriate method for exploring patients’ views on follow-up care. Interviews have been demonstrated to be useful in other studies and disease areas to explore follow-care needs and preferences (Beaver, Latif et al. 2010; Hudson, Miller et al. 2012).

The interviews were semi-structured using a topic guide (see appendix patient interviews) which outlined the main areas to be covered within the interview. Interview schedules or topic guides were generated to guide, prompt and to explore patient and GPs issues across interviews, taking care not to restrict or influence their perspective (King and Horrocks 2010). This semi-structured approach and topic guide allowed the interviews to be drawn from the findings of the best evidence synthesis and meta-synthesis papers. The models of follow-up care identified in the best evidence synthesis were discussed at length with the patient, for example, how an alternative approach would meet their needs or preferences.

The topic guide ensured that all issues were covered but still allowed flexibility to probe salient points (Arthur 2003). The guide was restructured after the first four interviews were analysed by the author and academic supervisors to enable new areas to be explored. Re-structuring was done repeatedly as new themes were identified during the interview (King and Horrocks 2010).

Field notes were collected during the interviews, which were digitally recorded with the participants' consent. Field notes provide a written record of what the researcher sees and hears outside of the immediate context of the interview, such as emotional contexts (Arthur 2003). Field notes may be a structured or unstructured method of keeping notes but keeping a field note diary is important to maintain record keeping and a reflexive approach to the data (Silverman 2005). The interviews lasted on average one hour (range 40-60 minutes). In addition to the field notes, a reflexive account of each interview was also maintained to allow the researcher to assess her own responses to the data and the impact of this on participant responses and data analysis (Mauthner and Douchet 2003).

3.5.3 GP interviews (see Paper 4)

As with patient interviews, individual interviews were considered the most appropriate method for exploring the GPs' current and potential role within IBD. The interviews were semi-structured using a topic guide (see appendix GP interviews). Interview schedules were used to explore GPs' current role in IBD diagnosis and management during quiescent disease and flare-ups. Their views were sought on the role of primary care in IBD management, existing barriers that impede primary care delivery, shared care between primary and secondary care issues, and how integrated care could be better provided and shaped within the new NHS climate. The GP topic guide was re-structured after the first four interviews as the transcripts were discussed during academic supervision.

17 interviews took place in GPs' surgeries, and three in GPs' homes. All were digitally recorded, transcribed verbatim, and lasted on average 48 minutes (range 28 – 79 minutes).

3.6 Transcribing qualitative interviews

Transcribing involves the voice recorded interview to be typed up however, it is often pointed out that the transcripts cannot ever produce the verbatim account of the interview, given the interpretive and analytical decisions which are made (McLellan and MacQueen 2003). The researcher must also make decisions about whether it should include non verbal as well as verbal details, such as inserting facial expressions or emotions into the text. The interview transcripts generally do not include pauses and non verbal sounds such as laughter and so collated field notes are usually relied on to account for non-verbal cues.

Ideally, the voice recording should be transcribed by the same person who undertook the interview (Easton, McCormish et al. 2000) and is often regarded as the first step in analysis. Transcribing the data ones-self helps the researcher to become immersed in the data (Wray, Markovic et al. 2007). Enhancing the familiarity with the data allows one to recognise realisations or ideas which emerge during the data analysis (Bailey 2008). Yet there are common pitfalls to avoid when transcribing qualitative data such as transcription errors, misrepresentation or mispronunciation and wrong punctuation, which can completely alter the meaning of the sentence (Easton, McCormish et al. 2000). This may lead to missing themes or wrongly interpreted themes during the analysis phase, which supports the proposal that the original researcher should transcribe the recording.

The interviews from papers 2 and 3 were recorded digitally and transcribed verbatim. The decision to have the recording professionally transcribed was based on time and expertise. Contextual information was provided to the transcribers alongside the voice recording, such as aims of the interview and the setting (Bailey 2008). It has been proposed that two typists independently transcribe the recording and comparisons made to assess agreement between the two transcripts (Kvale 1996) but this was too costly.

The optimal strategy within this study was to have the recording transcribed by the professional transcribers with instructions not to tidy up the transcript but to transcribe verbatim. The recordings were listened to prior to sending the recordings to the transcribers as the first stage of analysis.

There was the option from the transcribing company to have the recordings transcribed ‘verbatim intelligent’ but this was not considered. All pauses, nuances and slang were required for the richness of data. However, it was not assumed that the transcripts were correct and so the recording was listened to repeatedly to check against the transcript and also to transfer field notes onto the margins of the transcript. For example, the participant laughed a few times during the interview and this was bracketed in italics in the transcript. The laughter was nervous laughter and not joyful which I added in the margin. This process was a safeguard to having the recordings transcribed.

3.7 Computer assisted qualitative data analysis software packages (CAQDAS)

A continued area of controversy is whether to manually code the data or to use a computer package and this depends on the size of the project, funding and time availability and the commitment of the researcher (Basit 2003). There are a number of computer assisted qualitative data analysis software packages (CAQDAS) available to help to sort and manage the vast amounts of qualitative data which are amassed during qualitative research projects. The CAQDAS helps the researcher to order, sort, manage and locate material within a research study, by the creation of nodes and coding trees. It does not interpret nor analyse the data (Thorne 2000).

Sorting and managing data is particularly helpful when there is a large amount of data from many interviews, focus groups or observations. CAQDAS allows the organisation of complex coding systems into formats and hierarchies which the brain cannot do (Saldana 2009). The transcript can be broken down line by line to assist with open coding and illustrate more complex relationships within the data.

Ceswell (2007) proposes that CAQDAS allows one to examine the data closely and reflect on the meaning of each sentence. Opposing this, it has been argued that there is a risk of 'quick and dirty research' when using computer programmes (Lee and Fielding 1991). It is argued that the meaning of the text cannot be computerised (Kelle 1995) and that these programmes lead to a loss of control of the data (Saldana 2009) and distancing of the researcher from the data (Weaver and Atkinson 1994).

There is little doubt about the value of using a CAQDAS within qualitative research as long as caveats are addressed (Lee and Fielding 1991; Saldana 2009). Initial analysis of all transcripts was coded manually using coloured pens. Once familiarisation with the data was achieved and a number of codes identified, the anonymised transcripts were then imported into a CAQDAS package, NVivo© 9.0. Once this was imported the codes were then changed into 'nodes' and data analysis continued using the principles of Framework analysis.

3.8 Data analysis in qualitative research

There are many approaches to data analysis in qualitative research. It is often referred to as taking the raw data from a transcript or field notes and raising it to a conceptual level (Corbin and Strauss 2008). Ritchie and Lewis (2003) purport that there is emphasis in the literature upon how data are managed, sorted or reduced, but there is a lack of credibility about how the generation of findings from qualitative studies have been concluded.

Different approaches may be used to analyse interview transcripts, such as content analysis (Bernard and Ryan 2010), thematic analysis (Braun and Clarke 2006) and framework analysis (Ritchie, Spencer et al. 2003). Content analysis can be described as a method of systematically coding and analysing qualitative data (Bernard and Ryan 2010). Content analysis is actually quantitative analysis of qualitative data and involves the cataloguing of codes and then analysing the distribution of these statistically.

Thematic analysis is seen as the basis of data analysis in qualitative research and is an inductive method of data analysis (Braun and Clarke 2006). It is a process of identifying themes which emerge at different levels through the data, and thematic networks add structure to the themes (Attride-Stirling 2001). Some argue that thematic analysis is not a method of data analysis in its own right but an approach used across different approaches to analysis (Meier, Boivin et al. 2008). Thematic analysis moves beyond counting words and focuses on identifying and describing ideas within the data, referred to as themes (Guest, MacQueen et al. 2012). The approach is flexible and shares the inductive qualities of Grounded Theory but does not necessarily create a theoretical model (Guest, MacQueen et al. 2012).

A further form of data analysis is Framework Analysis. This was developed by social policy researchers at the National Centre for Social Science (NATCEN) in the 1980s as a transparent method to analyse qualitative data in applied policy research (Ritchie and Lewis 2003). Framework analysis starts deductively from pre-set aims and objectives, and data collection tends to be more structured than other approaches to qualitative data collection. The analytic process is more strongly informed by *a priori* reasoning (Pope, Ziebland et al. 2000; Ritchie, Spencer et al. 2003), and as such it proceeds on pre-identified ideals not concerned with generating new theory or lived experience of a phenomenon.

The analysis is a continuous and iterative process encompassing five key stages: familiarisation; developing a thematic framework; indexing; charting; and mapping and interpretation. Data from transcripts are labelled, sorted and compared once the researcher is thoroughly ‘familiar’ with it. Themes emerge during this familiarisation process and then are ‘indexed’. The indexed material is then synthesized to define the framework (see figure 8 Framework Analysis).

A benefit of using Framework Analysis is that strategies and recommendations for practice and policy may emerge as synthesis of the data takes place (Ritchie, Spencer et al. 2003). It offers a structured rigorous process for managing data but is also flexible, allowing for easy retrieval of data (Green 2004; Swallow, Lambert et al. 2011). Framework Analysis (Ritchie, Spencer et al. 2003) is being used more frequently in health service research due to the structured interconnected staged approach which provides transparency and an audit trail back to the original data (Dixon-Woods 2011; Johnston, Milligan et al. 2011; Smith and Firth 2011).

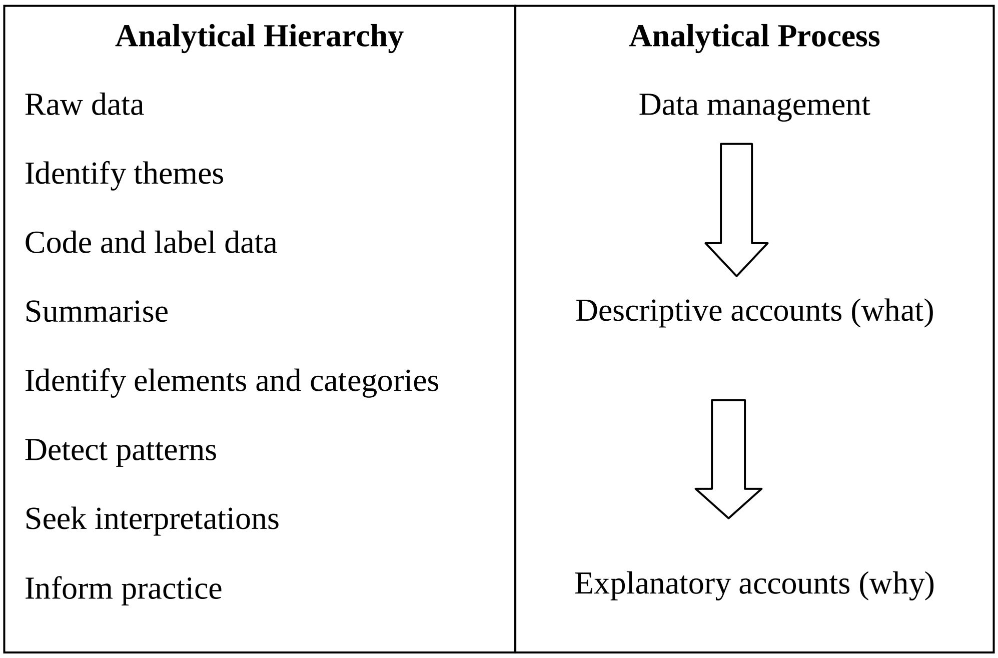
A major criticism of Framework Analysis is its label as a generic approach (Braun and Clarke 2006) combined with its lack of theoretical underpinnings (Smith and Bekker 2011). Traditional researchers suggest that there is no place for qualitative analysis that has no clear theoretical framework (Reeves, Albert et al. 2008) and any findings from this approach would lack methodological coherence and affect the study's validity (Morse, Barrett et al. 2002; Rolfe 2006). However, theoretical frameworks can be restrictive in that the findings become abstract theories and not relevant to the patient or their needs or clinical practice. The method of qualitative enquiry should stand alone without the underpinning or allegiance to a philosophical stance (Patton 2002). This is discussed further in this chapter outlining rigour in qualitative research.

Ritchie (2003), within the domain of applied social policy, states that:

'emphasis is placed on producing qualitative evidence that has been rigorously collected and analysed, is valid, as neutral and unbiased as possible, and clearly defensible' (Ritchie 2003, pg 19).

Acknowledging the importance of reflexivity, Ritchie (2003) maintains that the social world exists independently of individual subjective understanding, but is only accessible in qualitative research via participants' interpretations which are further interpreted by the researcher (Hammersley 1992; Hammersley 1995).

Figure 6: Framework Analysis, adapted from Ritchie (2003) pg 212



3.8.1 Data analysis of patients and GP interviews

Framework Analysis (Ritchie, Spencer et al. 2003) was considered to be the most suitable method of data analysis for this study as the study had *a priori* issues or research questions sought from a predetermined population (Srivastava and Thomson 2009), in this case, the best evidence synthesis and meta-synthesis. In addition, Framework Analysis has been utilised in previous exploratory studies of investigating living with IBD (Mukherjee, Sloper et al. 2002; Welfare 2006; Cooper, Collier et al. 2010).

Data analysis of interviews from patients and GPs followed the five steps of familiarisation; developing a thematic framework; indexing; charting; and mapping and interpretation. The next section within this chapter outlines the steps taken in much more detail than is given in papers 2 and 3.

Stage 1: Familiarisation

The aim of familiarisation is to become immersed in the data (Srivastava and Thomson 2009). This entailed reading and re-reading the transcripts, listening to the voice recordings and comparing the voice recordings to the transcripts and field notes, applying the field notes to the transcripts. Field notes allow the researcher to describe what they see and hear outside of the 'context' of the interview, to write down their own thoughts, and are used in the data analysis process (Arthur 2003). Even at this early stage, key and recurrent themes emerged within the data (Srivastava and Thomson 2009).

Stage two: Developing a theoretical framework

Once familiarisation of the data was completed, a coding framework of *a priori* themes and sub-themes, identified from the topic guide, was developed. This was initially applied manually, using coloured pens, to all of the transcripts. This was time consuming but allowed for a greater understanding of the data and emergent new themes. The data were then entered into NVivo© 9.0 (see appendix example of NVivo© 9.0). During this phase, the researcher's thoughts were maintained in the reflexive journal to record why decisions were being made regarding the data, such as why a particular theme or concept was identified. New concepts, and the journal, assisted to restructure the topic guide and purposively select the participants.

A priori themes are derived from the characteristics of the phenomenon being studied and these 'first pass' themes are usually generated from the topic guide (Bernard and Ryan 2010). However it was important to remain open to new themes and not to force the data to fit the *a priori* themes (Ritchie and Spencer 1994). In this way, for example, the theme of attitudes to new approaches to care and the content of the ideal consultation were identified during the analysis of the patients' data (see Paper 2, pg 146).

Stage three: Indexing and charting

Within this stage, the transcripts were indexed (coded) line by line, originally by coloured pens, and then using NVivo© 9.0, where they became known as 'nodes'. Initially there were many indexed themes that overlapped. As concurrent analysis and interviews were undertaken, inductive reasoning was used to explore new themes within the data. Inductive reasoning is described as extrapolating patterns from cases to form a conceptual category (Charmaz 2006).

Index themes were discussed at academic supervision and refined, collapsed and the thematic framework adjusted accordingly. A chart was drawn up using Microsoft Excel (see appendix example of Excel©) with headings of each participant and demographics with their corresponding quotes and extracts from the transcript. This means that the text was lifted from the original transcripts and NVivo© 9.0 and placed into the chart. Each section of original text within the chart was numerically identified and easily tracked back. This process refined the themes within the framework and provided grounding for the next stage of mapping and interpretation.

Stage five: Mapping and interpretation.

Refinement of the framework in stage three assisted with the mapping and interpretation of the data. The NVivo© codes and Excel charts combined provided a schematic diagram of the study which guided the interpretation of the data (Srivastava and Thomson 2009). It made looking at all charts, themes and participant demographics easy to read. Once again, coloured pens were used to identify patterns, associations, continued overlap of themes and allowed the researcher to compare and contrast participants' experiences of follow- up care.

This process led to the final list of themes and thematic framework used in papers 2 and 3.

3.9 Synthesis of 'Best evidence synthesis, Papers 1, 2, 3 – Modelling phase of MRC Framework for development of complex interventions (Paper 4)

There is ambiguity about how the stages of the MRC framework should be 'modelled' into the intervention (Lovell, Bower et al. 2008). In addition there has been criticism directed at studies of complex interventions which lacked transparency as to how the intervention was developed and modelled (Shepherd, Lewin et al. 2009; Mohler, Bartoszeck et al. 2012).

The conceptual modelling approach used for this study had been carried out by the researcher's academic supervisor on a number of occasions (Lovell, Bower et al. 2008; Bradshaw, Wearden et al. 2012) and provided a pragmatic framework to synthesise key data from the best evidence synthesis, meta-synthesis in Paper 1, the patient interviews in Paper 2 and GP interviews in Paper 3.

A matrix grid was developed, each column documenting the key points from each paper (see table 17, pg 202 and appendix). The end column was left blank; to be populated as the modelling progressed. 'Experts' were invited to attend the 'synthesis day' (see Paper 4, pg 188). These were a Consultant Gastroenterologist, a General Practitioner, a patient with Crohn's Disease and the researcher's academics supervisors. The academic supervisors helped to facilitate the meeting and acted as scribes to record salient points. The day was also audio-recorded and transcribed verbatim to allow for further clarification of the day.

An overview of the key findings from the phases of the study was presented by the researcher (see appendix PowerPoint Presentation synthesis day). This was followed by an interactive exercise to synthesise the data, populate the 'blank' column and map the 'active ingredients' (Craig, Dieppe et al. 2008) of the pathway of the intervention, focussing on how things fitted together on a practical level.

The MRC framework suggests that the use of focus groups, surveys or case studies may assist in defining the ingredients during the modelling phase. There is no right or wrong way to 'model' the phases of the MRC framework to develop the intervention and this approach has strengths and weaknesses, outlined in Paper 4. However, this approach outlines one option, provided transparency and represented the views of a patient with IBD and a range of healthcare professionals.

3.10 Rigour in qualitative research

Rigour has been described as the means by which integrity and competence are demonstrated within a study (Tobin and Begley 2004) and without it 'research is worthless' (Morse, Barrett et al. 2002) pg 2. Rigour in qualitative research differs from rigour in quantitative studies which predominantly uses the concepts of validity and reliability (see figure 9: Rigour in quantitative and qualitative research, pg 68). Alternative criteria of credibility, transferability, dependability and confirmability can be applied to qualitative studies to demonstrate 'rigour' (Lincoln and Guba 1985).

Credibility questions whether the analysis is credible. Transferability refers to the generalisability of the findings; dependability refers to the auditing process and confirmability relates to the data interpretation and whether the conclusions are derived from the data. Generalisability or transferability is concerned with how transferable the research findings are beyond the study population (Lewis and Ritchie 2003).

Meetings with academic supervisors continued regularly throughout the study period. During these meetings transcripts were reviewed, topic guides were revised, themes identified and reassessed in the light of new themes. The first four transcripts of patients and GPs were reviewed with academic supervisors, topic guides were changed and analysis was on going. Each step of the study was discussed in depth from the sampling strategy to final writing up of manuscripts (papers 1-4).

Keeping a research diary, minutes of academic supervision, documenting processes and presenting the evidence which led to particular conclusions, was used to support my role as researcher, reduce bias and provide an audit trial, within this study (Seale 1999; Finlay 2002).

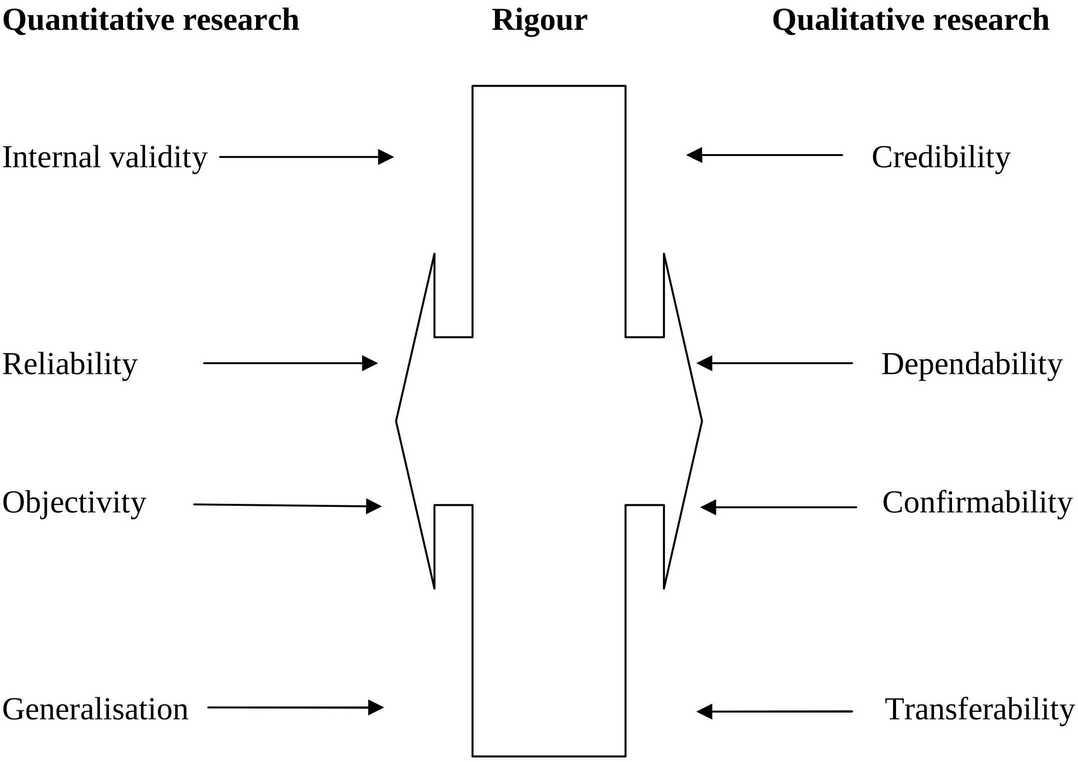
To further meet the criteria of confirmability, where the neutrality has to be moved from the researcher and focused on the project (Hamberg, Johansson et al. 1994), methods must be systematic with the researcher continuously questioning the findings as they emerge. A reflexive stance was adopted by the researcher during the conduct of the study. Within the thesis accounts are given of the researcher's role within data collection and how the researcher may have impacted upon the interviews (see Reflexivity: a personal reflection). The researcher's dual role of a clinical nurse: nurse researcher was discussed at great length during academic meetings and strategies to assist the researcher to manage this were identified, such as re-reading transcripts where this challenge occurred so as to avoid this in future interviews.

Steps were taken within this study to address dependability. A primary element of dependability of a study is its ability to demonstrate the appropriateness of the science behind the methodology (Maggs-Rapport 2001). This is described as ‘methodological coherence’ (Morse, Barrett et al. 2002) pg 12. The research question must match the method, which must match the data and analytic process. The MRC framework and Framework Analysis are described step by step within the study (see Paper 2, figure 165 and Paper 3, pg185), worked example of Framework Analysis). The sample was appropriate and adequate, composed of participants with experience and a detailed understanding of follow-up care in IBD, until ‘saturation’ was reached. Framework Analysis adopts a deductive approach but is flexible enough to allow for new emerging concepts within the data.

Credibility may also be met by ‘member checking’ the interview transcripts. This is a strategy used as a means of validating the data by asking the participants to review the transcripts and interpretation (Lincoln and Guba 1985). The decision was made not to use this approach for a number of reasons: the transcripts and interpretation would be scrutinised by the researcher’s academic supervisors; and the data would be further synthesised into the intervention by an ‘expert’ team. The evidence surrounding this method is also ambiguous. Asking participants to review and change transcripts may change the spontaneous response offered during the interview and may not necessarily introduce new insights pertaining to the research subject (Hagens, Dobrow et al. 2009).

Qualitative findings are not generalisable in the way that quantitative results are (Hamberg, Johansson et al. 1994). In order to make transferability judgements from qualitative research, the study must be described in context and demographics of the participants outlined (Hamberg, Johansson et al. 1994). The focus of this study was follow-up care in adults with IBD and it recognised the changing needs of the patients and GPs. It was set within the new NHS, linking policy with care. Demographics of all participants are detailed within the papers.

Figure 7: Rigour in quantitative and qualitative research (adapted from Hamberg, 1994, pg 178)



3.11 Reflexivity and sensitivity

Reflexivity is an important component of qualitative research and requires the researcher to scrutinise their experience, values, and biases and to what extent these have influenced the inquiry (Charmaz 2006). Strauss and Corbin (1998) acknowledge the role of reflexivity, describing it as examining the role of the researcher on the research process.

Although it is widely accepted as essential, there remains controversy regarding the feasibility of adopting a reflective stance, with researchers proposing how one can be reflexive during research as the process takes place at a much deeper level of consciousness (Cutliffe 2003). Furthermore, Glaser (2001) suggests that reflexivity is unnecessary and is ‘paralysing, self-destructive and stifling of productivity’ (Glaser 2001).

In determining what the researcher brings to the study, Glaser (1978) suggests that the focus should be on sensitivity. In contrast to objectivity, sensitivity is about insight, the ability to pick up on relevant issues and what is happening with the data and present the view point of the participant (Corbin and Strauss 2008). The researchers' theories, experiences and knowledge informs the research (Sandelowski 1993), and influences their response to the data. The findings are a product of the data *plus* what the researcher brings to the analysis (Corbin 2003).

3.12. A personal reflection on patient interviews

Morse, Barrett et al (2002) argues that 'research is only as good as the investigator', (pg 10), and it is the researcher's skill in using verification strategies *throughout* the research, not post hoc at the end, which determines the reliability and validity of the study. I have been an IBD nurse specialist for 14 years and so was sensitive to the needs of patients and the role the GP had within IBD care. Due to this I came to the research with an extensive knowledge of the field of practice and vast experience of nursing patients and meeting their needs, which allowed me to probe and explore during interviews with patients and GPs. However there was a disadvantage to interpreting the data through this lens. It may be argued that I came to the research with preconceived ideas and was not open to other views or interpretations of the data. It was vital that I relinquish any ideas that were poorly or not supported within the emerging data (Morse, Barrett et al. 2002).

I was acutely aware of the power imbalance in relationships with the participants (Karnieli-Miller, Strier et al. 2009). Steps were taken to address this, such as interviewing in the participant's home, as opposed to the hospital setting where the researcher was employed as a clinical nurse. Addressing this power-imbalance accentuated the importance of reflexivity. Patients were offered a choice of where to be interviewed with the majority being interviewed in their home. Two were interviewed in hospital directly after their outpatients appointment.

During initial analysis of early transcripts, it was highlighted by my research supervisors that I was slipping into 'nurse mode' during the interviews. Even though none of the participants were personally known to me, they knew that I was a specialist nurse in IBD. It was inevitable that I would form a relationship with the participant (Wilson 2009). It was with some difficulty that the blurring of the role between nurse and researcher was differentiated and slipping into ‘nurse mode’ was recognised and halted during the interviews: it was difficult not to put ‘words into patients mouths’ (Mercer 2007).

Role conflict for the nurse as a researcher has been documented in past studies (Seymour and Ingleton 1990; Colbourne and Sque 2004; Newbury 2011). This conflict can arise as the nurse is not only committed to the research but he/she cannot divorce herself from the welfare of patients (Holloway and Wheeler 2002). Holloway and Wheeler (2002) also point out that this may also be a cause of confusion for patients who may not understand that the nurse is present in a research capacity and not to ‘care’ for the patient. However, in trying to control this dual role and separate the nurse from the researcher, this may well hamper the relationship between the nurse researcher and participant (Chesney 2001). Chesney (2001), during her research in midwifery, points out that the key lies in how reflexive the nurse researcher is in recognising the ‘me’ of the research.

During the interviews with patients within this study, I would concur with Colbourne and Sque (2004) that when interviewing an ‘information-deprived’ participant, it is easy to forget and slip back into the nurse role (Colbourne and Sque 2004).

Despite the declarations of Glaser (2001), I reflected upon my understanding of IBD, my experience of following-up these patients and what I thought their needs would be and acknowledged this throughout. In terms of data analysis, this was important to enhance the credibility of the findings (Silverman 1998). Other measures to avoid conflict included introducing me in the capacity of a researcher, not being in uniform and trying to avoid interviews at the hospital where I was employed.

3.13. A personal reflection on GP interviews

I am a health care professional specialising in the area of IBD and interviewing one’s peers presented significant challenges. One drawback of interviewing one’s peers, despite contributing rich insightful responses, is the issue of shared conceptual blindness (Strauss and Corbin 1990). This is defined as allowing the interviewer's own feelings, experiences and opinions about the research area to govern the discourse and interpretation (Andersson, Troein et al. 2001). The interviewer is unable to disentangle themselves from the healthcare professional role, resulting in the rigour of the project being compromised (Chew-Graham, May et al. 2002).

There were occasions during interviews that the GPs disclosed they had read up about IBD the night before, worrying that their knowledge was to be under scrutiny during the interview and they did not want to appear unknowledgeable. Other GPs used the interview as a source of knowledge gathering, asking me questions about managing patients with IBD (Coar and Sim 2006). I was often seen and referred to as an 'expert' in IBD which may have led to more cautious responses from the GPs (Chew-Graham, May et al. 2002). On occasion there was a feeling of interview reciprocity, the exchange of the researchers knowledge for the exchange of the GPs views, referred to succinctly as *'I'll show you mine if you show me yours'* (Mercer 2007).

3.14 Ethical and research governance in qualitative research

The key ethical challenges in qualitative research surround issues of informed consent, voluntary participation, confidentiality, the relationship between the researcher and participant and the role of the nurse-researcher (Houghton, Casey et al. 2010)

Informed consent is fundamental to research governance (DH 2005) and must be obtained from the participant prior to undertaking research. There must be no coercion, the participant must be allowed time to reflect on the research and have access to all information (DH 2005). It is imperative that the researcher discusses the research in detail to ensure the participant is fully informed (Pothier 2008), including consent to withdraw from the study at any point and the capacity to consent (Mental Capacity Act 2007).

Despite this, the issue of informed consent is still debated and criticised (Cassell and Young 2002; Moore and Savage 2002; Griffiths 2008) with some researchers suggesting that acutely ill patients should not be bothered to obtain consent (Griffiths 2008).

The researcher has a responsibility to the participant to ensure confidentiality and anonymity, which can be challenging in qualitative research. Confidentiality ensures that participants remain unexposed and cannot be identified to anyone other than the researcher (Lofland 2006). It is good research practice to anonymise all transcripts, remove all identifying descriptions and restricting access to the data (DH 2005).

The issue of avoidance of harm is central to any research project, including qualitative projects where the participant may not necessarily be exposed to direct harm. However, qualitative research often involves researching sensitive topics which can be potentially distressing for the participant. Support processes must be in place prior to conducting the research (Coyle and Wright 1996). Within this study, the formation of a distress policy and system for forwarding referral to the consultant gastroenterologist or IBD nurse were in place.

Separating the role of the nurse and the role of the researcher can be difficult, especially if the researcher is a professional practicing within the area of study (Orb, Eisenhauer et al. 2001). This can lead to a blurring of roles but where the researcher is a nurse, the nurse is governed by The Code (NMC 2008) and there is always a clear commitment to the welfare of the participant (Gerrish 2003). Boundaries must be set (Dickson-Swift, James et al. 2006). However there are advantages to this dual-role in the possession of specialist knowledge and language assisting the research enquiry (Pellatt 2003; Savage 2003).

Ethical approval for all of this study was granted from the North West 2 Research Ethics Committee REC number 10/H1005/50 (see appendix ethical approval). Research governance for Paper 2 was given by Central Manchester and Manchester Children’s University Hospitals NHS Foundation Trust (R01325/47651) and approval was given from 11 Primary Care Trusts to undertake the interviews for Paper 3. The study was also adopted by the National Institute of Health Research Greater Manchester Clinical Local Research Network (GMCLRN).

Steps were taken to ensure confidentiality and anonymity as each participant agreed to be interviewed (DH 2005). Each participant was allocated a personal identification number at the start and this was used on all documentation relating to that participant. Digital interview recordings, field notes, hard copies of interview transcripts and the participant log was placed in a locked cupboard in keeping with research governance. All identifiable information on the transcripts was removed, including names and places.

3.15 Summary

This chapter has expanded the methods discussed in papers 1, 2, 3 and 4. It has provided a description and critique of the methods of qualitative research and provided the rationale and outline of methods used in the study. By using the first phase in the MRC framework for the development of complex interventions, the rationale for using a qualitative approach, using semi-structured interviews and framework analysis is clear. The following section of the thesis presents the best evidence synthesis and Papers 1, 2 3 and 4.

Chapter 4

A best evidence synthesis review of follow-up care models in inflammatory bowel disease

4.1 Aim of the best evidence synthesis

The aim of the best evidence synthesis (Slavin 1986) was to identify, comprehensively examine, critically appraise and synthesise follow-up care models used in inflammatory bowel disease (IBD) and explore patient acceptability of the models.

4.2 Method

In order to locate relevant literature a range of search processes were employed. The literature was identified by electronic databases and hand searching. Hand searching included journal scans, searching citations, bibliographies, and conference proceedings. Citation alerts were also set for the main papers identified and maintained throughout the study period. Books and grey literature were included to identify unpublished work and this was achieved by searching thesis databases and contacting authors of unpublished work. Searches were conducted from the date of inception of the databases on the Ovid platform to November 2012. Inclusion and exclusion criteria were established prior to searching.

4.2.1 Inclusion criteria

Research studies and audits relating to adults.

Studies of models of follow-up care in patients with IBD.

Unpublished papers / theses, abstracts.

All types of studies i.e. randomised controlled trials, qualitative studies, and systematic reviews.

4.2.2 Exclusion criteria

Studies related to patients <16 years.

Studies relating to transitional period of follow-up care of adolescents.

Studies relating to follow-up care of IBD patients following surgery.

Non English papers.

4. 2.3 Search terms

Search terms ‘inflammatory bowel disease’, ‘Crohn’s Disease’, and ‘ulcerative colitis’ were exploded and searched with terms from Table 2: summary of search terms. The MeSH terms were refined using Boolean operators and truncations.

Table 3: Summary of Search Terms

Search words	Search term	To capture
Self management	(self AND management*), exp Self care, exp Self management/ exp Self care skills. exp Self management /OR exp Chronic illness / OR exp Intervention/ OR exp Healthcare services.	Self management, intervention studies if self and management.
Follow up	exp Health services accessibility/ Outpatient clinics, hospital/ exp follow up studies, exp After care/OR exp Gastroenterology care/ exp Patient Healthcare delivery, Outpatient care/OR exp Outpatient department/OR exp Outpatient /Or exp Organisation and management/ OR exp Outpatient service. exp Healthcare utilisation/ exp Healthcare services/ (open AND access)ti,ab. (patient AND initiated AND referral)ti,ab. exp Continuity of patient care/ exp Follow up studies/ OR exp Healthcare utilisation/OR exp Post-treatment follow up	Interventions of follow up studies, including open access, patient initiated referral systems of follow up care.
Telemedicine	Telemedicine/OR exp tele-health/ Technology in healthcare/ exp Telephone/ exp E-Health/ (telephone AND clinics)ti,ab	Telemedicine and e-health.
Patient satisfaction	exp Patient acceptability /exp Patient satisfaction/ exp Personal satisfaction,/exp Patient acceptance of health care, (patient AND satisfaction)ti,ab. exp Client attitudes/	Patient satisfaction patient acceptability
General Practitioners	exp General Practitioners / exp Primary Care, exp Primary healthcare, exp Physicians, Family/ exp Family practice	GPs, Primary Health Care.

4.2.4 Databases searched

The databases were chosen to ensure a systematic search of a wide range of literature in nursing, medicine, social sciences, psychological and health service research. Searching commenced at the start of the study, January 2010, and continued throughout the study period, to November 2012. The databases searched were:

Cumulative Index to Nursing and Allied Health Literature (CINAHL)

British Nursing Index

Embase

PsychInfo

Medline

Web of Knowledge (used to search citations and citation alerts)

Cochrane database

Database of Abstracts and Reviews of Effectiveness (DARE)

Health Technology Assessment

ProQuest Dissertation Abstracts International

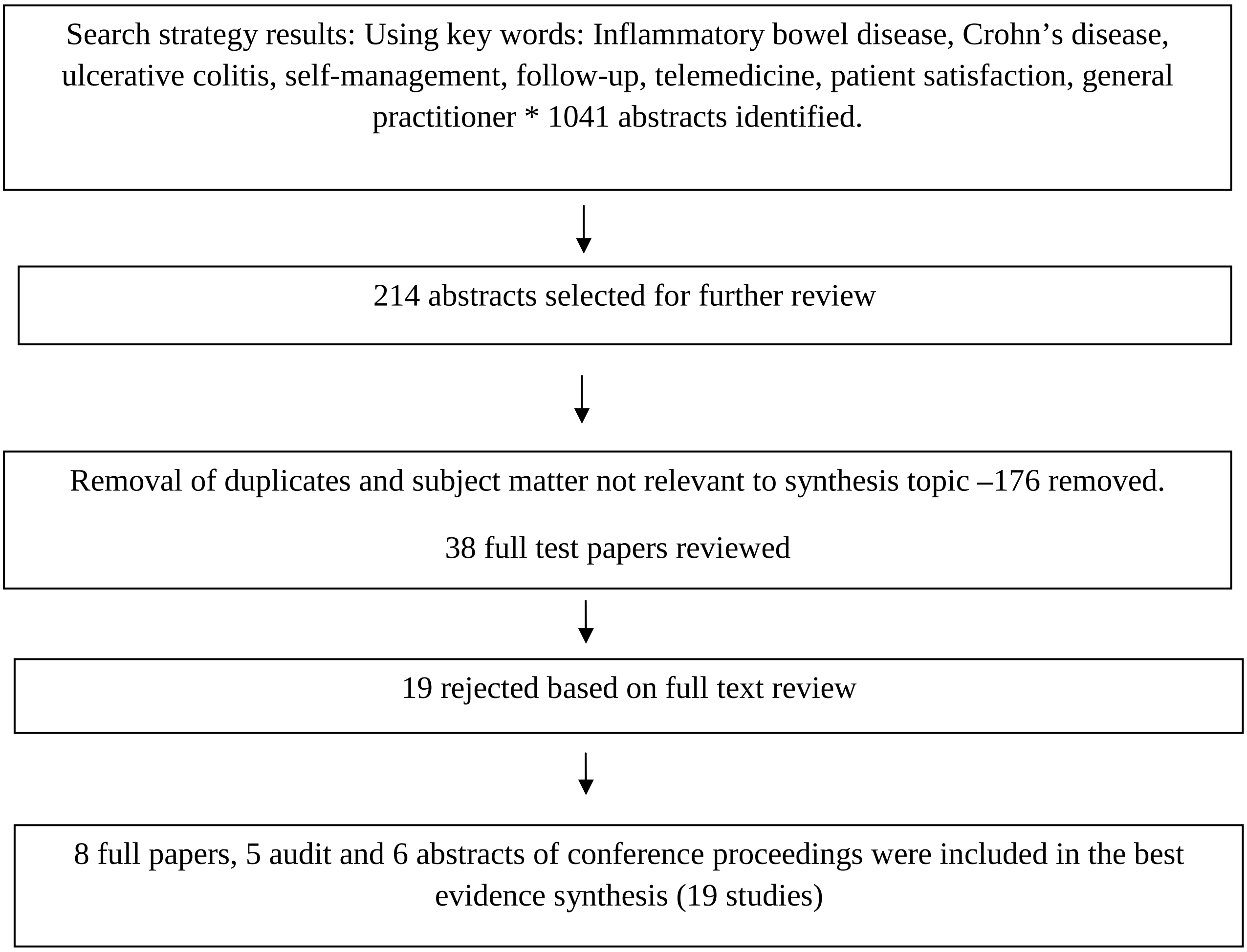
4.3 Results

Nineteen studies met the inclusion and exclusion criteria and were included in the synthesis (see Figure 8: Search strategy for best evidence synthesis). Full details of the search strategy, excluded and included studies can be found in tables 3-8 pg 77. Of these 19, six were RCTs (Williams, Cheung et al. 2000; Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003; Elkjaer, Shuhaibar et al. 2010; Krier, Kaltenbach et al. 2011; Cross, Cheevers et al. 2012), one was a population based longitudinal design study (Rejler, Spangeus et al. 2007) and one a qualitative study (Cheung, Dove et al. 2002). Five were retrospective audits (Miller, Caton et al. 2002; Gethins, Robinson et al. 2007; Stansfield and Robinson 2008; Gethins, Duckett et al. 2011; Hunter, Claridge et al. 2012). The remaining six were abstracts of conference proceedings (Schilstra, Bouma et al. 2005; van Dullemen, Doorn et al. 2005;

Castro, Cross et al. 2006; Duncan, Caulfield et al. 2010; Plener, Morgan et al. 2011; Jakobsen, Bager et al. 2012).

One Health Technology Assessment (HTA) was identified for the review (Kennedy, Nelson et al. 2003). There were 6 separate publications from the HTA (Kennedy and Rogers 2002; Kennedy, Nelson et al. 2003; Rogers, Kennedy et al. 2004; Kennedy, Gask et al. 2005; Rogers, Kennedy et al. 2005; Richardson, Sculpher et al. 2006) (see Table 7: Papers published in Kennedy (2003) HTA, pg 108). The full HTA will be reported within the review rather than the individual publications.

Figure 8: Search strategy for best evidence synthesis



Search strategy results: Using key words: Inflammatory bowel disease, Crohn’s disease, ulcerative colitis, self-management, follow-up, telemedicine, patient satisfaction, general practitioner * 1041 abstracts identified.

214 abstracts selected for further review

Removal of duplicates and subject matter not relevant to synthesis topic –176 removed.

38 full test papers reviewed

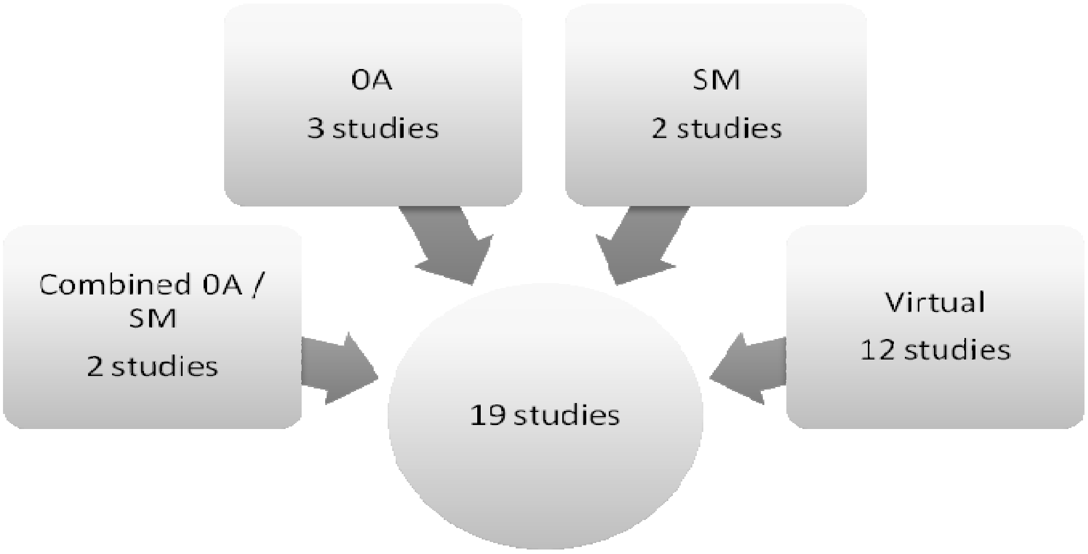
19 rejected based on full text review

8 full papers, 5 audit and 6 abstracts of conference proceedings were included in the best evidence synthesis (19 studies)

4.3.1 Data extraction

All data were extracted and key models of follow-care care identified and synthesised into four main models of care: open access, a combination of open-access and self-management, self-management, and ‘virtual’ care (Tables 8a-d). The following section of the best evidence synthesis describes the models in detail. The CASP tool (CASP 2010) was used to critically appraise the RCT studies (Williams, Cheung et al. 2000; Robinson, Thompson et al. 2001; Kennedy, Robinson et al. 2003; Elkjaer, Shuhaibar et al. 2010; Krier, Kaltenbach et al. 2011; Cross, Cheevers et al. 2012). The audits and conference abstracts added to the body of evidence of follow-up care but were not critically appraised.

Figure 9: Types of studies



OA/SM = combined open access and self management, OA = open access, SM = self management

4.3.2 Open access

The literature identified three main studies which developed open access as an innovative way of following up patients with IBD (Williams, Cheung et al. 2000; Cheung, Dove et al. 2002; Rejler, Spangeus et al. 2007). Direct access system (Pope 2005), patient initiated appointment (Hewlett, Kirwan et al. 2005), patient-and demand-directed care (Rejler, Spangeus et al. 2007) patient directed follow-up (Tholstrup, Wielondek et al. 2004) or open access (Rogers, Kennedy et al. 2004) are all terms used to describe alternative approaches to the traditional fixed appointment review system. These terms describe a review system whereby the patient is responsible for initiating the clinical review; the patient is effectively self-referring back into the hospital system based on their clinical need. There are numerous advantages to adopting this system in diseases which are defined by periods of remission and relapse. In the case of IBD, the archetypal portrayal of the patient feeling well and then unwell very quickly, fits well within this framework.

Three studies explored open access as a model of care with 626 patients and 91 general practitioners (GPs). One study was a qualitative exploration of GPs views of open access (Williams, Cheung et al. 2000), one RCT (Williams, Cheung et al. 2000) and the third was a population based longitudinal study (Rejler, Spangeus et al. 2007).

Williams, Cheung et al (2000) study population of 180 mild stable IBD patients were randomised to open access or routine follow-up care. They hypothesised that follow-up care through open access would be no worse than routine care for quality of life (QoL), total resource use and patients and GP preference. Intervention patients were discharged to the care of the GP, stopped routine appointments and offered a rapid access back into the hospital system. Rejler, Spangeus et al's (2007) sample of 466, the full cohort of patients, were transitioned into patient-and-demand-directed care. Within this a nurse specialist was appointed to provide a telephone helpline and rapid access back into clinic.

Williams, Cheung et al (2000) found no difference in the QoL in the intervention and control group and reported fewer outpatient consultations and secondary care contacts in the intervention group. Rejler, Spangeus et al (2007) found no difference in clinical and functional QoL in the population and reported a reduction in waiting times and unplanned hospital admissions. An important aspect of Williams, Cheung et al's (2000) study was the patients' difficulty with getting back into the system for urgent appointments emphasising the pivotal role of the general practitioner in the success of open access.

Exacerbations of disease flare ups are often used as a patient outcome measure. Williams, Cheung et al (2000) found no difference in the number of relapses whilst Rejler, Spangeus et al (2007), using the Short Health Scale, reported 88% of patients achieved set clinical targets. They did not directly measure disease flare ups. Open access reduced costs and these, expectedly, were related to the reduction in hospital appointments (Williams, Cheung et al. 2000) and reduced hospitalisations (Rejler, Spangeus et al. 2007).

Both studies measured patient satisfaction and responses were mainly positive and supportive of the systems. However, not all patients wanted this, reporting that the security of the fixed appointment was important to them and concerns expressed with the failure of the centre to provide urgent assistance (Williams, Cheung et al. 2000). Rejler, Spangeus et al (2007) lacked qualitative data, such as patient experience, which would have strengthened the evidence for this care package.

Only one study directly included the GP in the care package and this was the shift of care from the hospital to the GP (Williams, Cheung et al 2000). The views of the GPs involved in this trial were explored in a further study reporting that, in general, they supported open access, although caveats were expressed (Cheung, Dove et al. 2002). Written information for the patient, specialist nurse involvement and a more integrated approach between the hospital, nurse, GP and patient was required. Interestingly 30 of the 91 GPs had limited experience of the trial itself and nine experienced difficulty managing IBD patients. This study used a combination of semi-structured interviews and postal questionnaires to assess GPs' view of the open access study they were participating in. The questionnaires and interviews were coded into only three responses: positive, negative and neutral and analysed using quantitative tests of Cohne's Kappa and chi square tests. The authors state that 'differences were resolved by discussion' but make no reference to what the 'differences' were, or explain them or the impact this had on the overall results.

The three studies presented have all adopted open access, some with the addition of a variety of components. Williams, Cheung et al (2000) shifted the care to the GP whilst Rejler, Spangeus et al (2007) implemented open access and utilised the skills of a specialist nurse.

It is important to note that Williams' (2000) study was undertaken more than 10 years ago, at a time when there were no targets for cancer care, no 18 week pathway and new to follow-up ratios for clinic appointments (DH 2010).

There are methodological and statistical questions surrounding Williams, Cheung et al's study (2000). The authors concluded that the cost of the open access system was lower and even with the added cost of primary care, there was no significant difference in the total costs. These results regarding costs have been contested with reports that the wrong statistical measure was used (Barber 2000). In addition, despite the authors alluding to the problems of open access, there are some areas which require further deliberation. This study focused on patients with inactive or mild disease so its findings are applicable to only this group of patients. Contacts with accident and emergency or other urgent services were not included in the study which would have added to the cost of open access care. A patient with uncontrolled disease or experiencing a relapse must be able to access specialist services without delay but the patients expressed concerns re access to hospital. Williams, Cheung et al (2000) omits patient demographics data and the control and intervention groups were instead stratified into diagnostic groups such as ulcerative colitis affecting more than rectum and Crohn's Disease of small or large bowel.

Rejler, Spangeus et al's (2007) study was a population based longitudinal study design with 466 patients, all of the patients added to a new IBD register. The study identified clear research aims expressed as quality goals. The authors used coeliac patients as a comparator control group. This was an inappropriate control group to use, as the authors acknowledged that these patients were often reviewed by their GP anyway and so the GP contacts in this group do not reflect control practice. The strength of longitudinal studies, by reporting data from one group of individuals over a long period of time, is that they allow the researcher to differentiate change over time, both in the data and individuals (Gravetter and Foranzo 2011). Rejler, Spangeus et al (2007) were confident that most patients were included in their study and they were able to monitor continuous follow-up care.

Overall the studies provided clear research aims, primary outcomes, the null hypothesis and randomisation protocol were stated (Williams, Cheung et al. 2000).

4.3.3 Combined open access and self management

There were two randomised controlled trials with 903 patients exploring the combined package of open access and self-management in IBD (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003). Although both studies included open access and self management, Kennedy, Nelson et al (2003) provided a much more complex care package.

Robinson, Thompson et al (2001) randomised 203 UC patients in remission of disease, across four hospitals for 14 months, to a guided self management and open access intervention compared to normal treatment and follow-up care. Consultants were trained to deliver guided self-management in 15-30 minute consultations. No further follow-up hospital appointments were offered and a telephone helpline was established. The primary outcome was the time between symptom development and commencement of treatment. Secondary outcome measures were quality of life (QoL), the number of primary and secondary care consultations, cost to patients and acceptability of the new system to patients and consultants.

The HTA report (Kennedy, Nelson et al 2003) was a cluster randomised trial of 700 patients across 19 hospitals over a one year period. Consultants were given two-hour training sessions to deliver self-management to patients. Outcome measures were the number of hospital appointments, QoL and patient acceptability. Additional economic evaluation looked at health service use and costs. As part of the care package, the authors added an ulcerative colitis disease specific guide book for patients, developed from a previous study, which was used to support the self-management aspect of the study. Patient and consultant satisfaction was measured through qualitative interviews of 28 purposefully sampled patients and 11 consultants from the intervention hospitals.

Robinson, Thompson et al (2001) found no difference in the number of disease-related flare ups in the two groups yet saved 154 appointments where as Kennedy, Nelson et al (2003) reported fewer relapses in the intervention group. Robinson's study revealed that the relapses were treated earlier in the intervention group and there was a definite trend towards a shorter duration of the length of a flare up.

A significant point was highlighted when measuring the relapses in the two groups in Kennedy, Nelson et al's (2003) study; there was a difference in the number of patient reported relapses compared to the medically reported relapses. Patients maintained diaries for the duration of the study and reported what they personally felt was a relapse. No difference was found between patient reported disease activity or relapses in the control and intervention groups.

Both studies failed to detect any difference in QoL between the intervention and control group. Importantly both studies found increased patient satisfaction in the guided self-management approach.

Exploring whether self-management is cost effective, Kennedy, Nelson et al’s study (2003), assessed the costs of a self-management plan compared to a control group of traditional care in patients with IBD. The main cost saving was identified as a reduction in hospital appointments, which is only to be expected when open access is adopted as part of the self-management approach. Kennedy (2003) found that both the self-management and control group were slightly worse off over a 12 month period, measured by a reduction in the QUALY.

Robinson, Thompson et al (2001) and Kennedy, Nelson et al (2003) provided clear research aims, primary outcome measures stated and population to be studied. Randomisation protocols were described. Robinson, Thompson et al (2001) randomised patients to control and intervention within each hospital’s *department* and there is an acknowledgement that patients in the control arm of Robinsons’ study may well have adopted self-management practices from the intervention patients and instigated treatment earlier than previously. It is also questionable that self-management can be delivered effectively in a 15-30 minute consultation.

Kennedys’ HTA (2003) randomised the *hospital* to the control and intervention arm to reduce contamination between the control and intervention groups. The participant demographics are reported in both studies and matched the groups for age and gender. The control arm of the studies was usual follow-up and these comparator groups reflected the current follow-up care practice in the UK at that time.

4.3.4 Self-management

There were two retrospective audits of nurse-led self management services (Stansfield and Robinson 2008; Gethins, Duckett et al. 2011). There is no clear outcome data from Stansfield and Robinson (2008), apart from reporting patient satisfaction of which 90% of patients reported the service to be excellent. Patients reported less time off work, reduction in stress and increased confidence in their ability to self-manage although no explanation is offered as to how a reduction in employment sick leave or stress was calculated. Similarly, Gethins, Duckett et al (2011) reported the results of a patient questionnaire and concentrated on patient satisfaction with the service, but reported the number of patients referred back into the service and the reasons why, adding strength to the audit.

4.3.5 Tele-health and ‘virtual’ care

Tele-health or ‘virtual’ care papers formed the largest theme of the synthesis, but only three were RCTs. The remaining were three retrospective audits and six conference abstracts, demonstrating the emerging interest in this area of healthcare.

The term ‘virtual clinic’ encompasses tele-management (Cross, Cheevers et al. 2012), e-health via the internet (Elkjaer, Shuhaibar et al. 2010), tele-consultations (virtual outreach) (van Dullemen, Doorn et al. 2005; Hunter, Claridge et al. 2012) and telephone clinics (Miller, Caton et al. 2002). These approaches to follow-up care offer the patient an alternative way of being reviewed and monitored away from the hospital setting, often in the patient’s home.

There are three RCTs reporting the use of tele-medicine in IBD with 414 patients (Elkjaer, Shuhaibar et al. 2010; Krier, Kaltenbach et al. 2011; Cross, Cheevers et al. 2012).

Elkjaer, Shuhaibar et al’s (2010) study was a two centred RCT carried out in Denmark and Ireland, with 333 patients over a 12 month period. They compared an e-health intervention using a specific educational and home self-treatment programme to standard care. The study measured the feasibility of the approach, its influence on patients’ compliance, patient knowledge, QoL, disease outcomes, safety and cost. Patients randomised to the intervention were trained to use the web based e-health system, which was a guided treatment programme for UC. Web ‘ward rounds’ were conducted weekly by the investigators and patients status was coded red, yellow or green. Red indicated active disease.

Disease specific QoL, knowledge and anxiety improved in the intervention patients yet the number of relapses was more but with a shorter duration. There was no difference in hospitalisations or the need for surgery in the control and intervention groups.

Krier, Kaltenbach et al’s (2011) study was an RCT of 34 patients of a hospital based tele-medicine system, randomising patients to a standard face-to-face consultation or a combined face-to-face and tele-monitoring consultation, both taking place at the hospital clinic. The patients in the intervention group had a face-to-face consultation with a gastroenterology fellow and then a combined tele-medicine consultation with the gastroenterology fellow and gastroenterology specialist who was 40 miles away. The study outcomes were patient-centred as opposed to disease specific, measuring patient experience and satisfaction as well as clinic appointment times, with the additional tele-medicine time added on. Patients rated the tele-medicine consultation highly with no difference in total appointment time.

Cross, Cheevers et al (2012) conducted an RCT of an UC home tele-management system (UC HAT), randomising 47 UC patients to the UC HAT system or best available care over 12 months. The authors hypothesised that the HAT would improve disease activity and disease specific QoL compared to best available care. The UC HAT system did not improve disease activity or adherence. Inflammatory Bowel Disease Questionnaire (IBDQ) scores, which were higher in the control group at baseline, increased in the intervention group but remained stable in the control group. There was no significant difference in the overall IBDQ scores in the two groups throughout the study period.

The UC HAT system and patient experience was evaluated in a separate abstract (Castro, Cross et al. 2006). Qualitative exit interviews were carried out in patients who had used the system for six months. Overall the system was well accepted and patients reported feeling empowered and more in control.

Interestingly both Elkjaer, Shuhaibar et al (2010) and Cross, Cheevers et al (2012) reported higher than expected rates of attrition in the intervention. Elkjaer (2010) also reported an improvement in depression score of the *control* group.

All of the three RCTs (Elkjaer, Shuhaibar et al. 2010; Krier, Kaltenbach et al. 2011; Cross, Cheevers et al. 2012) provided clear research aims. The randomisation schedule was outlined in all studies. However the randomisation protocol used in Krier, Kaltenback et al’s (2011) study was based on the randomisation of the intervention by day of clinic availability and not patients. A healthcare professional randomly selected patients to attend clinic but was blind to the allocation of clinic to the intervention or control arm. In Cross, Cheevers et al’s (2012) study, the groups were concealed until baseline data were collected. Elkjaer, Shuhaibar et al (2010) used a randomisation programme but does not give any further details.

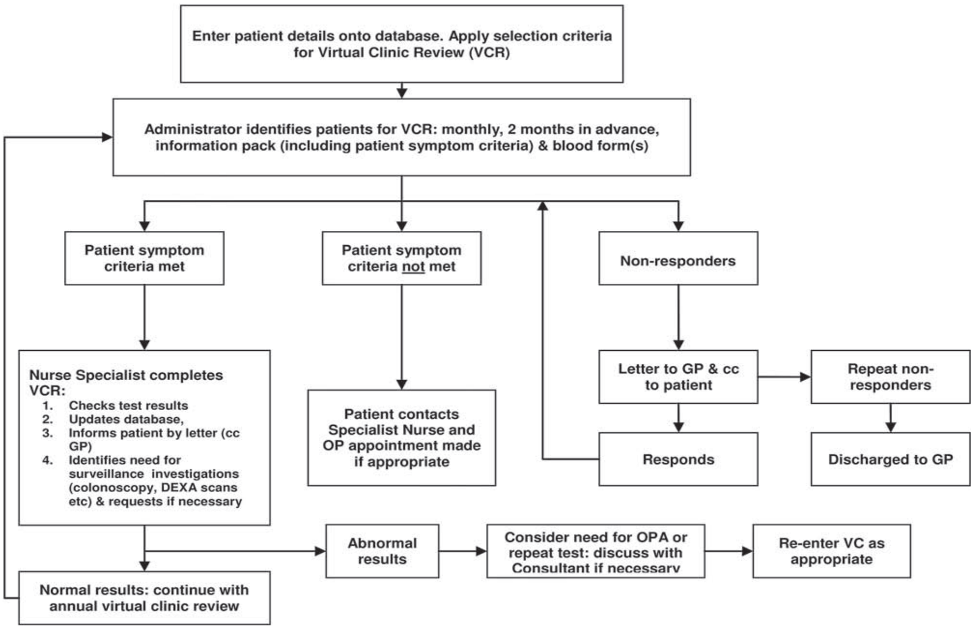
Intervention and control groups were matched in Cross, Cheevers et al’s (2012) study but Krier, Kaltenbach et al’s (2012) intervention group had greater disease duration than the control group. Elkjaer, Shuhaibar et al’s (2010) groups in the Denmark arm had different age and sex distribution.

The three studies report important clinical outcomes in terms of the use of tele-medicine in IBD. Krier, Kaltenback et al (2012) reported that their system would be valuable in training non specialists in IBD management but the patient was still required to travel to the hospital for the consultation visit. Elkjaers, Shuhaibar et al’s (2010) e-health package would complement the complex care package used by Kennedy (2003), providing remote monitoring for those patients who chose to self-manage and depended on the link to the hospital.

The ‘virtual clinic’ has been demonstrated in three conference abstracts (Schilstra, Bouma et al. 2005; van Dullemen, Doorn et al. 2005; Duncan, Caulfield et al. 2010) and one retrospective audit (Hunter, Claridge et al. 2012). Referred to as ‘The Groningen Project’, this provided distal monitoring using an IBD-related questionnaire (van Dullemen, Doorn et al. 2005). The authors posted questionnaires and blood request forms to patients at fixed time points and provided written feedback to the patients depending on the results. There was a 33% reduction in outpatient visits during the two year observation period with no adverse event or deterioration in the patient’s disease. A survey evaluation of this system found that 30% of patients preferred the *traditional* system (Schilstra, Bouma et al. 2005).

Hunter, Claridge et al’s (2012) study was very similar to van Dulleman, identifying patients in remission and enrolling them into a ‘paper’ clinic. As with van Dulleman’s study, outpatient appointments were saved but this service was rated highly by the patients, with 90% preferring it to the traditional system. Van Dullemen, Doorm et al (2005) reported the cost effectiveness of the service, taking into account the cost of the IBD nurse. Both studies placed great emphasis on proper patient selection for inclusion into the ‘virtual paper clinic’.

Figure 10: The IBD virtual clinic pathway (Hunter 2012)



‘Biologics’ is a general term for a class of medications that are produced by means of a biologic process. Duncan, Caulfield et al (2010) introduced a weekly virtual multidisciplinary biologics clinic for patients receiving biologics, unlike all IBD patients in van Dullemen, Doorm et al (2005) and Hunter, Claridge et al (2012) studies. Duncan, Caulfield et al (2010) concluded that the biologics virtual clinic was effective in monitoring and reviewing the patient whilst avoiding unnecessary follow up appointments (Duncan, Caulfield et al. 2010). However, the 'virtual biologics clinic' utilised time from consultant gastroenterologists, IBD nurses, a pharmacist and an administrator on a weekly basis questioning the real cost of this. A full economic evaluation is therefore required.

Many studies of telephone clinics in IBD are retrospective audits and include only patients with quiescent disease. One such study reported that 86% of patients who entered the telephone clinic were well and did not require a face-to-face appointment, with a corresponding potential saving of £11,000 (Gethins, Robinson et al. 2007). 95% of patients were satisfied with the telephone clinic demonstrating the flexibility, convenience and value of telephone clinics. Other audits of telephone clinics reported reductions in unnecessary follow- up face to face appointments and opening up appointments for rapid care (Miller, Caton et al. 2002). The conference abstract of Jakobsen, Bager et al (2012) highlighted the difficulty in implementing telephone clinics including proper patient selection and additional training of the nurse.

Despite lacking robust evidence of the use of telephone follow-up in IBD, the effectiveness of telephone follow-up in medicine and cancer services has been firmly established (Wasson, Gaudette et al. 1992; Cox and Wilson 2003; Beaver 2009).

A Canadian audit, still only in abstract form, has been published relating to the use of email in the management of IBD patients (Plener, Morgan et al. 2011). The author reported that over a six month period, emails demonstrated clear economic benefits both for the patient and health service and that incorporating them into a self-management plan would result in $1.5 billion savings. Patients rated the email service highly and reported a reduction in stress levels regarding their IBD management. As this is still only in abstract form it is difficult to evaluate how the cost savings were calculated but the use of emails in IBD management warrants further investigation.

The use of telemedicine and 'virtual' clinics using distal monitoring does appear to be a safe and judicious use of resources and would fit well with the patient with quiescent disease or in drug induced remission

4.3.6 Patient acceptability of follow-up care models

No patients were consulted in the development of the models or interventions prior to implementation or trial but some studies did evaluate patient satisfaction at the end them. However there are critiques of using patient satisfaction measures: they are prone to ceiling effects and it is difficult to distinguish between an adequate service from an excellent service (Rosenthal and Shannon 1997). Levels of satisfaction through patient surveys have concluded that by considering issues of duty and culpability, patients could make allowances for poor care and so avoid negative evaluation (Williams, Coyle et al. 1998). There is a move away from ratings of satisfaction to reports of experiences (Black and Jenkinson 2009). Patient experience is a 'measure of patient-centeredness' (Browne, Roseman et al. 2010) pg 921, which patients then define as central to quality of care (Sofaer and Firminger 2005). Patients want to know about the experiences of other patients, such as how long other patients waited to see their doctor rather than 'how satisfied' they were with waiting times (Edgman-Levitan and Cleary 1996). It could be argued that applying patient satisfaction questionnaires after the trial or implementation does not reflect patient acceptability of a model of follow-up care.

4.4 Discussion

There are many interventions reported in the literature to assist patients to cope with living with IBD, ranging from educational programmes, relaxation, psychological treatment and exercise programmes, all report varying degrees of effectiveness (Shaw 1987; Waters 2001; Quan, Present et al. 2003; Waters, Jensen et al. 2005). However it is the self-management aspect of studies which generate the largest number of positive outcomes (Barlow 2010).

The aim of self-management is to improve outcomes and QoL for patients with a long term condition whilst reducing demand on health care services. A review of the evidence for self-management states that self-management, while still in its ‘infancy’, is demonstrating its ability to improve people’s QoL, improve clinical outcomes and more efficient use of health resources (de Silva 2011). Used in many long term conditions such as asthma, diabetes, and arthritis, guided self-management is a shared arrangement between the healthcare professional and the patient, combining the development of guidelines and action plans (Kennedy, Nelson et al. 2003). Active support for patients to self-manage in long term conditions is one of The King’s Fund ten priorities for commissioners within the new NHS structure of clinical commissioning groups (Imison, Naylor et al. 2011), forms part of the NHS Outcomes Framework (DH 2011) and is in the recent commissioning guide for gastrointestinal services from the British Society of Gastroenterology (BSG 2012).

Questions remain about the concept of self management, its effectiveness for patients with long term conditions, and how to quantify its value and effect on the QoL in patients with IBD. One reason for this is due to the wide range of initiatives which describe and define ‘self management support’ in the literature, of which some are more successful than others (de Silva 2011). Cultural and environmental barriers remain problematic and a key problem identified in the literature was the lack of knowledge by non-IBD specialists hindering the process (Cooper, Collier et al. 2010). Open access and self-management must be combined with a range of additional strategies for it to be of benefit to all patients with IBD, regardless of their disease status.

There are other barriers to the implementation of self-management. A study by the National Primary Care Research Centre, Manchester, exploring self-management in primary care, suggested GPs found it difficult to open up dialogue with patients and caused conflict with other values of professional responsibility (Blakeman, Bower et al. 2010). The relationship with the health care professional is vital to its success. In the outpatient department time pressures can hinder the development of guided self-management. It takes time to work with a patient to self-manage, yet it is exactly this problem which the implementation of self-management may help to alleviate (Rogers, Kennedy et al. 2005).

The main studies presented in the synthesis had all adopted open access, some with additional components. Williams, Cheung et al (2000) shifted the care to the GP, Robinson, Thompson et al (2001) included a guided self-management aspect where as Kennedy, Nelson et al's (2003) package comprised of a self- management whole systems approach. Rejler, Spangeus et al (2007) was the only study to utilise the skills of a specialist nurse but did not explore self-management within their care package.

None of the studies included in the synthesis measured the standard of care that the patients in the fixed appointment system received and, more importantly, the effect of open access and self-management on the long term outcome of IBD, given that the responsibility for blood monitoring related to drug therapy, is then placed on the patient.

None of the studies of open access alone or combined with self management were conducted in the current healthcare system nor were required to meet the demands and targets of today's NHS pressures. These studies demonstrate the value of open access but also that open access as a stand-alone system is not entirely effective; additional elements of care are required and need to be combined to provide effective, feasible and acceptable care. All of the models of care are secondary care based and report mixed results with patient satisfaction measured after they had been exposed to the intervention. It has been recognised that problems exists when using satisfaction questionnaires in this context as they have a tendency to record consistently positive responses (Edwards 2004).

The MRC Framework for the development of complex interventions (Craig, Dieppe et al. 2008) emphasises phase one of the approach; defining the components of the intervention and how qualitative research can be used to identify how the components can be tailored to meet individual patients needs (Corrigan, Cupples et al. 2006). In order to achieve this, patient views and needs must be ascertained prior to and during the development of any follow-up care package. Patients were not involved in the development of the care package in any of the studies.

Robinson, Thompson et al (2001) and Kennedy, Nelson et al (2003) demonstrated that the educational sessions related to guided-self management were instrumental in patients monitoring their IBD. This knowledge led to earlier treatment interventions for a flare-up and reduced the risk of complications related to the relapse. Other work has evaluated the impact of formal education information booklets for patients with CD (Smart, Mayberry et al. 1986), concurring the supportive nature of the role of the guide book in the intervention by Kennedy (2003). In contrast, one study disputed the value of educational disease specific booklets, finding that they did not improve the patients quality of life or may potentially even worsen it (Borgaonkar, Townson et al. 2002).

Further studies have found contrasting results with one study reporting that patients who are better informed have lower levels of concerns (Moser, Tillinger et al. 1995) whilst a more recent study found that better patient knowledge is associated with greater anxiety (Selinger, Lal et al. 2012). Education related to guided self-management may have an impact on disease related concerns of patients with IBD but warrants careful planning, content and appropriateness of the information (Barlow 2010), and further investigation given the contrasting evidence presented in this synthesis.

4.5 Limitations

The review synthesis is based on studies during the last thirteen years from a range of countries with differing health services. The tariff payment-by-results programme (Featherstone, Whittham et al. 2010) in the UK changed the UK NHS economic system during this time period and it may be argued that earlier studies were not controlled or concerned with targets, which may have affected later studies.

Of the 19 studies only six were RCTs, one was a population based study and one qualitative study. The remaining studies were retrospective audits and the largest proportions of studies within the synthesis are abstracts of conference proceedings. Audits and abstracts offer limited details and cannot be critically appraised. These were included however as they offered insights into innovative models of follow-up care.

4.6 Conclusion

The current health care system may no longer be appropriate for managing increasing numbers of patients with long term conditions. Studies of CD in the UK, Europe and North American have reported significant increases in its incidence. There is a rising demand for services with concomitant limited access yet there exists a lack of quality literature and evidence about the delivery of gastroenterology services in the UK (Williams, Roberts et al. 2007) and a lack of clarity of how these should be shaped.

Self-management has received cautious support from patients yet there is great emphasis placed on their ability to self-manage, continuity of care, and access to services in an emergency situation (Williams, Roberts et al. 2007). The role and value of self management in IBD may be questioned further as the long term outcomes of IBD have not been evaluated. It is questionable whether self-management in IBD is safe without some form of remote monitoring, besides which there is only a small window of opportunity for the patients to self-manage a flare up of their disease. If symptoms are not controlled within a maximum seven day period, intervention from the IBD nurse or healthcare professional must happen to avoid serious complications occurring. Access to secondary care at this point is vital to prevent complications of IBD.

Williams, Roberts et al et al (2007) recommended the reconfiguration of specialist services and emphasised the need to establish a robust evidence base for models of service delivery. There are no models of follow-up care delivery for IBD, which incorporate self management, ‘virtual’ care or which straddle the social, primary, secondary and tertiary care divide.

The studies included in this synthesis encompass a variety of strategies to improve the patient’s QoL and symptom management and to relieve the pressure on services. Each of the strategies are effective, some more so than others, which suggests a combined approach to care is needed. However, there was no difference in the QoL in the intervention and control groups and not all patients have the ability to self- manage and what happens to this group of patients? Self-management has the potential to produce more effective results if integrated into existing care. Some patients do not trust the open access system and others prefer the face-to-face contact with the health care professional.

One important omission from all of the studies reviewed is the lack of patient involvement in their development. It is unclear what patients really want from their follow-up care, what value it plays in their disease and life. A further criticism is the lack of GP and IBD Nurse involvement. What is the role of the GP and the specialist nurse and has their potential been recognised? Many patients remain in long term hospital follow-up and there is a growing need for this to be reviewed (Reeve, Baxter et al. 1997). The translation of the open access studies and self-management has failed to reach clinical practice with no centres adopting this.

Care for patients with IBD requires different approaches at different times within their disease and no single model is appropriate for all patients. A choice between three approaches has been identified: hospital care, shared care, and assisted self-managed care (Hellier, Sanderson et al. 2007) yet what are the strategies, or the main ingredients, within each approach? Which combination of interventions based on the patients' values produces the greatest relative improvements in care? Improvement in IBD care is not just based on new modalities of treatment, such as biologic therapies, but requires evidence about the changes to the delivery of care. Synthesis of the studies included in this best evidence synthesis demonstrated the value of different interventions but there were vital components missing within all of them. These included: the possibility of an integrated shared care system and how this would fit in; the knowledge and skills of GPs to enable integrated care; the needs and preferences of follow-up care from the patients' perspective; whether patients wanted their GP to be involved and if so how and to what extent; and how and to what degree GPs wanted to be involved.

It is the aim of this study to provide a unique insight into patient's perceptions of how follow-up care should be planned and delivered, to provide a clear and practical understanding of follow-up care delivery, to explore the role of the GP and IBD nurse, and the barriers, if any, to the patient's choice of delivery of care. In combination these insights will lead to the development of a realistic intervention of follow-up care for patients with IBD.

Table 4: Full papers selected for review for inclusion in best evidence synthesis

1.Impact of a nurse-led telephone clinic on quality of IBD care. Gastrointestinal Nursing, Feb 2007, vol. 5, no. 1, p. 34-39, (February 2007) Gethins, S; Robinson, R; De Caestecker, J.
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4.Establishing an inflammatory bowel disease service. Nursing Times, Jun 2006, vol. 102, no. 23, p. 28-29, (June 6, 2006) Pearson, C.
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Lancet, 22 September 2001, vol./is. 358/9286(976-981), Robinson A; Thompson DG; Wilkin D; Roberts C.
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Frontline Gastroenterology, April 2012, vol./is. 3/2(76-80), (April2012)
Hunter J.; Claridge A.; James S.; Chan D.; Stacey B.; Stroud M.; Patel P.; Fine D.; Cummings J.R.F.

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2006(872),
Castro H.K.; Cross R.K.; Finkelstein J.

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Plener, I; Morgan M; Garbens A; Seth R; Saibil F.
(Abstract available only)

Table 6: Excluded papers

Studies considered for best evidence synthesis	Why excluded
1.Audit of an inflammatory bowel disease (IBD) telephone helpline set up and managed by IBD specialist nurses. Gastrointestinal Nursing, Jun 2012, vol. 10, no. 5, p. 24-30, (June 2012) Anderson, G; Marsden, E.	Audit is of a helpline and not a telephone clinic
2.Establishing an inflammatory bowel disease service. Nursing Times, Jun 2006, vol. 102, no. 23, p. 28-29, (June 6, 2006) Pearson, C.	Follow-up care not included
3.The Potential Role of a Self-Management Intervention for Ulcerative Colitis: A Brief Report From the Ulcerative Colitis Hypnotherapy Trial. Biological Research for Nursing, 01 January 2012, vol./is. 14/1(71-77), Keefer, L; Kiebles, JL.; Kwiate, OP; Taft TH; Martinovich Z; Barrett TA.	Reported interim findings of a larger RCT. Aim was to determine acceptability and feasibility of hypnotherapy in UC. Not related to follow-up care at this point.
4.The therapeutic potential of the internet: exploring self-help processes in an internet forum for young people with inflammatory bowel disease. Gastroenterology Nursing, 01 November 2011, vol./is. 34/6 (439-448), Malik, S; Coulson, NS.	Study was of online support groups, not follow-up care and self management
5.Implementing a colitis education and support programme. Gastrointestinal Nursing, 01 June 2006, vol./is. 4/5 (12-19), Corbett S; Welfare M; McColl E; Lecouturier J; Devine Z.	Follow-up care not included
6.Patient-perceived usefulness of online electronic medical records: employing grounded theory in the development of information and communication technologies for use by patients living with chronic illness. Journal of the American Medical Informatics Association, 01 May 2005, vol./is. 12/3 (306-314), Winkelman WJ; Leonard KJ; Rossos PG.	Follow-up care not included
7.Development of a rapid access service for patients with exacerbating inflammatory bowel disease. Foundation of Nursing Studies: Developing Practice Improving Care Dissemination Series, 02 January 2005, vol./is. /(3-4), Pearson C.	Follow-up care not included.
8.An integrated model of care for inflammatory bowel disease sufferers in Australia: Development and the effects of its implementation Inflammatory Bowel Diseases, August 2012, vol./is. 18/8 (1573-1581),	Whole systems approach explored, psychological and physical needs of the patients but did not include follow-

Mikocka-Walus A.A.; Turnbull D.; Holtmann G.; Andrews J.M.	up care service
9.IBD patient follow up: A randomized trial of nurse specialist versus standard gastroenterologist care Citation: Canadian Journal of Gastroenterology, February 2009, vol./is. 23/, 0835-7900 (February 2009) Stewart M.; Phalen-Kelly K.; MacIntosh D.; Leddin D.; Farina D.	Concentrated on the nurse and gastroenterologist and not the follow-up service
10.Challenges in the design of a Home Telemanagement trial for patients with ulcerative colitis. Clinical Trials, December 2009, vol./is. 6/6(649-57), 1740-7745; (2009 Dec) Cross RK; Finkelstein J	Full RCT reported in Cross et al (2012) which was included in best evidence synthesis
11.Feasibility and acceptance of a home telemanagement system in patients with inflammatory bowel disease: a 6-month pilot study. Digestive Diseases & Sciences, February 2007, vol./is. 52/2(357-64), (2007 Feb) Cross RK; Finkelstein J.	Full RCT reported in Cross et al (2012) which was included in best evidence synthesis
12.Self-care agency and quality of life among adults diagnosed with inflammatory bowel disease. Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation, 2001, vol./is. 10/4(379-387), Smolen, D M; Topp, R.	Study explored a self care agency in relation to anxiety, stress and pain in IBD patient. Not related to follow-up care or self-management.
13.Population-based controlled study of social support, self-perceived stress, activity and work issues, and access to health care in inflammatory bowel disease. Inflammatory Bowel Diseases, April 2008, vol./is. 14/4(526-35), 1078-0998; (2008 Apr) Rogala L; Miller N; Graff LA; Rawsthorne P; Clara I; Walker JR; Lix L; Ediger JP; McPhail C; Bernstein CN.	Subject matter of follow-up care not included
14.Broadening the access to specialized IBD care using a consumer grade affordable telemedicine system Citation: Gastroenterology, May 2010, vol./is. 138/5 SUPPL. 1(S473), (May 2010) Krier M.J.; Kaltenbach T.R.; McQuaid K.R.; Soetikno R.M.	This was the abstract, full RCT included in best evidence synthesis
15.IBD patients in remission strongly prefer annual telephone calls by IBD nurses compared to outpatient visits Journal of Crohn's and Colitis, February 2011, vol./is. 5/1(S175), (February 2011) Bager P.; Hentze R.; Markussen T. (abstract only available)	Abstract actually reported how to set up self-management and not telephone calls.
16.Effects of a comprehensive lifestyle modification program on quality-of-life in patients with ulcerative colitis: A twelve-month follow-up.	Study reported effects of a comprehensive lifestyle modification program on health-

Scandinavian Journal of Gastroenterology, 2007, vol./is. 42/6 (734-745), (2007) Langhorst J.; Mueller T.; Luedtke R.; Franken U.; Paul A.; Michalsen A.; Schedlowski M.; Dobos G.J.; Elsenbruch S.	related QoL, distress, and clinical parameters. Subject matter of follow-up care not included
17.The medical management of inflammatory bowel disease in primary care: The north bristol experience Gut, April 2011, vol./is. 60/(A130), (April 2011) Arthurs E.A.; Gholkar B.; Burley K.; Williams L.; Lockett M.	Abstract reported medical / medicines management in GP practices, not follow-up care.
18.Gastroenterologist specialist care and care provided by generalists - An evaluation of effectiveness and efficiency American Journal of Gastroenterology, January 2003, vol./is. 98/1(21-28), Provenzale D.; Ofman J.; Gralnek I.; Rabeneck L.; Koff R.; McCrory D.	Follow-up care not included
19. Evidence: Helping people help themselves, a review of the evidence considering whether it is worthwhile to support self management The Health Foundation Unit Inspiring Improvement, 2011 de Silva,D	Review, not a study

Table 7: Papers published from Kennedy's (2003) HTA

1. A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease. Health Technology Assessment, 01 January 2003, vol./is. 7/28(0-120), Kennedy A; Nelson E; Reeves D; Richardson G; Roberts C; Robinson A; Rogers A; Sculpher M; Thompson D
2. Uncovering the limits of patient-centredness: implementing a self-management trial for chronic illness. Qualitative Health Research, Feb 2005, vol. 15, no. 2, p. 224-239, (February 2005) Rogers, A; Kennedy, A; Nelson, E.
3.Is self-care a cost-effective use of resources? Evidence from a randomized trial in inflammatory bowel disease. Journal of Health Services Research & Policy, 01 October 2006, vol./is. 11/4(225-230), Richardson G; Sculpher M; Kennedy A; Nelson E; Reeves D; Roberts C; Robinson A; Rogers A; Thompson D.
4.Training professionals to engage with and promote self-management. Health Education Research, October 2005, vol./is. 20/5(567-578), (Oct 2005) Kennedy, A; Gask, L; Rogers, A.
5.A randomised controlled trial to assess the effectiveness and cost of a patient orientated self management approach to chronic inflammatory bowel disease. Gut, November 2004, vol./is. 53/11(1639-45), (2004 Nov) Kennedy AP; Nelson E; Reeves D; Richardson G; Roberts C; Robinson A; Rogers AE; Sculpher M; Thompson DG.
6.Patients' experiences of an open access follow up arrangement in managing inflammatory bowel disease. Quality & Safety in Health Care, October 2004, vol./is. 13/5(374-8), (2004 Oct) Rogers A; Kennedy A; Nelson E; Robinson A.
7.Improving patient involvement in chronic disease management: the views of patients, GPs and specialists on a guidebook for ulcerative colitis. Patient Education & Counseling, July 2002, vol./is. 47/3(257-63), (2002 Jul) Kennedy AP; Rogers AE.

Tables 8 a-d: Summary of characteristics of models of follow-up care studies in best evidence synthesis

Table 8a: Summary of open access studies

Study	Research setting and year of study	Study design	Sample size	Intervention	Key results and conclusions
Williams et al (2001)	UK 1995-1996	RCT	180 UC and CD patients	Open access follow up for IBD patients. Responsibility of care with GP.	Patients had a strong preference for open access, fewer OPD visits. No difference in QoL. Cost of resources remains an area of controversy.
Rejler et al (2007)	Sweden 2000 - 2006	Population based longitudinal study	466 UC and CD patients	Patient and demand directed care, helpline manned by specialist nurse, available urgent appointments daily. Annual face to face appointment for patients receiving immunomodulators	Reduction in hospital admissions. >92% of patients scored higher than 3 in QoL criteria. Clinic waiting time reduced; <unplanned patients admitted to hospital; no changes in clinical and functional indices and no changes in QoL
Cheung (2002)	UK	Qualitative interviews and postal questionnaires	91 GPs	GPs who participated in Williams (2000) study of open access. 37 GPs through group interviews and 32 via postal questionnaires were asked about their experience and views of open access. Analysed quantitatively.	Responses from GPs divided into three categories: positive, negative and neutral. Most GPs in favour of open access but many favoured the position of nurse specialist to support care, greater rapid access to secondary care, written information for the patient and greater integrated acre between primary and secondary care.

Table 8b: Summary of combined open access and self-management studies

Study	Research setting and year of study	Study design	Sample size	Intervention	Key results and conclusions
Robinson et al (2001)	UK Period of 18 months	RCT	203 UC only patients	Guided self management plan given to patient and patient directed follow up. All OPDs cancelled, helpline offered.	Intervention group had fewer hospital visits; fewer primary care visits. Intervention group treated relapses quicker. No difference in QoL or number of relapses in the two groups.
Kennedy et al (2003)	UK	RCT	700 UC and CD patients (297 intervention sites, 403 at control sites)	Training consultants to provide patient centred approach to care; provision of guide books for patients; self management plan; self refer back to secondary services.	The intervention group had fewer hospital visits No difference in DNA results, no difference in QoL Open access system more successful for the more 'experienced' patient. 74% patients preferred open access. No difference in reported relapses in both groups.

Table 8c: Summary of self-management audits

Study	Research setting and year of study	Study design	Sample size	Intervention	Key results and conclusions
Gethins 2011	UK 2011	Retrospective Audit	157 patients, 122 UC, 31 CD.	Individual self-management plan developed and booklet given to the patient. IBD nurse helpline for patient to contact and rapid referral or self-refer. Traditional scheduled appointment given on patient request.	Service evaluated using patient satisfaction questionnaire. 74% response rate. 100% said self-management plan adequately explained, 97% happy with the programme.8 patients referred back into secondary care
Stansfield (2008)	UK 2008	Retrospective Audit	150 IBD patients, CD or UC not stipulated	Individual self-management programmes developed. Information leaflet and monitoring booklet given to the patient. Nurse helpline set up for patients to contact and rapid access	41% patients responded to patient satisfaction questionnaire. 90% reported service to be good. Authors suggest benefits reduced time off work, reduction in patient stress, increased confidence to self-manage. Author states that cost savings due to reduction in outpatient appointments but not directly measured.

Table 8d: Summary of telemedicine and ‘virtual’ clinics

Study	Research setting	Study design and duration	Sample size	Intervention	Key results and conclusions
Hunter (2012)	UK	Retrospective audit 4 years	1810 patients UC or CD not stipulated	Selected patients transferred to ‘virtual’ paper clinic. Patients posted out health questionnaire, blood monitoring forms. If patients answered ‘yes’ to any of the questions asked to contact IBD Nurse for further management. Blood results reviewed by IBD Nurse.	90% patients preferred ‘virtual’ clinic to traditional clinic. 1262 face to face appointments avoided.
Elkjaer (2010)	Denmark and Dublin, Ireland	RCT 12 months	333 patients UC or CD not stipulated, 39 patients withdrew (27 in intervention group, 12 in control group)	Patients randomised to ‘constant.care.dk’ web package or usual care. Patients trained how to use the web package, education and practical aspects of IBD covered within the package. Patients asked to log on and follow the package of care and follow treatment instructions in the event of a relapse. Feasibility, influence of the care package on patient compliance, patient IBD knowledge, QoL, disease outcomes, safety and cost were measured.	88% patients preferred the web programme, patients’ knowledge and QoL increased in intervention group. Median relapse duration 18days in intervention group compared to 77days in traditional care group. Reduction in face to face visits saved £189 Euro per patients per year. There was no difference in relapse frequency, hospitalisation, surgery or adverse events in the two groups.
Duncan (2010) *Abstract only*	UK	Retrospective audit 6 months	72 patients. 65 CD, 6 IBD	Patients receiving biologic therapy (inflixmab and	159 patient management decisions made in 53

			unclassified, 1 oro-facial granulomatosis	adalimumab) transferred into ‘virtual’ clinic from traditional face to face clinic. Patients then reviewed in a multidisciplinary format clinic using case notes and blood monitoring results.	patients. Reduced new to follow up ration from 2.86 to 1.72. Patient satisfaction not assessed.
Gethins (2007)	UK	Retrospective audit 3 months	49 patients UC or CD patients not stipulated	Patients selected from face to face IBD clinics and transferred into telephone clinic	95% patients satisfied with telephone clinic compared to traditional clinic. Reduced DNA rate and reduced waiting time for face to face clinic from 112 weeks down to 4 weeks
Van Dulleman (2005) *Abstract only*	The Netherlands	Prospective audit 2 years	427 IBD patients UC and CD not stipulated	Patients selected for remote monitoring from traditional clinic. Patient posted out a health related questionnaire and blood forms. Feedback of questionnaire was by Gastroenterology Consultant to patient and GP. IBD nurse manned a ‘help desk’. Software developed to manage monitoring and scheduling of questionnaires. Patient previous care served as their own control	920 remote monitoring took place, with a reduction of 548 face to face appointments, 33% reduction compared to traditional follow up when patients served as their own control. No adverse events, no deterioration in standard of health. Proper selection and clear information were prerequisites for patient satisfaction.
Schilstra (2005) *Abstract only*	The Netherlands	Satisfaction audit monitoring study	127 IBD patients, UC and CD not stipulated	Random sample of patients within the remote monitoring system of van Dullemans (2002) study. Patients asked to complete IBDQ, the Illness Cognition Questionnaire,	44% of patients positive about remote monitoring but 30.7% preferred traditional follow-up. Women reported higher satisfaction rate, more perceived control and

				the Social Support List and Mastery Scale.	emotional functioning than men.
Cross (2012)	USA	RCT 12 months	47 UC patients randomised, 16 withdrew (11 from intervention group, 5 from control group)	Patients randomised to UC home tele-management system (UC HAT) or best available care. Primary end points were the difference in Seo Index scores, used to measure clinical disease activity, the IBDQ for disease specific QoL and adherence using the Morisky Medication Adherence Score.	UC HAT did not improve disease activity, QoL or adherence compared to best available care group. IBDQ scores, which were significantly higher in the control group at baseline, increased in the intervention group but remained stable in the control group. There was no difference in the overall scores in the two groups throughout the study period but changes from baseline IBDQ scores were significantly improved in the intervention group
Plener (2012) *Abstract only*	Canada	Retrospective audit 6 months	137 IBD patients, UC and CD not stipulated	Communication changed to email correspondence with patients. At 6months, patients surveyed as to the impact of using email.	76% of email-managed IBD patients made 1-2 fewer face to face visits. 77% reported a reduction in stress levels and 90% reported a preference for email use.
Krier (2011)	USA	RCT 9 months	34 IBD patients, 19 UC and 15 CD.	Patients randomised to a combined face to face (with gastroenterology fellow) and telemedicine (with specialist 40 miles away) encounter or to standard face to face encounter. Primary study end point was patient clinical experience using a Likert Scale	57 encounters were recorded. Patients rated the tele-medicine consultation highly, similar to the face to face consultation. Clinical satisfaction indices of patient concerns, bedside manner and skill of the doctor, were all rated as excellent in both

					intervention group and control group. There was no difference in total appointment time between the two groups.
Miller (2002)	UK	Retrospective audit	150 patients	Patients in remission invited to take part in telephone clinic instead of usual care.	Reduced unnecessary follow-up appointments, provided rapid help during flare-ups. Patient and healthcare professionals' feedback via questionnaires was positive, increasing the quality of face to face appointments.
Jakobsen (2012) *Abstract only*	Denmark	Descriptive study Duration not stated	Not stated	Process describing tasks required to set up annual telephone calls to replace face to face appointments	Descriptive abstract describing steps need to implement annual telephone appointments, included the need for supervision and education of IBD nurses, development of documentation, auditing and patient satisfaction of the system.
Castro (2006) *Abstract only*	USA	Semi-structured interviews 6 months	23 UC patients	Patients interviewed at exit of study. Transcripts analysed using Framework Analysis.	Three themes emerged: content of the system, the interface between system and user, process of using the system. The system empowered patients, giving them greater control over their disease via regular monitoring. Increased control resulted in greater satisfaction and outcomes

Paper one

Understanding the health and social needs of people living with inflammatory bowel disease

Kemp K, Griffiths J and Lovell, K

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Ms. wjg/2012/033386 **BRIEF ARTICLE**

Understanding the health and social care needs of people living with inflammatory bowel disease: A meta-synthesis of the evidence

Karen Kemp, Jane Griffiths, Karina Lovell

Kemp K *et al*. Meta-synthesis of living with inflammatory bowel disease

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Abstract

AIM: To undertake a meta-synthesis of qualitative studies to understand the health and social needs of people living with inflammatory bowel disease (IBD).

METHODS: A systematic search strategy identified qualitative studies exploring the phenomenon of living with inflammatory bowel disease. Databases included MEDLINE, PsychInfo, EMBASE, CINAHL and the British Nursing Index via the OVID platform. Qualitative search filters were adapted from Hedges database (http://www.urmc.rochester.edu/hslt/miner/digital_library/tip_sheets/Cinahl_eb_filters.pdf). Qualitative empirical studies exploring the health and social needs of people living with inflammatory bowel disease were selected. Study eligibility and data extraction were independently completed using the Critical Appraisal Skills Programme for qualitative studies. The studies were analysed and synthesised using meta-synthesis methodology. The themes from the studies allowed for common translations into a new interpretation of the impact of living with inflammatory bowel disease.

RESULTS: Of 1395 studies, six published studies and one unpublished thesis fulfilled the inclusion criteria. First iteration of synthesis identified 16 themes, 2nd iteration synthesised these into three main 2nd order constructs: *'detained by the disease'; 'living in a world of disease'*; and *'wrestling with life'*. *'Detained by the disease'* is the fear of incontinence, the behaviour the patients display due to the fear, and the impact this has on the individual, such as social isolation and missing out on life events. All of these serve to '*pull*' the patient back from normal living. *'Living in a world of disease'* is the long term effects of living with a long term condition and the fear of these effects. '*Wrestling with life'* is the continued fight to thrive, the 'push' to continue normal living.

CONCLUSION: The meta-synthesis provides a comprehensive representation of living with IBD. The unmistakeable burden of incontinence is exposed and its ongoing effects are demonstrated. The combined overall impact of living with IBD is the tension these patients live with: 'Pushed and pulled: a compromised life', people living with IBD experience a constant conflict throughout their lives, they *push* to be normal but IBD *pulls* them back. The impact of the fear of incontinence and behaviour of the individual as a result, requires further qualitative enquiry.

Key words: Inflammatory bowel disease; Meta-synthesis; Qualitative; Incontinence

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Kemp K, Griffiths J, Lovell K. Understanding the health and social care needs of people living with inflammatory bowel disease: A meta-synthesis of the evidence

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5.1 Introduction

Inflammatory bowel disease (IBD) is a chronic inflammatory disease of the gastrointestinal tract that is divided into two subgroups: Crohn’s Disease (CD) and Ulcerative Colitis (UC). Characterised by periods of remission and relapse, bowel movements may be up to 20 times per day with associated faecal urgency and incontinence. IBD is also associated with extra intestinal manifestations, affecting joints, eyes, skin, bones and organs as a consequence of the disease process (Mowat, Cole et al. 2011).

The disease often has a negative effect on the patient’s emotional and social life, which are not always visually apparent(Pizzi, Weston et al. 2006). Loss of bowel control, feeling dirty and smelly, producing offensive body odours, unfulfilled potential in the workforce and issues with sexual relationships, were concerns ranked highly in a patient survey of people with IBD (de Rooy, Toner et al. 2001). One of the most prevalent concerns is fatigue (Drossman, Leserman et al. 1991; de Rooy, Toner et al. 2001). Fatigue in people with IBD was found to be comparable to those suffering from cancer (Minderhoud, Oldenburg et al. 2003). Fatigue affects the ability to work and socialise, confirming the disability associated with IBD (Mallett, Bingley et al. 1978). Unemployment and sick leave is more common in IBD patients compared to the general population (Bernstein, Kraut et al. 2001; Bernklev, Jahnsen et al. 2006), with ability to work regarded as a global marker of the total impact of IBD (de Rooy, Toner et al. 2001).

People with IBD have a poorer quality of life than the general population (Guassora, Kruuse et al. 2000; Canavan 2006; Graff 2006; Lix 2008; Jaghult, Saboonchi et al. 2011) and are more likely to report increased levels of anxiety and depression with increased disease activity (Porcelli, Leoci et al. 1996). Evidence reveals that the disease continues to impact on the individuals psychological status even when in remission (Tanaka and Kazuma 2005; Lix 2008). Overall, evidence suggests that the subjective experience of ill health associated with IBD does not always correlate with clinical disease activity.

The Health–related quality of life (HRQoL) of people with IBD has been extensively evaluated with the development of two key disease specific tools: the Inflammatory Bowel Disease Questionnaire (IBDQ) (Guyatt, Mitchell et al. 1989) and the Rating Form for Inflammatory Bowel Disease Patients' Concerns (RFIPC) (Drossman, Leserman et al. 1991). The IBDQ was developed using survey methodology and measures subjective emotional and social functioning. The RFIPC was developed to measure neglected but important IBD concerns including disease related, body related, and inter / intrapersonal and sex related.

Whilst useful measures, the IBDQ and RFIPC fail to capture the essence of living with IBD from the patient's perspective (Guyatt, Mitchell et al. 1989; Drossman, Leserman et al. 1991). For example, the RFIPC includes loss of bowel control as a concern but fails to encapsulate the real impact this has on the individual (Dudley-Brown 1996). A study exploring concerns and worries of patients with Crohn's Disease identified other concerns and worries that were not captured within the RFIPC (Stjernman, Tysk et al. 2010). Objective indices within the tools do not fully summarize the patient's clinical symptoms, nor reflect the individual's experience of IBD (Kunsebeck, Korber et al. 1990; Wolfe and Sirois 2008; Waljee, Joyce et al. 2009). Failure to capture the lived experience of IBD has been confirmed by the European Federation of Crohn's and Colitis Associations (EFCCA) patient survey (Ghosh 2007) which reported that quality of life (QoL) and patient concerns were not taken into account when caring for patients with IBD, despite the plethora of studies highlighting this fundamental principle (Moser, Tillinger et al. 1995; Casati, Toner et al. 2000; Mussell, Bocker et al. 2004). The EFCCA study identified that half of the patients surveyed were not questioned by their doctor about the impact of their symptoms on their quality of life.

In contrast to quantitative measures, qualitative methods are more able to capture the essence of living with IBD from the patients perspective (Pope and Mays 1995; Vanderheyden, Verhoef et al. 2006)· They can provide insight into the meanings, behaviours, experiences and beliefs of the participants with the aim of "drawing out understandings and perceptions and understand the linkages between process and outcomes" (Centre for Reviews and Dissemination 2008).

In order to understand IBD, tailor treatment and provide personalised care, capturing the patient experience is imperative. There are a number of small scale qualitative studies exploring the experience of living with IBD from the patient's perspective but there is a need to synthesis this evidence to further understand this before undertaking larger in-depth qualitative studies. The studies relating to IBD are small and often are not published in journals normally accessed by healthcare professionals responsible for managing these patients. Meta synthesis meets this need by the systematic selection, comparison and analysis of these qualitative combined studies and translating them to create new interpretations (Centre for Reviews and Dissemination 2008).

The qualitative meta-synthesis is a set of techniques for the interpretive integration of qualitative research findings (Sandelowski and Barroso 2007), it overcomes the limitations of small studies (Sandelowski and Barroso 2003) and has the ability to promote a greater understanding in a particular area (Mays, Pope et al. 2005). In this study, the purpose was to integrate and interpret the qualitative studies of the experience of living with IBD. Systematic reviews are accepted as the cornerstone of evidence based practice (Dixon-Woods, Booths et al. 2007) and are based on reviews of effectiveness and of 'what works'. However there is now a move toward addressing the wider questions, such as why there is a problem in the first place and how it has come about. These questions need to be answered in order to develop patient centred interventions (Thorne and Paterson 1998; Sheldon 2005) implement studies of effectiveness and provide answers for the policy makers (Mays, Pope et al. 2005; Sheldon 2005)

5.2 Materials and methods

Inclusion criteria

Qualitative studies which explored the phenomena of living with IBD from the patient's perspective were included in the synthesis. Additional inclusion criteria were studies restricted to English language only, published and unpublished studies and sample population adults >16 years.

Exclusion criteria

The study focused on only one aspect e.g. living with a colostomy or diet, and mixed studies of irritable bowel syndrome (IBS) and IBD.

Systematic search

Electronic literature searches were conducted in MEDLINE (1966-2010, PsychInfo (1967-2010), EMBASE (1980-2010) and CINAHL databases (1982-2010) and the British Nursing Index (1994 -2010) via the OVID platform. Search filters developed by the Hedges database from McMaster University Health Information Research Unit and Kathryn Nesbit, Edward G. Milner Library, University of Rochester Medical Centre, were adapted to aid the search. (http://www.urmc.rochester.edu/hslt/miner/digital_library/tip_sheets/Cinahl_eb_filters.pdf). The search was conducted from the inception of the databases to August 2010. Web of Knowledge and CINAHL were used for citation searches, foot note chasing and journal runs. Author searches were also incorporated into the search of the literature from journals including Qualitative Health Research, Gastroenterology Nurse, and Inflammatory Bowel Diseases (Bates 1989).

Of the 1395 papers generated by the preliminary search of all the databases combined, 1282 were excluded as they were irrelevant to the study question.113 abstracts were selected for further review, of which 92 were excluded based on duplication, quantitative methodology, and wrong subject matter. Four unpublished dissertations were identified within this and obtained, two excluded due to the quantitative methodological approach used (Zeigler 1980; Sevick 2005), the remaining two were included for initial screening (Foulds 1984; Burger 2005). Full text papers were obtained for the remaining 17 papers. These 17 papers and two dissertations were then screened for initial inclusion using three screening questions: does this paper report on findings taken from qualitative work? Did the work involve both qualitative methods of data collection and analysis? Is this research relevant to the topic area? (Campbell, Pound et al. 2003).

Of the 17 papers and two dissertations screened, 11 papers and one dissertation were excluded from the synthesis. The dissertation was excluded as no qualitative methodological analysis was undertaken (Foulds 1984). The remaining papers were excluded based on: methodological approach used an online survey method (Wolfe and Sirois 2008); paediatric age group (Brydolf and Segesten 1996); subject matter focused on living with an ostomy (Savard and Woodgate 2008); narrative journey with no qualitative methodology (Defenbaugh 2008); participant responses used to validate commonly used indices (Waljee, Joyce et al. 2009) and six papers excluded as the subject group was a mixture of patients with IBD and irritable bowel disease and unable to distinguish between responses from each group (Fletcher and Schneider 2006; Jamieson, Fletcher et al. 2007; Fletcher, Jamieson et al. 2008; Fletcher, Schneider et al. 2008; Schneider and Fletcher 2008; Schneider, Jamieson et al. 2009).

The final selection of six papers (Dudley-Brown 1996; Daniel 2001; Hall 2005; Lynch and Spence 2007; Cooper, Collier et al. 2010; Pihl-Lesnovska, Hjortswang et al. 2010) and one un published dissertation (Burger 2005) were reviewed by all three authors. Data extraction forms were developed and data extraction, including study eligibility, study demographics, study characteristics, and themes, and data extraction were independently completed by three reviewers (KK, KL, JG).

The CASP (CASP 1999) tool was used to quality appraise the papers and also to aid the interpretation and exploration process of the synthesis (Popay, Rogers et al. 1998). Further synthesis of the themes from the studies was agreed collectively at synthesis meetings to develop the new translations. The search summary is found in Figure 11, pg 137 and full details of the search strategy are available from the authors.

5.3 Results

Seven studies met the inclusion criteria. Summaries of the included studies are given in Table 9,pg 138 and their corresponding demographics in Table 10, pg 140. A list of excluded studies is available from the authors.

Characteristics of included studies

The seven selected studies were published from 1996 – 2010. Two were conducted in the UK (Hall 2005; Cooper, Collier et al. 2010), one in Sweden (Pihl-Lesnovska, Hjortswang et al. 2010), one in Canada (Daniel 2001), one in New Zealand (Lynch and Spence 2007), and two in America (Dudley-Brown 1996; Burger 2005). All of the studies used in depth interviews (Dudley-Brown 1996; Daniel 2001; Burger 2005; Lynch and Spence 2007; Cooper, Collier et al. 2010; Pihl-Lesnovska, Hjortswang et al. 2010) and one study combined interviews with focus groups (Hall 2005).

A total of 86 patients with an age range was 16-83 years were included and only one reported one patient from an ethnic background (Pihl-Lesnovska, Hjortswang et al. 2010). Two studies focused on Crohn’s Disease only (Lynch and Spence 2007; Pihl-Lesnovska, Hjortswang et al. 2010), and one study UC patients only (Dudley-Brown 1996). The remaining studies included people with both UC and CD. Patients were recruited from relevant national IBD charities (Burger 2005; Lynch and Spence 2007), directly from outpatients clinics (Dudley-Brown 1996; Cooper, Collier et al. 2010; Pihl-Lesnovska, Hjortswang et al. 2010), media advertisements (Daniel 2001), and from a previous community based study (Hall 2005). The theoretical perspectives were mainly phenomenology (Dudley-Brown 1996; Daniel 2001; Burger 2005; Lynch and Spence 2007) and grounded theory (Hall 2005; Pihl-Lesnovska, Hjortswang et al. 2010) with one study using Framework (Cooper, Collier et al. 2010).

Synthesis of the evidence

The three authors independently reviewed all of the studies. The emergent themes were subject to constant examination until an argument to explain the data of the combined studies was developed. The themes and findings of each study were compared with one another repeatedly to identify the 1st order constructs. This revealed the similarities and differences in the data, which led to 2nd order constructs and the interpretation of all of the synthesised studies. For example, study 1 may have had findings AB and C, study 2 may have findings AC and D, a new finding. The synthesis from study 1 and 2 was compared to study 3 and so forth, until all of the papers were synthesised (Britten, Campbell et al. 2002; Sandelowski and Barroso 2007). Early on in the synthesis it was clear that the relationship between the studies was mutual, all sharing common themes (Noblit and Hare 1998). As the studies had a 'reciprocal' arrangement, a new argument was developed. This process was followed systematically, starting with the oldest study first (Dudley-Brown 1996) in keeping with the model of 'line of argument' synthesis (Noblit and Hare 1998). The themes and concepts are illustrated in Table 11, pg 141 and the relationship between them identified in Figure 12 pg 142.

Results - synthesis of the evidence

The synthesis of the seven studies identified that people with IBD endure many daily challenges, stress, pain, fatigue, and fighting for control. The combined impact of living with IBD is the tension they live with. The meta-synthesis has provided an in-depth exploration of living with IBD: 'Pushed and pulled: a compromised life', people living with IBD experience a constant conflict throughout their lives, they push to be normal but IBD pulls them back.

Living in a world of disease

A disease for life: Participants were acutely aware that they had been diagnosed with a long term condition with no cure. Facing and accepting the incurable illness was met with a variety of responses yet the need to get back to normal, but inability to do so, was a theme running through all of the studies.

Fear of long term effects: The fear of long term effects, of death and dying left people feeling powerless (Pihl-Lesnovska, Hjortswang et al. 2010). The risks of cancer development and passing on the illness to children added to the burden of living with the physiological aspects of the illness (Burger 2005; Pihl-Lesnovska, Hjortswang et al. 2010).

Invisible disease: A difficult aspect of living with IBD is its invisibility (Dudley-Brown 1996; Burger 2005; Lynch and Spence 2007; Pihl-Lesnovska, Hjortswang et al. 2010). The studies detail how this concept affected the individuals. The lack of understanding from others doubting that they were actually sick as it was not visible, added to their feelings of anger and frustration, in particular with family members (Daniel 2001). ”*My sister says I’m blowing this up...it’s an act...I’m trying to get attention*” (Daniel 2001).

Wrestling with life: Striving to thrive (‘Push’)

Acceptance yet fight: A common theme throughout all of the studies was the individual’s willingness and need to wrestle with their illness. Three of the studies discussed the acceptance of living with the illness yet continuing to fight it (Burger 2005; Lynch and Spence 2007; Cooper, Collier et al. 2010; Pihl-Lesnovska, Hjortswang et al. 2010). This can be interpreted as neither a submission to the illness nor as out and out combat but more where individuals made peace with their illness. “*This is how I am...to me it’s no different than saying I have a dog*” (Burger 2005).

Control: The concept of control is visible in all seven studies, whether this was trying to control the illness (Hall 2005), controlling bowel urgency (Burger 2005) or losing control (Daniel 2001). Individuals fought to gain and maintain control and find a balance between what they could control and what they needed to control, for life to be acceptable (Cooper, Collier et al. 2010). Gaining 'control' had a positive impact on the individuals, recognising 'performance accomplishments'(Cooper, Collier et al. 2010) and allowing them to feel 'normal' (Hall 2005). However the cost of achieving this was a large trade off which was capable of wearing the individual down and losing its ability to continue to fight, fatigue becoming a significant problem (Hall 2005). Attempting to control their illness was their attempt to try to maintain 'normality' for many people within the studies (Burger 2005; Hall 2005; Lynch and Spence 2007; Pihl-Lesnovska, Hjortswang et al. 2010).

Knowing my body: Participants voiced the theme of 'knowing my body', with accounts of knowing when their illness flared up better than their doctor. An increased awareness of their body led the individuals to try to identify triggers or patterns and recognise when their illness flared up. By learning about their own body the individual tried to gain some scale of control but often this concluded in them feeling helpless and misunderstood (Lynch and Spence 2007). He stated that he knew it was not his Crohn's Disease even though it was the physician's first inclination" (Burger 2005).

Wrestling with life culminates with the individual **pushing** to be normal, accepting their illness yet striving to thrive and survive.

Detained by the disease ('Pull')

Fear of incontinence (unpredictability, humiliation): All of the studies report the patient's fear of incontinence and how they try to live with this (Dudley-Brown 1996; Daniel 2001; Burger 2005; Hall 2005; Lynch and Spence 2007; Cooper, Collier et al. 2010; Pihl-Lesnovska, Hjortswang et al. 2010). The fear appeared to be associated with past experiences of actual episodes of incontinence and remembering the humiliation this produced. Actual episodes were rare but the fear remained constant. Patients felt ashamed, not only of the actual incontinence but also of their ongoing fear. Some people reported the overwhelming shame of incontinence. Shame and humiliation was even experienced within the family unit, one grandmother describing the embarrassment should her grandchildren know that she cannot make it to the bathroom (Daniel 2001; Burger 2005; Cooper, Collier et al. 2010). This fear of incontinence was all consuming for some patients and became a focus of living with IBD, over and above the physical symptoms. “*It’s terrible, but that’s the biggest fear*” (Burger 2005).

Behaviour due to fear of incontinence (avoidance): The fear of incontinence and its unpredictability had a profound effect on the individual’s behaviour. For many this fear led to an avoidance or curtailing of daily activities and impaired individuals work, social and leisure and private functioning (Dudley-Brown 1996; Daniel 2001; Burger 2005).

Individuals used a range of coping strategies to either manage or avoid incontinence and included carrying potties and spare clothes, wearing nappies and identifying bathrooms prior to any travel (Dudley-Brown 1996; Burger 2005). Travelling anywhere required extra time and was dictated by the individual’s bowel frequency and control. *“Planning an escape route provided a sense of security even if it was not needed”,* (Burger 2005).

The impact of this behaviour led to avoiding places and people. Studies describe patients only attending safe places (Hall 2005) with a dependency on toilets (Daniel 2001) or avoiding public places all together (Dudley-Brown 1996).

Impact of behaviour (missing out on life events, socially isolated): The fear of incontinence, coupled with avoidance behaviour, was immensely detrimental to the individual’s quality of life. They became socially isolated very easily: had limited activity with family and friends (Burger 2005); became reclusive (Hall 2005); and missed out on life events (Daniel 2001). The self enforced social isolation led to feelings of social inadequacy, lacking the necessary societal skills for everyday living (Daniel 2001). “*I’ve just missed a whole part of my life*” (Daniel 2001).

Individuals expressed feeling damaged, a failure, weak and feeble with overwhelming feelings of anger, frustration and depression (Daniel 2001; Hall 2005; Lynch and Spence 2007; Pihl-Lesnovska, Hjortswang et al. 2010). Unable to identify a pattern or trigger for their disease reinforced all of these negative emotions (Dudley-Brown 1996; Burger 2005; Lynch and Spence 2007).

Stress was overtly discussed in five studies (Daniel 2001; Burger 2005; Lynch and Spence 2007; Cooper, Collier et al. 2010; Pihl-Lesnovska, Hjortswang et al. 2010). Triggers for stress ranged from the illness itself to outside factors such as the ability to work and financial concerns and manifested itself in the form of fatigue and exacerbations of their disease. Lack of understanding from family members and feeling redundant in the family home (Hall 2005) left people feeling alienated from partners and family (Daniel 2001), and people reported complex emotions of 'letting people down' (Lynch and Spence 2007).

Fatigue, tiredness and exhaustion contributed to people's feelings of frustration, stress and powerlessness (Pihl-Lesnovska, Hjortswang et al. 2010). Some people felt that fatigue was a sign of weakness (Lynch and Spence 2007) and was generally misunderstood by others (Hall 2005) as it was not evidently visible, reinforcing the invisibility of the disease.

Detained by the disease became evident as the analysis of the studies revealed that the fear of incontinence, the behaviour associated with it and the resultant enforced social isolation, resulted in **'pulling'** the individual back from **'normal'** living.

Line of argument

A line of argument was derived from the synthesis of the seven studies (Noblit and Hare 1998). The common translations from the studies were taken a step further and constructed into a new interpretation.

Line of argument synthesis: the ongoing factors identified by the qualitative studies impact on the individual's *whole life* with IBD leading to a *compromised life:* the individual *pushes* to be normal yet IBD *pulls* them back. The individual is in constant conflict, fighting to be normal with the impact of this resulting in constant tension within.

The synthesised studies revealed the fear and humiliation surrounding incontinence which resulted in severely reduced social interactions. Descriptions how the illness 'intruded' into the participant's life and the constant 'fight' for normality was evidenced throughout all of the studies. Phrases, including the 'see-sawing of fears and hopes', illustrate the uncertainties and contradictions of living with IBD. Importantly, the individuals describe the courage required to break the social isolation resulting from bowel symptoms. All of these aspects of living with IBD are directly related to everyday life.

5.4 Discussion

The aim of this meta-synthesis was to provide an interpretation of the health and social needs of patients living with IBD by synthesising qualitative studies and key issues emerged. People with IBD endure many daily challenges including stress, pain, and fatigue and fighting to maintain normality. The combined overall impact of living with IBD is the tension these patients live with. The value of meta-synthesis is the interpretation of all of the synthesised studies to provide an inclusive representation of living with IBD: 'Pushed and pulled: a compromised life', people living with IBD experience a constant conflict throughout their lives, they *push* to be normal but IBD *pulls* them back.

Considering the plethora of evidence pertaining to the patient's quality of life, symptom burden, and psychosocial factors related to IBD (Drossman, Patrick et al. 1989; Casati, Toner et al. 2000; de Rooy, Toner et al. 2001; Canavan 2006; Graff 2006; Larsson, Loof et al. 2008), there are few qualitative studies directly *exploring the patient's beliefs and behaviours from the patient's perspective. Only seven* studies were identified, six published and one unpublished thesis, the earliest undertaken in 1996 and the latest in 2010, during a 14 year time span. The studies amount to only 86 patient accounts of living with IBD.

People diagnosed with a chronic disease must adjust to the demands of the disease as well as to the treatments for their condition (Goldstein 2006). The disease may affect how the individual perceives him or herself and their relationship with others. The Shifting Perspectives Model of chronic illness determined that life with a chronic illness does not follow a predictable trajectory but people experience a ‘complex dialectic between themselves and their world’(Thorne and Paterson 1998). This process of debate and argument, trying to cope with the disease is all encompassing; the individual with IBD lives in a world of disease, even when in remission.

Studies have identified the long term complications of IBD, such as bone problems and colorectal cancer (Peyrin - Biroulet, Loftus et al. 2011). These potential long term complications heighten the individual’s fear of the disease. The uncertain nature of the illness and developing cancer were concerns ranked highly for people with IBD (Drossman, Leserman et al. 1991; Mussell, Bocker et al. 2004). The fear of long term complications and dying are difficult discuss with others when outwardly the individual appears fine (Daniel 2001; Burger 2005).

The issue of control is important within all of the studies. The ability to take control and the relationship with psychological functioning has been established in the literature. Personal control may be informed by self efficacy (Bandura 1977) or the Common Sense Model whereby the extent to which the individual believes that their illness is manageable and possible to control, becomes focal to their behaviour (Leventhal, Nerenz et al. 1984). Individuals with IBD have been found to have significantly poorer psychological health than those without IBD (Graff, Walker et al. 2009) and the meta-synthesis has illustrated that control and coping are important factors and assist the psychological well being in these individuals. Controllability and coping strategies were closely linked to knowing how their body reacted to their illness and identification of flare ups (Burger 2005), maintaining normality and acceptance of IBD within the individual’s life (Hall 2005; Lynch and Spence 2007; Cooper, Collier et al. 2010; Pihl-Lesnovska, Hjortswang et al. 2010).

The unmistakeable burden of the fear of incontinence, the behaviour related to this fear and the impact of this behaviour on the individual, is exposed and its ongoing effects are demonstrated much more clearly by the meta-synthesis. An early study identified urgency of defecation and the fear of incontinence as factors affecting the quality of life in individuals with Crohns Disease (Cooper, Collier et al. 2010). Behaviour due to fear and coping strategies, such as avoidance of public places, carrying potties when leaving the house (Burger 2005), changing working schedules (Waljee, Joyce et al. 2009), have been identified in other studies, but the collective impact of this fear and behaviour reveals the true impact IBD has on the individual. The humiliation of incontinence and unpredictable nature of the disease leave the individual socially isolated and missing out on important life events. The reality that this fear and behaviour continues into disease remission compounds the stress, fatigue and debilitative nature of it.

All of the synthesised studies identified the issue of incontinence but the unmistakeable burden of this is exposed and its ongoing effects are demonstrated much more clearly by the meta-synthesis, supporting the value of the meta-synthesis and its ability to interpret studies into new translations.

There are limitations to the meta-synthesis: the low number of people with IBD included in the synthesis; the subjective nature of the synthesis; and grouping studies from various countries with different and changing health care systems over a period of 14 years and combining them and the advent of biologic drugs. The countries have similar socio-economic systems with developed healthcare resources but differ in terms of the financial aids required to access healthcare. Over the past decade the profile of chronic disease management has increased due to the aging population and the role of health care in the management of this area has changed dramatically with greater emphasis placed on self management. Early studies may be deemed outdated. However the methodology of the metasynthesis and the accounts of living with IBD in the studies remain important to capture the phenomenon of living with IBD.

Based on our analysis, we conclude that the fear of incontinence, the behaviour related to this fear and the impact of this behaviour on the individual, are perhaps the most significant issues to emerge from the meta-synthesis. The findings highlight the daily challenges and tensions that individuals with IBD face, whether their disease is in remission or not. Evidence has found the incidence and prevalence of IBD to be increasing, indicating its emergence as a global disease (Molodecky, Soon et al. 2012). Perhaps with the emergence of biologic therapies and gene identification, emphasis has been placed upon the acute aspect of IBD and the chronicity of the disease is forgotten.

The physical symptoms alone do not validate the subjective impact of living with IBD (de Rooy, Toner et al. 2001). The psychological burden of living with IBD, quality of life and specific psychological co morbidities are described as ‘un-promoted issues’: issues that are not always addressed in the medical literature (Andrews 2010). Identification and clarity of these ‘un-promoted issues’ can only be met by undertaking qualitative studies and health care professionals need to be aware of the influences these have on the individual when developing treatment strategies. More focused attention on the patient’s perspective of living with IBD is needed to provide patient centred care and structure health care services. The emergence of the immense impact of incontinence, fear and behaviour on the individual from this meta-synthesis requires further qualitative enquiry.

5.6 Comments

Background

The incidence and prevalence of inflammatory bowel disease is increasing and it is being recognised as a global long term condition, with significant morbidity and cost. In order to provide patient centred care, an understanding of the impact of living with inflammatory bowel disease, from the patient’s perception, is important. The Ratings Form for Patient Concerns and Inflammatory Bowel Disease Questionnaire are widely used measures to describe what it is like to live with inflammatory bowel disease but these fail to capture the essence of this. There are few qualitative studies which fully demonstrate the impact of living with this condition. By using meta-synthesis methodology, this study adds significant understanding of inflammatory bowel disease and the impact of living with inflammatory bowel disease, from the patient's perspective.

Research frontiers

There is growing emphasis that the needs and preferences of patients must be addressed when developing and evaluating new models of care delivery. Incorporating patient preference, choice and experience is acquired through qualitative studies. Synthesising qualitative studies of inflammatory bowel disease gives a profound insight into the disease. Capturing this evidence can lead to a greater understating of the condition and help to tailor treatments and provide personalised care.

Innovations and breakthroughs

Recent audits from the European Federation of Crohn's and Colitis Association (EFFCA) has demonstrated, on a large scale, the impact inflammatory bowel disease has on the individual's personal, work and social life. This audit highlighted some important considerations of inflammatory bowel disease care in Europe, however, a more immersed understanding is required. This is the first meta-synthesis of inflammatory bowel disease and provides a comprehensive insight of what it is like to live with.

Applications

The findings from this study emphasises the impact incontinence has on the individual, even in **remission**. The fear of incontinence, the behaviour related to this fear and the impact of this behaviour on the individual, are the most significant issues to emerge from the meta-synthesis, and requires further qualitative enquiry.

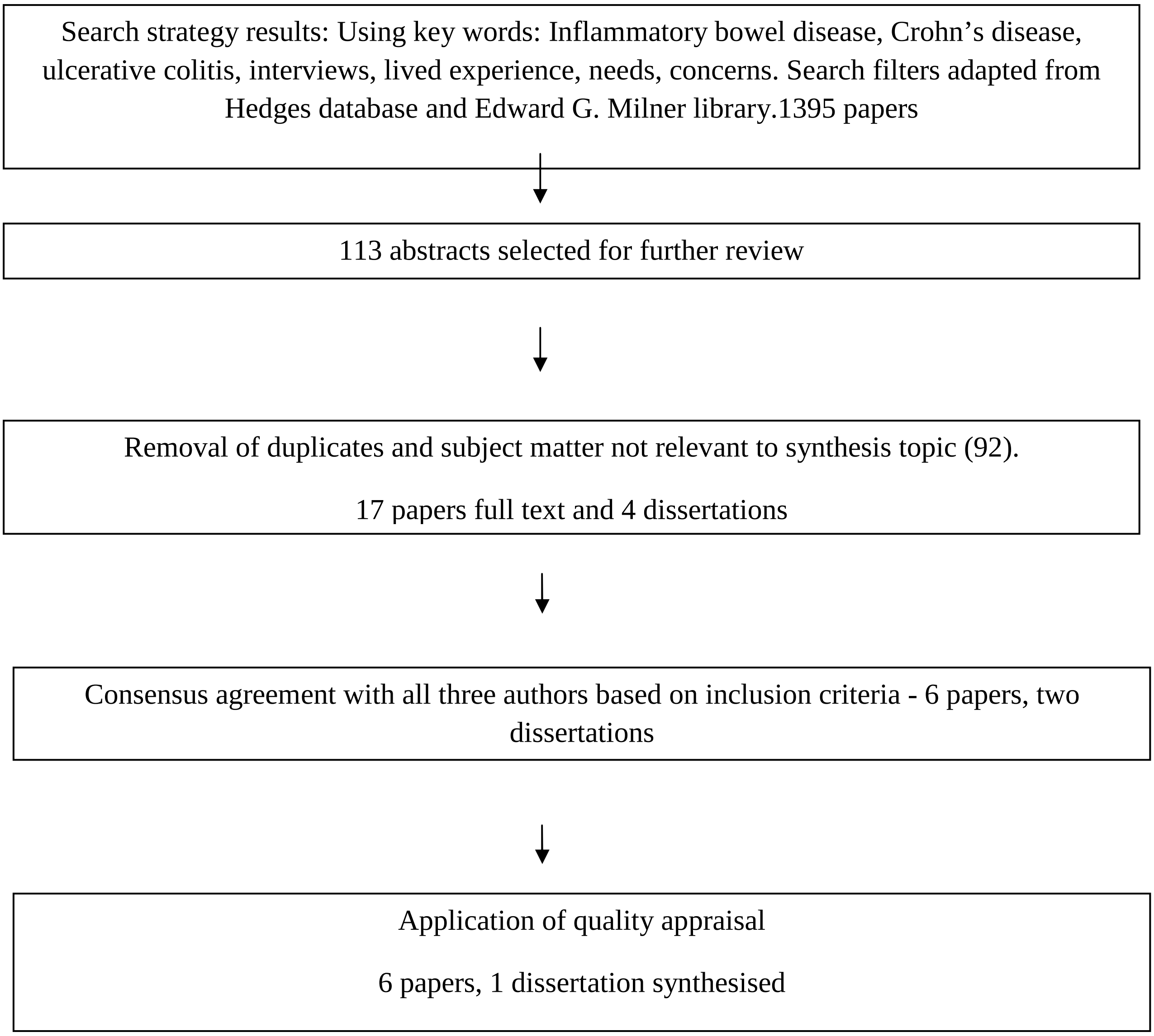
Terminology

Inflammatory bowel disease is a collective term for Crohn’s Disease and ulcerative colitis. Qualitative studies typically use focus groups and / or interviews to gather data. Qualitative studies, from the patient’s perspective, are used to highlight the lived experience of a phenomenon. Meta-synthesis is method of identifying and bringing together (synthesising) relevant research evidence from a variety of qualitative studies. Meta-synthesis methodology seeks to expand the understanding of patient experience.

Peer review

The enclosed meta-synthesis analyses the data from the literature regarding understanding the health and social care needs of patients with inflammatory bowel disease. The paper is very well written. The Authors observed that the most significant issues were fear of incontinence, the behaviour related to this fear and the impact of this behaviour on the individual. This paper adds a lot of important information on health quality of life in IBD patients and help readers to understand the IBD more.

Figure 11: Flow chart summarising search strategy



Search strategy results: Using key words: Inflammatory bowel disease, Crohn’s disease, ulcerative colitis, interviews, lived experience, needs, concerns. Search filters adapted from Hedges database and Edward G. Milner library.1395 papers

113 abstracts selected for further review

Removal of duplicates and subject matter not relevant to synthesis topic (92).

17 papers full text and 4 dissertations

Consensus agreement with all three authors based on inclusion criteria - 6 papers, two dissertations

Application of quality appraisal

6 papers, 1 dissertation synthesised

Table 9: Characteristics of synthesised studies

Study Aims / objectives	Theoretical perspective	Sampling Strategy	Recruitment setting	Data collection method	Analytical approach
1. Dudley-Brown (1996) To describe the real life experiences of patients with ulcerative colitis.	Phenomenological.	Convenience sample. (n= 3)	Patients sampled from IBD outpatient clinic when attending for their scheduled appointment.	In depth semi structured interviews.	Coding and memo system used, grouped and transformed into an interpretive understanding of the phenomenology of living with UC, with the extraction of emergent themes.
2. Daniel et al (2001) To describe the young adults experiences of living with IBD as it affects their personal, interpersonal and social systems.	Phenomenological.	Purposive sample (n=5)	Patients recruited by an advertisement in national newspaper.	In depth semi structured interviews.	Kings Goal Attainment Framework used as theoretical framework. Thematic content analysis of interviews to develop themes in line with this framework.
3. Hall et al (2005) To gain a better understanding of the perspectives and experiences of individuals living with IBD and a poor quality of life, as identified by UK-Inflammatory Bowel Disease Questionnaire (IBDQ).	Grounded theory.	Purposive sample. (n=31)	Recruited from a previous unconnected study, sampled by lowest quintile of UK-IBDQ, established low quality of life.	In depth interviews and focus groups.	Concurrent data collection and analysis to identify emerging themes. Selective coding was used to enabled theoretical framework. Respondent validation obtained from participants and 97% in agreement.
4. Burger (2005) To understand how people live with IBD on a day to	Interpretive phenomenological design	Convenience sample. (n=8)	Participants from mailing list of Indiana Chapter of	In depth interviews. Each participant interviewed 3 times.	Thematic analysis, identification analysis and identification of

day basis, how the illness affected the participant's life, the participants understanding of the illness and the experience of symptoms, their response to disruption and their practical knowledge of living with IBD.			Crohn's and Colitis Foundation of America, answered advert and recruited according to inclusion / exclusion criteria		paradigm cases used.
5. Lynch et al (2007) To explore the experiences of youths diagnosed with IBD to improve health care delivery.	Phenomenological	Purposive sample. (n=4)	Participants recruited from Crohn's and Colitis New Zealand.	Semi structured in depth interviews.	Thematic analysis from transcribed data, ongoing process of interpretation used to refine themes to describe nature of the experience.
6. Pihl-Lesnovska et al (2010) To identify and describe the meaning of quality of life of patients with Crohn's Disease.	Grounded theory	Theoretical sampling. (n=11)	Patients recruited from the gastroenterology outpatient clinic	Unstructured in depth interviews.	Constant comparative analysis used, saturation determined sample size. Core category and related categories identified. Two authors analysed all interview transcripts.
7. Cooper et al (2010) To explore participants beliefs about their role and the role of others in managing IBD.	Framework	Purposive sampling (n=24)	Patients sampled from IBD outpatient clinic when attending for their scheduled appointment.	Semi structured in depth interviews.	Thematic content analysis using Framework.

Table 10: Demographics of synthesised studies

Study	Date	Country	Age range	Gender	Disease	Disease duration	Sample size
1. Dudley – Brown (1996)	1996	USA	30-50years	1 Female 2 Male	3 Ulcerative Colitis	1-10years	3
2. Daniel et al (2001)	2001	Canada	18-24years	2Female 3Male	IBD not specified	<2 years	5
3. Hall et al (2005)	2005	UK	Not specified but all>16years	19 Female 12 Male	17 Ulcerative Colitis 14 Crohns's Disease	Not specified but all >2 years	31
4. Burger (2005)	2005	USA	30-65 years	6 Female 2 Male	6 Crohn's Disease 2 Ulcerative Colitis	2-40years	8
5. Lynch et al (2007)	2007	New Zealand	16-21 years	3Female 1Male	All Crohn's Disease	<18 months	4
6. Pihl-Lesnovska et al (2010)	2010	Sweden	29-83years	5Female 6Male	All Crohn's Disease	2-33years	11
7. Cooper et al (2010)	2010	UK	30-40years	11 Female 13 Male	12 Ulcerative Colitis 12 Crohn's Disease	1->10yrs	24

Table 11: Themes and concepts

1st order constructs	Relevant papers (number correspond to studies in Table 1)	2nd Order constructs	Line of argument synthesis
Limitations / missing out on life	1, 2, 3, 4, 5, 6, 7	**Detained by disease (“Pull”)**	
events.	1, 2,3. 5, 7	***Fear of incontinence –***	
Humiliation of incontinence	1, 2 ,3,4,5,7	unpredictability, humiliation	
Social isolation	2,3, 4, 5, 6	***Behaviour due to fear of***	
Unpredictability	1, 4, 5,7	***incontinence*** **–** avoidance	
Powerlessness	4, 5, 6, 7	***Impact of behaviour*** **–** socially	**“Pushed and Pulled: a**
Feeling damaged	1, 2, 3, 4, 5, 6, 7	isolated, missing out on life	**compromised life”**
Impact on relationships	1, 2, 3, 5, 6, 7	events, limited life, relationship	
Negative emotions	2, 4, 5, 6, 7	burden, feeling damaged	**Constant conflict between IBD**
Stress	2,3,4,5,6	Fatigue	**and normal life results in a**
Fatigue			**compromised life.**
A disease for life.	2, 4, 5, 6	Living in a world of disease	
Fear of long term effects	2, 5, 4, 6		***Pushes*** **to be normal but IBD**
Invisible disease	3,4,5,6		***pulls*** **individual back.**
Acceptance yet fight	4, 5, 7	**Wrestling with life (“Push”)**	
Knowing my body	4,5,7	Striving to thrive	
Control	2, 4, 6, 5, 7		
Maintaining normality	3,4,5, 6		

Figure 12: Relationship between synthesised studies

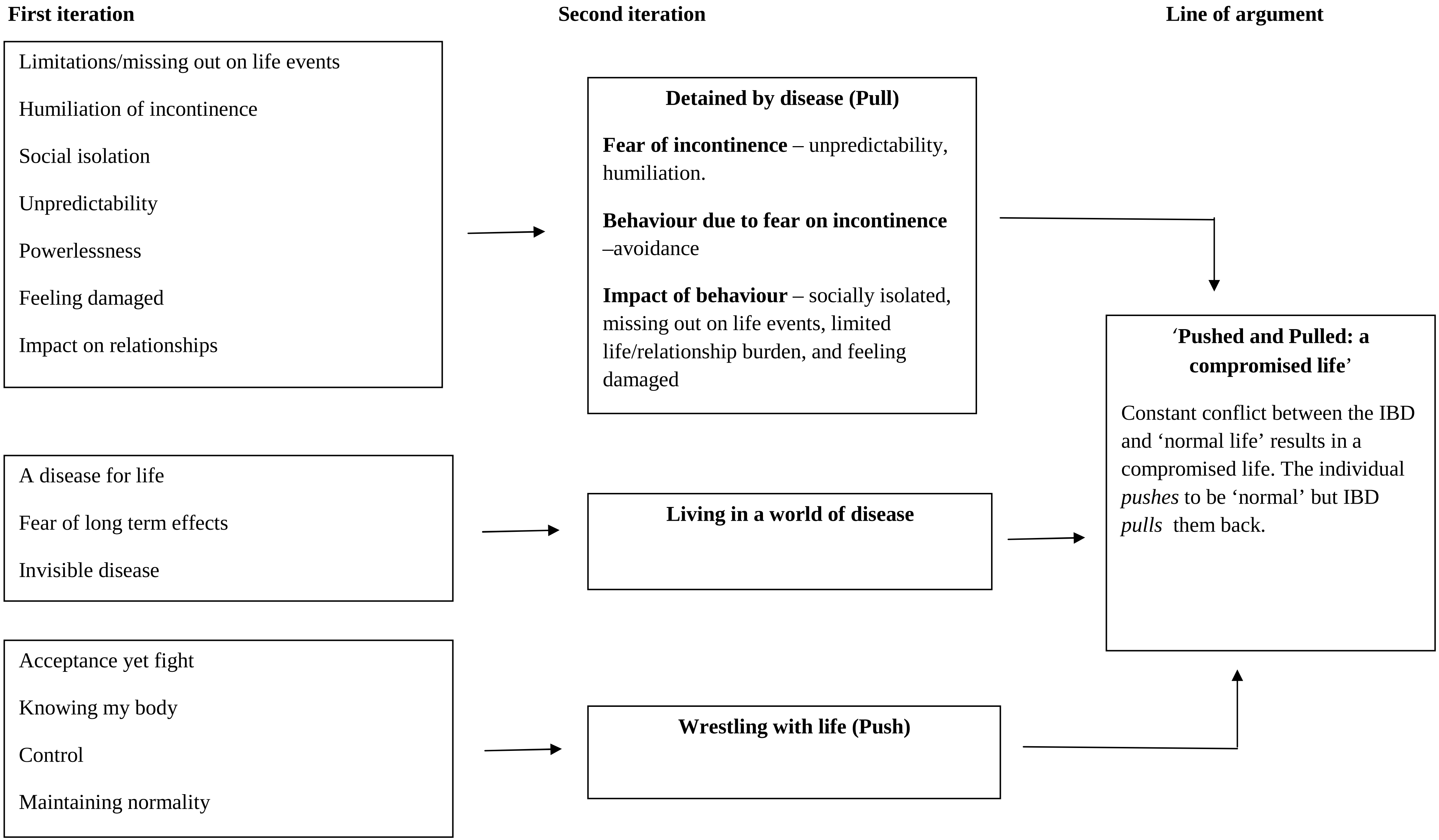


Table 12: Results of screening question applied to studies

Screening questions	Paper: Hall et al (2005) The fight for health related normality	Paper: Pihl-Lesnovska et al (2010) Patients perspective of factors influencing QoL while living with IBD	Paper: Lynch et al (2007) A qualitative study of youth living with CD	Paper: Daniel (2001) Young adults perceptions of living with chronic IBD	Paper: Dudley- Brown (1996) Living with UC	Paper: Savard et al (2008) Young people experience of living with uc and an ostomy	Paper: Brydolf et al (1996) Living with uc: experiences of adolescents and young adults	Paper: Walijee et al (2009) Patient reported symptoms during an uc flare: a qualitative focus group
1. Does this paper report on findings from qualitative research?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2.Did the work involve both qualitative methods of data collection and analysis	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3. Is this research relevant to the synthesis topic?	Yes	Yes	Yes	Yes	Yes	No	No	No
Include / exclude	Include	Include	Include	Include	Include	Exclude	Exclude	Exclude
Agreed?	KK, KL, JG	KK, KL, JG	KK, KL, JG	KK, KL, JG	KK, KL,JG	KK, KL, JG	KK, KL, JG	KK, KL, JG

<u>Screening questions</u>	Paper: Wolfe et al (2008) Beyond standard quality of life measures: the subjective experiences of living with inflammatory bowel disease	Paper: Defenbaugh (2008)Under erasure: the absent body in doctor-patient dialogue	Paper: Dissertation Burger (2005) Living with IBD: bodily and social responses to illness	Paper: Dissertation Foulds (1984) IBD as a cultural artefact: an ethnography of the politics of suffering	Paper: Fletcher et al (2008) ‘I know this is bad for me but.. A qualitative investigation of women with IBS and IBD: part II
1. Does this paper report on findings from qualitative research?	No	No	Yes	Yes	Yes
2.Did the work involve both qualitative methods of data collection and analysis	No	No	Yes	Yes	Yes
3. Is this research relevant to the synthesis topic?	Yes	No	Yes	Yes	No
Include / exclude	Exclude	Exclude	Include	Include	Exclude
Agreed?	KK, KL, JG	KK, KL, JG	KK, KL, JG	KK, KL, JG	KK, KL, JG

<u>Screening questions</u>	Paper: Schneider et al (2009) ‘one sip won’t do any harm... temptation among women with IBD / IBS to engage in negative dietary behaviours, despite the consequences to their health’	Paper: Jamieson et al (2007) A qualitative investigation of women with IBS and IBD’	Paper: Fletcher et al (2008) ‘I am doing the best that I can! Living with IBD and / or IBS (part II)
1. Does this paper report on findings from qualitative research?	Yes	Yes	Yes
2.Did the work involve both qualitative methods of data collection and analysis	Yes	Yes	Yes
3. Is this research relevant to the synthesis topic?	No	No	No
Include / exclude	Exclude	Exclude	Exclude
Agreed?	KK, KL, JG	KK, KL, JG	KK, KL, JG

Screening questions	Paper: Fletcher et al (2006) Is there any food I can eat? Living with IBD and /or IBS	Paper: Schneider et al (2008)'I feel as if my IBS is keeping me hostage!' Exploring the negative impact of IBS and IBD upon university aged women'	Cooper
1. Does this paper report on findings from qualitative research?	Yes	Yes	yes
2.Did the work involve both qualitative methods of data collection and analysis	Yes	Yes	yes
3. Is this research relevant to the synthesis topic?	No	NO	yes
Include / exclude	Exclude	Exclude	Include
Agreed?	KK, KL, JG	KK, KL, JG	

Table 13: Excluded papers for meta-synthesis

Paper	**Reason for exclusion**
Savard et al (2008) Young peoples’ experience of living with uc and an ostomy	Although the paper is qualitative, the topic focus on living with uc AND a colostomy. Even though 5 of the 6 participants no longer had the colostomy at the time of the research, their perception of the disease would still reflect living with a colostomy. The meta synthesis did not including living with a colostomy.
Brydolf et al (1996) Living with uc: experiences of adolescents and young adults	A qualitative paper but the age range is 11 – 31 years. Paediatrics are not included in the meta synthesis and it is difficult to identify the ages of the participants and their corresponding responses.
Walijee et al (2009) Patient reported symptoms during an uc flare: a qualitative focus group study	The aim of the study was to compare symptoms from focus groups with a pooled list of domains taken from validated commonly used disease activity indices, to correlate the indices with pt reported symptoms.
Wolfe et al (2008) Beyond standard quality of life measures: the subjective experiences of living with inflammatory bowel disease	The methodology was not qualitative, it approach was an online survey, asking patients one open ended question ‘How has IBD affected your life?’ The topic is relevant but this was a survey.
Defenbaugh (2008)Under erasure: the absent body in doctor-patient dialogue	This is a narrative journey with the author writing in the first person. The author’s experiences are mixed with patient’s experiences to form one ‘voice’. The author is telling a ‘story’.
Fletcher et al (2008) ‘I know this is bad for me but.. A qualitative investigation of women with IBS and IBD: part I	This is one of a series of papers involving the same sample of women. Over 60% of participants do not have IBD, questions directly aimed towards diet.
Fletcher et al (2008) ‘I am doing the best that I can! Living with IBD and / or IBS (part II)	One of the groups of papers from Fletcher et al. Same 8 women participants, 2 with UC, 1 with UC/IBS and the remaining 5 participants had IBS.
Jamieson et al (2007) A qualitative investigation of women with IBS and IBD’	One of the Fletcher series of papers. Same 8 women primarily aimed at dietary control again.
Schneider et al (2009) ‘one sip won’t do any harm.. temptation among women with IBD / IBS to engage in negative dietary behaviours, despite the consequences to their health’	One of the series of papers from Fletchers group.8 women participants, over 60% had IBS and unable to separate responses from IBS and IBD participants.
Fletcher et al (2006) Is there any food I can eat? Living with IBD and /or IBS	From the same group of authors and same group of participants. Study focuses on diet.
Schneider et al (2008)’I feel as if my IBS is keeping me hostage!’ Exploring the negative impact of IBS and IBD upon university aged women’	From the same group of authors (Fletcher et al). 7 women, unable to separate the responses from participants with IBD and IBS in results.

Paper two

An exploration of the follow-up up needs of patients with inflammatory bowel disease.

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Title

An exploration of the follow-up up needs of patients with inflammatory bowel disease.

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Running head (50 words): Follow-up care needs of patients with inflammatory bowel disease.

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Abstract

Background and aims

The rising incidence of inflammatory bowel disease (IBD) in adults and children has implications for the lifelong burden of disease and the provision of specialist services. Patients with IBD should have access to specialist care which is delivered according to their values and needs. However few studies have examined patients' views of follow-up care. The aim of this qualitative study was to explore patients' needs, preferences and views of follow-up care.

Methods

IBD patients were purposively selected from a gastroenterology clinic in a UK University Foundation Trust and invited to participate in individual interviews which focused on needs and role of follow- up in their disease, their experience of follow-up, service delivery, and other models of follow-up care.

Results

24 patients were recruited, 18 patients had Crohn's Disease, and 6 ulcerative colitis. Median age was 48.5 years (range was 27-72 years) and median disease duration 11.5 years (range 2 – 40years). Four main themes emerged: (1) experiences of current follow-up care; (2) attitudes to new models of care, including self-management, role of general practitioner, patient- initiated consultations and 'virtual' follow-up; (3) the personal value of follow-up care; and (4) the 'ideal' consultation.

Conclusion

The main finding was that patients would prefer a more flexible follow-up care system. 'Virtual' care as an adjunct to patient-initiated consultations and self-management, was identified as optimal approaches to meet the patients' needs of follow-up care. New models of follow- up care could improve the patients' experience of care, offer potential cost savings with reduction in face-to-face consultations and allow targeted care to those who need it.

Keywords

Inflammatory bowel disease; qualitative; Framework Analysis; interviews; follow-up care.

6.1 Introduction

IBD remains a challenging disease for healthcare services in its treatment, diagnosis and prognosis, assessment of disease activity and severity, and outcome of treatments (Dignass, Van Asshce et al. 2010; Dignass, Lindsay et al. 2012)· Evidence suggests that the prevalence of IBD is rising in both adults (Molodecky, Soon et al. 2012) and children (Barton 1989; Sawczenko, Sandhu et al. 2001; Henderson, Hansen et al. 2010) This is mirrored both in Europe (Perminow, Brackmann et al. 2009) and North America (Benchimol, Guttmann et al. 2009). This rise has implications for the substantial lifelong burden of this disease and the provision of specialists healthcare services.

Follow-up care for IBD differs from many other healthcare conditions. IBD is not only a life-long illness, it has a considerable spectrum of disease severity and complexity and a natural history characterised by periods of remission and relapse. In addition, the condition requires other active follow-up considerations when patients are clinically well for example colon cancer surveillance. The nature of the symptoms suffered by patients, reflecting the complexity of the disease, dictate that the follow-up facilities required are beyond those normally provided in general outpatients (Carter 2004).

As a chronic long term condition it has been recognised that patients with IBD should have access to specialised care (Mowat, Cole et al. 2011). The health care needs of patients fluctuate depending on the type of disease, and the care they receive during periods of remission and relapse. Factors such as the type of medical treatment they received, haematological monitoring required, level of support from primary care, and pattern of disease, such as penetrating, fistulising and number of flares per year, influence the follow-up care a patient with IBD requires or receives.

Traditionally patients are regularly followed-up and are not discharged from the gastroenterology service. In response to this, some IBD centres have implemented alternative services, such as telephone clinics and help lines to avoid unnecessary out- patient visits (Gethins, Robinson et al. 2007).

In summary there is little evidence on which to base the provision of follow-up care for people with IBD. Such follow-up care, as with any long term condition, should be delivered according to patients' values, within a system that anticipates patients' needs and a service based on evidence (Wagner, Austin et al. 2001; Coleman, Austin et al. 2009). Recent health care policy in the UK has emphasised the need to move long term conditions management from the hospital setting to primary care. However there has been a paucity of work which has explored IBD patients' perceptions of their follow-up care and which factors influence their needs and preferences for their care.

The study aimed to explore IBD patients' experience, needs and preferences of follow-up care.

6.2 Materials and methods

A qualitative study design was used to explore patients' needs and preferences for follow-up care.

Sample and data collection

Patients with IBD were purposively sampled from a University Foundation Trust in the UK. 24 patients were recruited from a gastroenterology clinic prior to their out-patient appointment, selected according to age, disease severity and duration to ensure diversity of sample and invited by post to participate in one-to-one interviews. All patients invited took part in the study. Inclusion criteria were: patients with an existing diagnosis of CD or UC; 18yrs or older; and able to give informed consent. Demographic and clinical characteristics of participants are shown in Table 14, pg 166. Interviews used a semi-structured topic guide and lasted approximately one hour (range 40 – 60 minutes) (see box 1, pg 168 interview topic guide). The interviews were digitally recorded and transcribed verbatim. Interviews continued until data saturation occurred.

Analysis

Interview transcripts were analysed using framework analysis (Ritchie and Lewis 2003)' Framework analysis is recommended when the objectives of the study are typically set in advance, in this case acceptable follow-up care based on patients' preferences. Framework starts deductively from pre-set aims and objectives, and data collection tends to be more structured than other approaches to qualitative data collection. The analytic process is more strongly informed by a priori reasoning (Pope, Ziebland et al. 2000; Ritchie, Spencer et al. 2003). There are five stages of data analysis within framework: familiarisation; identification of the thematic framework; indexing; charting; mapping and interpretation. Following familiarisation of the transcripts, the thematic framework was developed. The framework was then applied to the transcripts and the verbatim data were rearranged to 'fit' within the framework to form charts. For example, the theme of self- management contained summaries of patient views and experiences of this (see figure 13, pg 167). Mapping and interpretation of the data helped to define further concepts, create typologies, and find associations to explain the findings. Data were managed using NVivo© 9.0.

Rigour

Rigour describes the 'trustworthiness' of the research (Guba 1981).The following steps were taken. Field notes reflected the conduct of the study (Guba and Lincoln 1989; Davies and Dodd 2002). Following the initial four interviews, transcripts were analysed by three researchers to ensure the topic guide was appropriate and that the data captured were within the scope of the study. Ongoing identification of themes was undertaken by three authors by reviewing transcripts and identifying emerging themes.

Ethics

Ethical approval was granted from the North West 2 Research Ethics Committee REC number 10/H1005/50.

6.3 Results

The main themes to emerge were: (1) experiences and views of the current follow-up system; (2) attitudes to new models of follow-up care, including self management, the present and potential role of the GP, open access, and 'virtual' follow up (see figure 14, pg 170); (3) the personal value of follow-up care, including the value of the IBD nurse specialist; and (4) the 'ideal' consultation.

Experiences of current follow-up care system.

The patients were asked about their experiences and views of current follow-up care management. Patients reported that often the traditional system of scheduled, pre-fixed follow-up appointments was impersonal and inflexible.

Patients reported that 'when well' the traditional follow-up scheduled appointment was unnecessary and inconvenient. Most patients reported their frustration with this system, juggling their lives around what they felt were unnecessary, but with no alternative offered.

"There's not really much point in being there and I could just be getting on with my work… its one of the things about having a chronic illness, means that you do have loads of doctors appointments, and so it's about juggling time off work for all of them" (P010).

For some patients', reports of dissatisfaction with the system was more a reflection of their frustrations with their disease and lack of cure.

"I mean if I had my way now I would actually like to go and have somebody look at me and not send me away until they'd found out what was wrong with me, what will make it all go away, do you know what I mean?" (P015)

Attitudes to new models of follow-up care: Self- management

Only two of the 24 patients had heard of self-management although many patients considered themselves to be managing their illness to some degree. The definition and process of self-management was explained to participants who were unclear about what it involved. Four clear groups of patients emerged:

(1) Patients who embraced the concept of self-management and questioned why they had not heard of it prior to the interview.

"I think it would be really helpful… I think it's having an understanding and more awareness of what you can do, like treatments" (P023.)

(2) Patients who could perceive no advantages to self-management. This group of patients had experienced quite complex disease processes and were reluctant to self manage for fear of becoming unwell again.

"I'm not into self diagnosis and I'm not into self medication or self management. So I'm not going to do anything off my own bat without having checked with some medical mind somewhere, I don't want to be like I was before my surgery" (P013)

One participant had been diagnosed with CD as a child and suggested that the responsibility for her body lay with the hospital.

"I've been ill since I was so young… It has always been somebody else's responsibility...my body...and I'm not going to start now" (P012)

(3) Patients who were willing to embark on a self-management programme provided that if they could not manage they could revert back to the traditional care system.

"I'd love to be part of something like that. What if I can't manage? Can I come back in, come back to see the hospital?" *(P019)*

(4) Patients who required more knowledge about their illness and bodily response to their disease before considering self-management. All of these patients had been diagnosed less than three years.

"I would give it a go now… I wouldn't have done in the beginning nor a year ago, I was too needy, frightened to death actually. No I really needed the hospital at the beginning. It is just about learning to cope, learning how your body acts. But yes, now I would like to know about it" (P014).

Attitudes to new models of follow-up care: GP and integrated care

Patients with IBD are managed primarily in secondary care settings with some GP involvement within a restricted shared care protocol. There is a move to a more integrated care system with greater GP involvement yet it is unclear how IBD patients should be managed within primary care. Patients were asked about the current and potential role of their GP.

Many patients had experienced years of symptoms prior to diagnosis, in one case diagnosis took 10 years. This misdiagnosis, described by all participants, led to a loss of confidence in the GP for future care. This had an impact if they ever sought help from their GP in time of flare up or IBD related problems.

“At the end of the day he is a GP, he’s not a specialist and he doesn’t know me.” (P012).

Many patients reported that the lack of confidence in their GP and their GP’s lack of knowledge of IBD, often acknowledged by the GP, was a barrier to seeking their help.

“He said to me ‘well actually you know more than me about this’… that’s what my GP said to me” (P 005).

“It’s the trust, and the knowledge thing okay..he’s not a specialist...it’s not his field is it, he’s a general practitioner” (P016).

A number of patients stated that they were not aware they could seek help from their GP. They always referred back to secondary care and had no experience of GP led follow-up care.

“I’m just blinkered to oh, Crohn’s, hospital, yes.” (P 021).

Patients reported that they would be happy to increase the level of input from their GP but felt strongly that such care should be within an enhanced service under the direction of the IBD team. Patients were reluctant to be discharged from the IBD team completely but would accept reduced face-to-face contact in order to remain under the overall care of the IBD team.

Attitudes to new models of follow-up care: Patient initiated consultation.

The patients were asked whether direct access to hospital review initiated by them, would be acceptable, as opposed to the traditional follow-up scheduled appointment. Often referred to as open access care, all but one patient was in favour of this approach. The only caveat was the fear that during a flare up the patient would be unable to re-access hospital care.

“I know in myself what my triggers are… If I am well do I really need to take half a day off work to be seen? I am wasting time for you guys, but I’m also wasting my time, as long as I can be seen when I run into problems yes, this sounds a great idea” (P019).

Great emphasis was placed in the role of the nurse helpline within follow-up, often referred to as a ‘lifeline’ by the patients.

Attitudes to new models of follow-up care: ‘Virtual’ care

Patients reported a fear of being discharged from the IBD team but wanted to explore other models of care. This included tele-health and remote monitoring. All patients found this approach acceptable because it meant that they were not discharged from their IBD team but did not need to be seen when well.

"Anything that takes me away from the hospital system all of the time. I suppose its finding that balance between feeling well and not coming in to hospital, knowing that you are monitoring me, and being poorly and suddenly needing to see you". (P019).

The personal value of follow-up care

Despite wanting to explore other innovative follow-up care approaches, patients valued their follow up care, even when well. All of the patients reported that follow-up care was about contact, connection, continuity, expertise and reassurance. The personal value of follow-up care was based on the relationship the patient had with their nurse and consultant, and the confidence they had in their knowledge of IBD.

"It reassurance that I am doing OK, I don't think I could have done without it… It's my security blanket" (P015)

'Continuity, that's what it is all about for me, my nurse, my doctor, they know me, they look out for me. I would have moved away from here but for them' (P021).

All patients valued the IBD nurse, who was central to the IBD team, a liaison, and a constant identity in the hospital system. The patients were asked about the proposal for an IBD outreach nurse at the interface of primary/secondary care and were strongly in favour of this.

The 'ideal' consultation

Patients' views of an 'ideal follow- up consultation' were focussed on being treated as an individual rather than 'just someone with IBD'. They wanted to be listen to by a confident and knowledgeable practitioner, asked about how their illness was affecting them, and provided with a plan of action and goals.

"I suppose you need two minutes to pour your soul" (P020)

“nobody’s actually said, “You know, how are you actually coping with it?” and I think…I mean it’s bound to have affected me in some ways because it’s a real drain on your emotions but nobody…although they talk about, you know, the physical side of it nobody’s actually said, “How is it affecting you emotionally?” (P011).

6.4 Discussion

This study addressed patients’ needs and preferences of follow- up care. Patients wanted be consulted and involved in changing services or implementing new models of care so that these are aligned to their needs. The most striking finding from this study was that patients wanted a change in their traditional follow-up and wished to explore other models of care but their views had not previously been sought. Patients were frustrated with the traditional scheduled follow-up system and wanted to be seen only when unwell, except for compulsory reviews such as colorectal cancer screening. Alternative approaches to follow up care were met positively, with some conditions placed upon them, including their need to remain under specialist care. Patients placed value on the expertise of the gastroenterologist or IBD nurse and the relationship they developed. Their ‘ideal’ consultation comprised of being listened to by a knowledgeable practitioner and helped to devise a plan of action.

Self-management

Patients felt that they were ‘self-managing’ their illnesses to some degree but many were unclear that ‘self-management’, in addition to health promotion and lifestyle, was a guided, supportive, IBD specific programme to help them manage their illness. The concept of self-management required explanation and patients held very strong views about whether this was the right way forward or not. This study discovered four categories of patients, three of which were willing to enter into self-management programs. It was evident from this study that patient selection is paramount to the success of self-management in IBD. Some patients needed more time to recognise how their body reacted to their disease whilst some did not want to self manage in any form. The emergence of these categories perhaps reflects the complex nature of IBD and how it impacts on the individual, both physically and psychologically.

Self-management has been implemented in many IBD studies and has resulted in reduced consultation rates and reduced costs (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003). Self-management led to earlier treatment interventions for flare-ups and reduced the risk of potential complications related to the relapse (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003). Self-management in other long-term conditions has been shown to improve health outcomes for patients (Gibson 2009) and the Year of Care Programme for diabetes may be a model of care that could be used with IBD patients (Diabetes 2010)

However, questions remain about the concept of self-management such as its effectiveness for patients with IBD and its effect on the quality of life (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003). One reason for this is that self-management is not well defined and encompasses a wide range of initiatives (de Silva 2011). Any self-management programme must be compatible with other systems of care for those patients that cannot, or do not want, to self-manage.

Patient-initiated consultations / open access

The problem with the fixed appointment system and the rigidity of the outpatient structure means that patients' reviews may not coincide with an actual or impending relapse in their illness trajectory. The patients in this study suggested that patient-initiated consultations would offer some degree of control. One of the main fears identified was not being able to get back into secondary care to be reviewed during flare-ups, which has been identified in previous studies (Williams, Cheung et al. 2000). Patients wanted confidence in the system otherwise they would default to presenting themselves to emergency departments. Also not all patients wished to self-refer and relied heavily on face-to–face contact.

Patient-initiated access challenges the traditional follow-up schedule and reduces the volume of unnecessary care whilst directing support to where it is needed most. Patient-initiated access has been studied as a stand-alone service (Williams, Cheung et al. 2000) or combined with self management (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003; Rejler, Spangeus et al. 2007). Patient-initiated access has been shown to reduce costs which, expectedly, were related to the reduction in hospital appointments (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003). However, evidence has found no difference in quality of life in patients who entered the patient-initiated referral with self- management compared to the traditional model of care (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003) suggesting that more research is required into this combined approach.

Potential role of GP

The patients in this study had little involvement with their GP. One of the key reasons for not seeking GPs' help was their lack of knowledge of IBD. Patients identified the following acceptable ways of integrating follow-up care with their GP: the GP service must be enhanced to ensure equitable treatment with secondary care; the use of patient care pathways; care management plans; clear guidance interlaced with 'triggers' for rapid referral; increased shared care; and the integration of services facilitated by an IBD outreach nurse. There are currently no IBD nurse outreach services in the UK but evidence from the heart failure specialist nurse may be used as a comparator. Moving the heart failure nurse into an integrated role between primary/secondary care, has led to a co-ordinated multidisciplinary primary service for patients with heart failure, linking directly back into secondary care during exacerbations (Pearson and Cowie 2005).

The prevalence of IBD has been found to be higher in primary care than previously identified. Although studies in the UK have found that GPs play an important role in IBD care (Stone 2003; Rubin, Hungin et al. 2004), with care shared equally between gastroenterologists and the GPs (Rubin 2000), none of the participants in this study reported consulting their GP. There is some thought that the payment-by-results system, implemented in the past decade in the UK, has changed this and patients are predominately managed in secondary care (Featherstone, Whittham et al. 2010). However, GPs need relevant education and support if they are to share IBD care with gastroenterologists (Stone 2003). GP knowledge has been reported in other studies (Tan, Holloway et al. 2012). The proposition of developing an enhanced GP service, enhanced by educational and practical support from the IBD team, was acceptable to all of the patients and would assist in addressing patients' confidence in GPs knowledge.

Tele-medicine

All but one study participant welcomed the use of tele-medicine into their follow-up care, many preferring the use of smart phones and web portals instead of the landline telephones. Patients who were self-confessed 'techno-phobes' welcomed the idea of 'paper' clinics, or remote monitoring (van Dullemen, Doorn et al. 2005; Hunter, Claridge et al. 2012), the use of postal questionnaires to remotely monitor symptoms and quality of life. 'Virtual' care or tele-medicine, as an adjunct to patient-initiated consultations and self management, was identified within this study as an optimal approach to follow up care.

The term 'virtual clinic' encompasses tele-medicine (Krier, Kaltenbach et al. 2011; Cross, Cheevers et al. 2012) e-health via the internet (Elkjaer, Shuhaibar et al. 2010), tele-consultations (virtual outreach) (Wallace 2002) and telephone clinics (Gethins, Robinson et al. 2007). These approaches to follow up care offer the patient an alternative way of being reviewed and monitored away from the hospital setting, often at home(Holman and Lorig 2000). Recent developments in technology have led the way for an explosion in tele-health through which therapy can be delivered at any time and in any place (Rosser and Eccleston 2009).

The value of follow-up care and the 'ideal' consultation

Participants wanted alternative approaches to their follow-up care but held strong views about the value of the face-to-face consultation and its 'ideal' content. Patients wanted to retain an albeit reduced level of specialist management and face-to-face consultation when needed. During these they required ‘time’ to talk about their disease and ‘continuity’. The value of follow-up care and the ‘ideal’ consultation reflect the trustworthiness and the depth of relationship between the patient and gastroenterologist or patient and nurse.

These views mirror the findings of the Impact Survey, where patients stated that they did not discuss an important matter with their gastroenterologist and they wished they would ask more probing questions (Wilson, Lonnfors et al. 2012). So if patients value the relationship they have with their gastroenterologist / nurse, to what extent do they really want new methods of follow-up care? When probed, there was greater emphasis on the *content* of the face-to-face consultation when part of an alternative model of follow-up care, as previously reported by European Federation of Crohns and Colitis Association (Ghosh 2007). This ‘continuity’ and ‘knowledge’ referenced by the patients is in keeping with the core conceptual framework of the patient-doctor relationship (Ridd, Lewis et al. 2009), and the ‘continuous healing relationship’, a relationship which is vitally important and can be sustained not just by face-to-face visits (Institute of America 2001).

6.5 Implications for practice

There is concern in the UK that services for patients with long-term conditions, including IBD, are not organised to promote independence. There is silo working in primary and secondary care (Schoen, Osborn et al. 2007). The integration of primary and secondary care may be brought together formally through the development of models of care which can be applied to any healthcare setting. All countries are being compelled to provide cost effective care in partnership with patients to meet their needs. The growing prevalence of IBD across all countries (Molodecky, Soon et al. 2012) is impacting the ability of specialist services in all countries to achieve this. Self-management, tele-medicine or ‘virtual care’ are types of follow-up interventions not specific to the UK, with The Netherlands (van Dullemen, Doorn et al. 2005) Denmark (Elkjaer, Shuhaibar et al. 2010) and America (Krier, Kaltenbach et al. 2011) adopting ‘virtual IBD care’.

Patients are now being encouraged to contribute to the planning and development of health services and measuring patient experience is central to this (Poulton 1999; Sofaer and Firminger 2005; Black and Jenkinson 2009). Understanding the views of patients and engaging them in decisions about treatment and services can help improve the patient's experience of care and improve the patient's management of their condition within any healthcare setting or country. Engaging patients can also link the commissioning decision to the needs of the service user rather than the service and assist in the commissioning of them (Crawford, Rutter et al. 2002; DH 2003).

This study has identified patients' follow-up care needs and preferences. It is clear that one approach does not suit all patients and a variety of approaches should be considered. Patients want flexibility and choice. The lesson to be learned from previous research and the findings of this study is that patients' must be involved in the development of health service delivery and have confidence in the new approach. However, the views of gastroenterologists and other healthcare professionals must be sought prior to changing the follow-up care system to determine if the change would be acceptable and feasible. Reducing face-to-face consultations must be weighed against the impact it may potentially have on specialist medical training. Appropriate follow-up care within IBD contributes to patients disease outcomes. It is essential for drug reviews, disease assessment to help identify early complications of IBD, and reduce the development of complications as well as the psychosocial assessment of patients. The suggestion from patients within this study is that well patients can be reviewed by an enhanced GP or 'virtually' and complex patients should remain within a face-to-face specialist care system. Any new model of follow-up care must be subjected to rigorous testing with outcomes measured such as symptoms, functioning, patient reported outcome measures and acceptability.

There are limitations to this study. Qualitative research cannot be said to be generalisable but its strength lies in the *transferability* of knowledge to other contexts (Lincoln and Guba 1985; Paley and Lilford 2011). The sample comprised more patients with CD (18 CD, 6 UC) and these patients may have had more complex healthcare management than patients with UC, resulting in more follow-up care attendances. However studies have found no difference in quality of life in both CD and UC (Guthrie, Jackson et al. 2002). The hospital is a major hub for IBD care in the UK and the cohort were taken from a large tertiary centre. The participants may have had more complex disease than patients managed in a small hospital and this would reflect their follow-up care needs and preferences. However, both small District General Hospitals and large Foundation Trusts are experiencing the same problem of overbooked clinics and a growing demand on specialist health services. The option for more nurses or gastroenterologists to meet this demand is unlikely to be the way forward. The answer lies in new ways of working.

6.6 Conclusion

Studies of self management (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003), patient-initiated consultations (Williams, Cheung et al. 2000) and tele – health in IBD measured patient satisfaction but no patients were involvement the design of the interventions. There are challenges when engaging patients in developing healthcare services but there are clear benefits to changing the traditional secondary care based approach to follow-up care for patients with IBD. This study is the first to provide a unique insight into patients' perceptions of how follow-up care should be planned and delivered. It is clear that some needs are unmet and patients want change. The recommendations from patients outlined in this study: the need *not to be seen* when well; 'virtual' care as an adjunct to patient-initiated consultations, self management, integrated care with GP and IBD outreach nurses, were identified as optimal approaches to meeting their needs. These would form a complex model of follow-up care but one that could improve the patients' experience of care. New models of care offer potential cost savings with the reduction in face-to-face consultations and allow targeted care to those who need it at point of access, the patient with complex disease or during a flare-up.

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Contribution of authors: All authors made substantial contribution to the manuscript. KK designed the qualitative study and conducted the interviews. The topic guide for the semi-structured interviews was developed by KK, JG, SC and KL. Analysis of the data was conducted by KK, JG and KL. The manuscript was drafted by KK. JG, SC and KL contributed significantly to the draft of the manuscript and revised for intellectual content. All four authors read and approved the final manuscript.

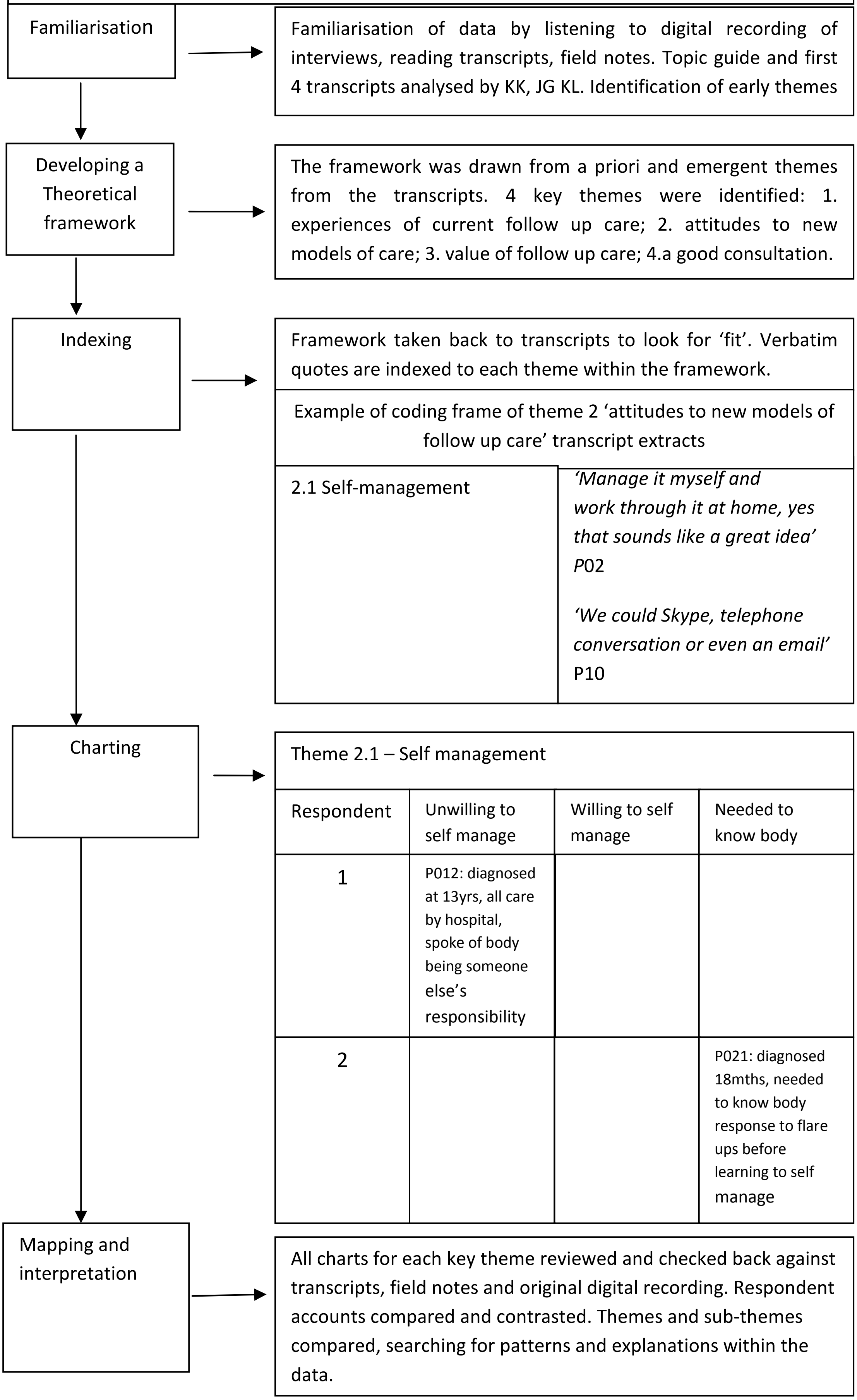
The manuscript, related data, tables or figures, has not been previously published nor under consideration elsewhere.

Table 14: Demographics and patient characteristics

Participant	**Gender**	**Median Age 48.5 yrs (range 27-72 yrs)**	**Disease**	**Median Disease duration 11.5 yrs (range 2-40yrs)**
P01	M	50	CD	29
P02	F	54	CD	36
P03	F	50	CD	9
P04	M	38	CD	15
P05	F	60	UC	22
P06	F	60	CD	7
P07	F	40	CD	7
P08	F	31	UC	10
P09	F	48	UC	6
P010	F	27	CD	14
P011	F	57	CD	3
P012	F	31	CD	18
P013	M	72	CD	40
P014	F	62	UC	2
P015	F	44	CD	20
P016	M	58	UC	10
P017	F	48	CD	13
P018	M	68	CD	38
P019	M	27	CD	3
P020	M	49	CD	30
P021	F	47	CD	20
P022	M	41	CD	25
P023	F	24	CD	13
P024	M	41	UB	17

CD= Crohns Disease; UC= Ulcerative Colitis; M= Male; F= Female

Figure 13: Framework Analysis Example of self-management theme



Familiarisation

Familiarisation of data by listening to digital recording of interviews, reading transcripts, field notes. Topic guide and first 4 transcripts analysed by KK, JG KL. Identification of early themes

Developing a Theoretical framework

The framework was drawn from a priori and emergent themes from the transcripts. 4 key themes were identified: 1. experiences of current follow up care; 2. attitudes to new models of care; 3. value of follow up care; 4.a good consultation.

Indexing

Framework taken back to transcripts to look for ‘fit’. Verbatim quotes are indexed to each theme within the framework.

Example of coding frame of theme 2 ‘attitudes to new models of follow up care’ transcript extracts	
2.1 Self-management	*‘Manage it myself and work through it at home, yes that sounds like a great idea’* *P*02 *‘We could Skype, telephone conversation or even an email’* P10

Charting

Theme 2.1 – Self management

Respondent	Unwilling to self manage	Willing to self manage	Needed to know body
1	P012: diagnosed at 13yrs, all care by hospital, spoke of body being someone else’s responsibility		
2			P021: diagnosed 18mths, needed to know body response to flare ups before learning to self manage

Mapping and interpretation

All charts for each key theme reviewed and checked back against transcripts, field notes and original digital recording. Respondent accounts compared and contrasted. Themes and sub-themes compared, searching for patterns and explanations within the data.

Box 1: Topic guide

The overall objective was to explore the patient's needs of their follow-up care, their experience of the current system and how they would wish it to be reorganised. Breaking down the key elements of the value and meaning of follow- up care.

Review of history of diagnosis and disease (will be referred back to when describing follow- up care experiences)

Experience of follow up care: Need to define follow-up care prior to this.

- Experience of follow-up care: Probe positive and negative aspects of follow up care they have experience of, the setting, why good or bad, problems identified, why they feel this way, what might account for this.
- How important is follow-up care.
- Ask participant to 'walk through' their follow-up care routine.
- Has their needs of follow-up care changed over the years.
- What did they want from follow-up care when first diagnosed?
- What do they want from follow-up care now?
- Is follow up care system providing everything needed in terms of your IBD, such as health promotion,
- How important is face-to-face contact?
- What happens when they don't get a follow-up appointment, or when they don't attend?

Other follow up care interventions: Probe their knowledge of other types of interventions, may need to outline types of follow-up interventions, offer scenarios if no knowledge of other interventions

1. How do they feel about managing their disease with no scheduled follow-up?
2. If you are unwell and try to manage your illness, how do you do this? At what point do you make that phone call to ask for help?
3. What do you think about patient initiated appointments, open access?
4. What do you think about tele-health or 'virtual' clinics, remote monitoring?
5. Are there other ways of providing follow-up care?

Changes to the current follow up system: Probe fully:

1. What would you change about the current system and why.
2. What specifics would you like to see changed.
3. Discuss the setting and why.
4. Discuss the time and why.
5. Discuss the 'who' and why.
6. Are we missing anything? i.e. psychological issues, health other than IBD?

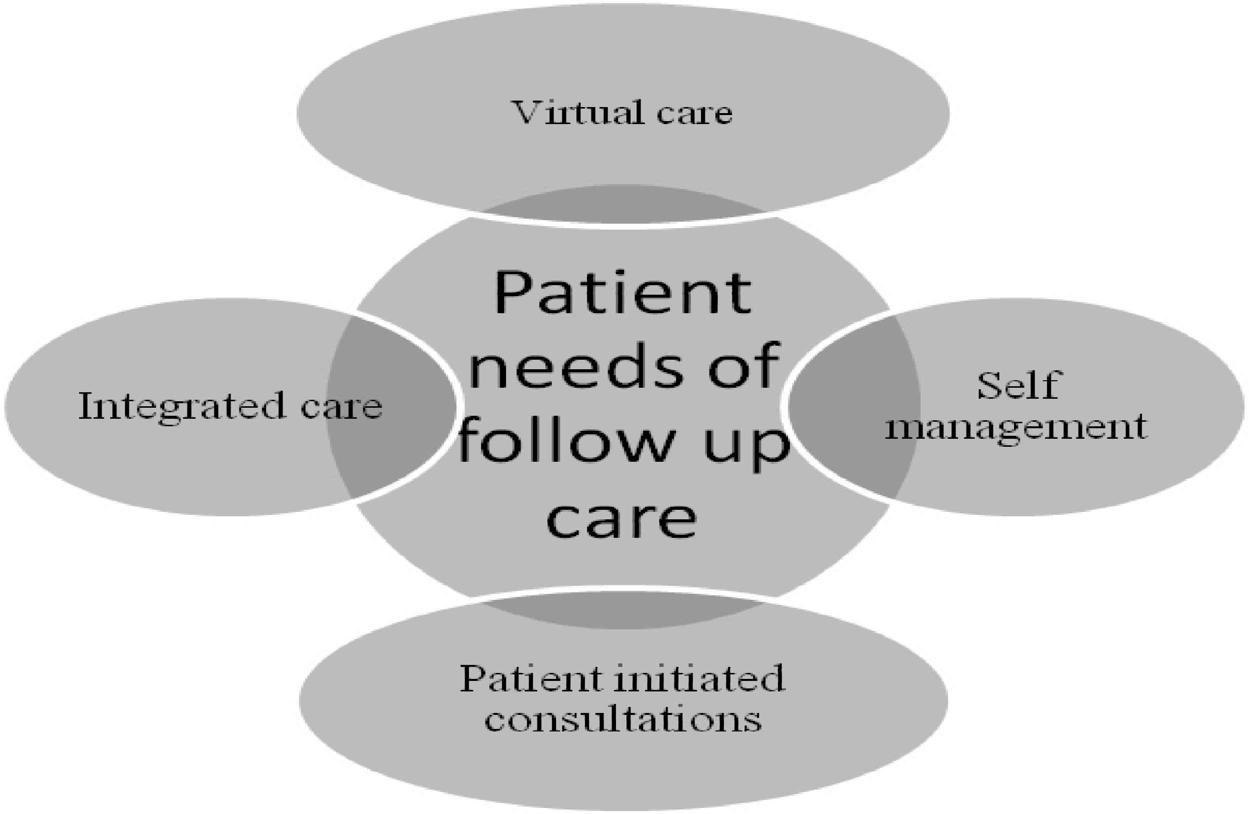
The perceptions of patients with IBD of health care provision

Summarise: Is there anything the participant would like to add about their experience of follow up and what they would like to see changed

Table 15: Developing framework themes - Patients

Early emergent themes	**Refined themes**	**Framework**
Frustration with current system	Frustration of current follow- up service	**Experience of follow up care service**
Choice of follow- up routine	Integrated GP IBD care	
Integrating GP into care	Self management	**Attitudes to new models of follow-up care** (*self management; GP integrated care*; *patient initiated consultation; 'virtual care*)
Self management	Patient initiated consultations	
Role of GP	'Virtual' care	
Patient initiated consultations	Value of follow up care	
Crisis helpline	Ideal consultation	**Personal value of follow-up**
Virtual care		
Tele-health		**The 'ideal' consultation**
Remote monitoring		
Value of follow up care		
Ideal consultation		

Figure 14: Patient needs of follow up care



Paper 3

General practitioners' perspectives of inflammatory bowel disease management in primary care.

Kemp K, Griffiths J, and Lovell K.

Submitted

Title

General practitioners' perspectives of inflammatory bowel disease management in primary care.

Authors

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Abstract

Background

Inflammatory bowel disease (IBD) is a long term condition (LTC) with a low incidence and low prevalence. Predominantly managed by secondary care, patients follow a traditional follow-up cycle, a practice in the current climate which is unsustainable and unsatisfactory. There is a drive to transition patients with LTCs into primary care but General Practitioner (GP) involvement is central to effective service development and implementation.

Aim

To explore GPs perspectives of IBD care, their role and responsibilities and identify how care in a primary care setting could be facilitated.

Design and Setting

A qualitative study using semi-structured interviews with GPs in the North West of England in 2011.

Method

Semi-structured interviews were conducted with 20 GPs. Purposeful sampling was used to capture a variety of experience of IBD care and diversity of views. Interview transcripts were analysed using Framework analysis.

Results

The predominant theme surrounded transferring IBD patients into primary care. Barriers identified were health policy, communication, knowledge and management of IBD, inclusion into Quality Outcome Framework, and secondary care. Facilitators included a range of practical recommendations of how IBD care should be administered: primary care management plans interlaced with ‘triggers’ for rapid referral to specialist services; rapid referral based on a follow-up tariff; and the integration of services facilitated by an IBD outreach nurse.

Conclusion

GPs wanted to be involved in IBD care. They were willing to implement new ways of working to ensure this and there was a great deal of frustration about secondary care. There is a clear need to share responsibility of IBD care within an integrated framework.

Key words

Inflammatory bowel disease; general practice; primary care; secondary care; qualitative.

How this fits in

Recent health care policy has emphasised the transition of long term condition management away from a hospital setting and back to primary care. IBD is a chronic disease of low incidence and low prevalence which follows a remitting and relapsing course. The unpredictable nature of IBD, varying need for medication, and the long term requirement for colorectal cancer surveillance has traditionally rooted patients under the follow-up care of hospital specialists. To provide appropriate quality care and enhance patient experience, a flexible integrated service to manage IBD patients between providers is essential. There is currently a lack of literature on how IBD patients should be managed within primary care, or how an exemplar, safe and consistent model of shared care should be established. With practical recommendations from GPs, this study identifies the barriers to overcome and the facilitators required to manage IBD patients in primary care.

7.1 Introduction

IBD comprises Crohn's Disease (CD) and ulcerative colitis (UC), and is an idiopathic, chronic inflammatory intestinal condition which follows a remitting and relapsing pattern. The incidence and prevalence of IBD is increasing and approximately 240,000 people are affected in the UK (Mowat, Cole et al. 2011). Follow-up care of long term conditions has been policy driven over the past decade (Featherstone, Whittham et al. 2010; Corrigan and Mitchell 2011)· The avoidance of unneccessary follow-up appointments, follow-up appointments in an appropriate care setting and a systematic integrated approach to care for patients with long term conditions would significantly improve service delivery (Institute for Innovation and Improvement 2007a). Self management, redesigning roles in general practice (Institute for Innovation and Improvement 2007b) and the drive to offer patient choice, treat patients closer to home, commission services by GP consortia and clinical commissioning groups (CCGs) (DH 2010) is changing the landscape of long term conditions care from secondary services into primary care. A percentage of IBD care could be transferred into primary care but an understanding of GPs' views should first be explored.

IBD care is predominantly delivered by secondary care and is a 'super-speciality' within gastroenterology (Irving 2012). Literature suggests Gastroenterologists follow-up IBD patients indefinitely (Probert, Jayanthi et al. 1993) reporting a perceived need to review symptoms, medications and blood tests, and express an unwillingness to discharge to primary care. It is also believed that patients expect secondary care hospital treatment (Burkey, Black et al. 1997). IBD patients follow the traditional follow-up care cycle yet this conventional practice in the current climate is both unsustainable and unsatisfactory, for the patient and provider alike. The relapsing and remitting pattern of IBD questions whether the current approach to care is the best way.The utilization of current out-patient spaces to regularly review stable patients is not just inappropriate for patient and CCGs, but places unnecessary strain on secondary care services.

To move a percentage of IBD patients from secondary services back into primary care, GP involvement is central to effective service development and implementation. Few studies have explored users' views of an acceptable service, or primary care's (GPs') role in the management of these patients. GPs are seldom consulted over the organisation of secondary care services, in particular one such as IBD, and how secondary care can support GPs. There are currently no existing models upon which to develop IBD services in primary care and a lack of evidence base on how best integrate primary and secondary care provision.

This study aimed to examine IBD care in both primary and secondary care from the GPs' perspective, to establish their perceived role and responsibilities in managing IBD patients and to identify how the provision of care in a primary care setting should be facilitated.

7.2 Method

A qualitative approach was adopted, using an interpretive framework(Ritchie and Lewis 2003). Semi-structured face to face interviews were conducted with 20 GPs within the North West of England in 2011.

Sample and data collection

20 GPs were recruited, 19 from the Primary Care Research Network (PCRN) (PCRN) and one from the Primary Care Society for Gastroenterology (PCSG) (PCSG). The PCRN invited 65 GPs to participate. 25 GPs contacted the PCRN and their details passed onto the researcher. Once the GPs had agreed to participate they were contacted directly by the researcher and sent out an information sheet, study protocol, and consent form. GPs were further purposively sampled from large and small practices, rural and inner city, deprived and affluent.

Interview schedules were developed to explore GPs' current role in IBD diagnosis and management during quiescent disease and flares. Their views on the role of primary care in IBD management, existing barriers that impede primary care delivery, shared care between primary and secondary care issues, and how integrated care could be better provided and shaped within the new NHS climate (DH 2010) were explored. 17 interviews took place in GPs' surgeries, 3 in GPs' home, and were digitally recorded, transcribed verbatim and coded.

Table 16: Characteristics of GP practices

GP ID	**Gender**	**Description of Practice**	**Practice size**
GP01	Male	Inner city	2.500
GP02	Male	Inner city	8,300
GP03	Male	Inner city	N/A
GP04	Male	Inner city	2,900
GP05	Male	Rural	16,000
GP06	Male	Inner city	3,900
GP07	Female	Rural	6000
GP08	Female	Inner city	8,500
GP09	Male	Inner city	3000
GP10	Male	Inner city	6,300
GP11	Male	Inner city	16,000
GP12	Male	Inner city	17,500
GP13	Male	Rural	4,500
GP14	Male	Locum	N/A
GP15	Female	Inner city	4,500
GP16	Male	Inner city	2000
GP17	Male	Rural	6,500
GP18	Male	Inner city	5,900
GP19	Female	Inner city	4,000
GP20	Female	Locum	N/A

Analysis

Analysis utilised the 'Framework' approach (Ritchie and Lewis 2003; Spencer, Ritchie et al. 2003), a method of analysis suited to applied policy research. Framework is a deductive method of data analysis working from pre-set aims and objectives strongly informed by a priori reasoning (Pope, Ziebland et al. 2000; Ritchie, Spencer et al. 2003). Framework analysis has five steps: familiarisation, identification of recurrent themes to develop an analytic framework; indexing; charting and mapping and interpretation. Key themes and concepts expressed by participants formed the basis of the framework which classified the data (Ritchie and L. 1994) (see table17: Developing framework themes, pg 186). Data were managed using NVivo© 9.0. (see Figure 15: worked example of Facilitators to care using framework analysis, pg 187).

7.3 Results

Participant and Practice characteristics are shown in table 16, pg 177. Interviews lasted on average 48 minutes (range 28 – 79 minutes). The main themes to emerge surrounded transferring IBD care to primary care and were (1) barriers, which included health policy, secondary care, communication, knowledge and management of IBD, IBD inclusion to the Quality Outcome Framework (QOF) and an overwhelming feeling of frustration directed at secondary care and the NHS tariff system and (2) facilitators which included a range of practical recommendations.

Barriers

Policy agenda

GPs felt powerless to change any aspect of the NHS system. Some claimed to being tied to block contracts with their secondary care provider and felt that care was driven by cost not quality.

'But the tail's wagging the dog isn't it really, we're keeping some enormous great hospital running and were doing these things in order to pay it, well that's ridiculous really, it grieves us' (GP15).

Payment by results and differing NHS payment tariffs for new and follow-up hospital appointments left GPs feeling hindered, unable to offer patient choice or flexible cost effective care. GPs wanted to manage their own patients, with an option to rapidly refer back into hospital under the same gastroenterologists when clinically required. The imposition of a 'new' patient tariff for such a referral was a contentious issue.

'*When hospitals became foundation trusts and they went on to the policy of payment by results it's hardly payment by results, it's payment per unit of activity. So the hospitals have fleeced primary care trusts'* (GP07).

Secondary Care

GPs expressed frustration about the role of secondary care. Many of these frustrations were based upon the perception that IBD is a disease of secondary care.

‘It’s a disease that has been diagnosed in secondary care, it’s a disease that has been maintained in secondary care’ (GP18).

GPs wanted to be more involved with the management of patients but felt they were not given the opportunity. They were critical of a system that held patients in secondary care with no option for GP involvement.

‘Secondary care are hanging onto people who don’t need to be hung on to...it drives me to distraction and it just perpetuates bad medicine’ (GP10).

‘Surely self management is the way to go, with open access but I want the patients to come to me first, not go to secondary care, the IBD nurse or whatever. That is how it should work. We are in the best position to manage people with long term conditions, we have to be’ (GP18)

The value of repeat follow-up appointments in ‘well’ patients was questioned by all GPs who did not recognise the appointments as a valued clinical consultation. They were described as ‘*reassuring cuddle appointments’* (GP04), with the perceived unnecessary follow-up appointments viewed as ways to generate ‘soft’ money for hospitals. Follow-up appointments for ‘well’ patients were believed to deskill and disempowered the GPs, perpetuating notions of IBD as a disease of secondary care. GPs were completely taken out of the loop with no patients seeking their advice. Some GPs placed the blame with the Gastroenterology Consultants repeatedly telling patients to telephone them if they became acutely unwell. Such by-passing of GP was believed to reinforce the concept that hospitals are best placed to manage these patients, which GPs felt impacted upon patients’ lack of confidence in GPs’ ability to manage them. GPs also felt that patients were measuring them against their secondary care colleagues. Comprehensive care from Gastroenterology Consultants and IBD Nurse Specialists raised patient expectations which GPs could not meet.

‘*So there’s a conception out there that patients feel that the disease is at a much higher level than what can be done by the GP, they have more or less been made to feel special, they’ve got a consultant who follows them up regularly, they’ve got a nurse who more or less answers all of their calls’* (GP18).

Low prevalence and incidence

Due to its low prevalence and incidence, GPs reported low exposure to IBD with few actual patients within their practice. GPs felt there was a '*mystique*' (GP03) about IBD, a disease they were not allowed to get involved with. GPs recognised that IBD was a long term condition and providing chronic disease management was within their remit. Most were confident about managing patients when well or with mild disease yet were apprehensive about managing IBD during a flare. Few GPs had attended educational updates to develop their IBD management skills and when they did so, felt that management issues were focused on secondary care.

A main source of knowledge in managing IBD patients came from the patient themselves. Great emphasis was placed on patients directing and negotiating their care with GPs, directing them in prescribing and developing the GPs knowledge.

'*Usually the patient can tell you what worked last time or what didn't work last time'* (GP12).

'*Can you prescribe me some mesalasine enemas or something, whatever and then I'll say, Okay, fine, I'll do that, I'll see you in ten days time to make sure you're OK'* (GP10).

Poor communication

All GPs expressed concerns about lack of adequate communication between primary and secondary care. GPs did not know who to contact and returning their calls came too late. The quality of letters was poor offering no guidance regarding medications or an action plan in the event of a flare. GPs were unsure about what the Gastroenterology Consultants wanted them to do.

'It wouldn't make any difference to us if our patients went to hospital in Belgium, I've said that for years and years. If they went to Belgium they would be no different. It doesn't matter that they go locally because the gulf is hundreds of miles wide, it wouldn't make any difference as long as they got the letter back in English' (GP06)

Quality and Outcomes Framework for IBD

There were mixed responses about including IBD within the QOF. Some GPs termed the framework as '*tramline medicine*' (GP02) with IBD another tick box exercise. They suggested that not all care should be directed by the framework as this suggests that GPs do not care about conditions unless they are within the framework.

‘*Everyone seems to want their particular pet QOF as some kind of status symbol to say that if it isn’t on QOF we don’t care about it’* (GP04).

Others believed that including IBD in the framework would raise its profile in primary care and make GPs obliged professionally, morally and financially to manage IBD.

Facilitators to care - Recommendations

There was consensus that a large portion of IBD could be managed away from hospital and delivered by a primary care. GPs recognised that primary care meant a package delivered by the team and that they were in a much better position to manage IBD as they understood patients and family circumstances.

GPs proposed recommendations about the way IBD care should be managed (see table 17, pg 186), with the key change being stopping routine hospital appointments when a patient is well. They felt that patients should be directed to their GP for them to decide on appropriate need for follow-up. Additionally, should a patient become acutely unwell, the potential to refer to a rapid access specialist in IBD was vital.

GPs were secure in managing well patients and some saw this as a trade off, allowing secondary care to consider other services to care for more complex patients.

‘Give us your well controlled colitics, give us your well controlled Crohns Disease and its going to cost us this much to look after them which is far less okay? Now as a soft option, what would you like to do? More colonoscopy’ (GP03).

‘*The magic words, shared care, and I do think that is the future. I think that just as I’m talking about improving the skills of general practitioners by enabling them to provide chronic disease management for these patients with an exacerbation service in the hospital, I’m sure the secondary care clinicians would be happier spending more time dealing with the complex cases for which they’re trained and less time seeing people who come in and say well I’m fine doc, I know how to handle my disease, see you next year* (GP01).

Written management plans, pathways of care and greater shared care were requested by all GPs, with some suggesting that a pathway of care could be included in their electronic reporting systems.

'*A good written plan of action is what we need for each patient, what to do if this happens, increase this for two weeks and the do bloods. Teach the patient to manage their condition, work with us. No more of these cuddle appointments, patient is managed where he should be, no waste of resources, and back to you for expertise when he needs it. It can't be any simpler. I just wonder why it doesn't happen'* (GP12).

All but one GP suggested that an IBD Nurse Specialist in the community would be effective in managing IBD patients in primary care to interlink with secondary care services.

'*That could be done in partnership with Primary Care, there are triggers...I mean the heart failure system works like that and it works quite nicely'* (GP01).

The recommendations came with one caution, cancer surveillance must remain the responsibility of secondary care with a robust recall system for scheduled colonoscopy.

7.4 Discussion

Summary of main findings

Three key messages emerged from the analysis: the GPs wanted to be involved in IBD care; they were willing to implement new ways of working to ensure this; and there was a great deal of frustration about secondary care.

GPs highlighted their role as family carers, providing holistic continuity of care extending beyond the disease (McWhinney 2000), which secondary care is unable to provide. GPs wished to resume care of IBD patients once diagnosed and stable, yet recognised their knowledge deficit in managing acute relapses. This has been reported in other studies (Tan, Holloway et al. 2012). GPs' recommendations in this study addressed these issues by requesting patient care pathways or primary care management plans, clear guidance interlaced with 'triggers' for rapid referral, increased shared care (Travis, Stevens et al. 1997; RCGP 2007; Crowe, Cantrill et al. 2010), and the integration of services facilitated by an IBD outreach nurse. There was no consensus on whether IBD should be within QOF, illustrating the controversy of whether care is disadvantaged if it is not measured or rewarded (Heath, Rubinstein et al. 2009; Raleigh and Foot 2010). This reflects the diverse national opinion toward the framework (Gillam and Siriwardena 2010) .

The study highlighted GPs frustration and tensions, not only with secondary care and IBD, but also with the NHS costing system as a whole. GPs raised concerns that resources and money must follow the patient. Although there was a degree of uncertainty regarding GP consortia and CCGs, there were positive feelings that current problems faced would be addressed within the new systems.

7.5 Strength and limitations

The strengths of this study are that in-depth views of GPs were explored about a low prevalence and incidence long term condition in secondary and primary care. It focused on an under researched area and provided an insight into how GPs wish to provide IBD care, their roles, responsibilities, frustrations, tensions and barriers to implementing this care. Another strength was that GPs were purposively selected from a range of practices to capture a variety of experiences of IBD care and diversity of views.

The study also has limitations. The PCRN invited 65 GPs across the North West to participate in the study. The descriptions of the total population of GPs who did not participate or reasons why, are limitations recognised within this paper. The sample of GPs was self-selected, volunteering to be interviewed after being approached by the PCRN. However, when asked why they agreed to take part in the study, they reported that follow-up care in long term conditions and how primary and secondary care can work together were important subjects and this type of approach to reorganising care was a proactive step forward.

7.6 Comparison with existing literature

One study has explored GPs views of IBD but this was about open access in IBD (Cheung, Dove et al. 2002). There is no existing literature that examines views of GPs regarding IBD care, their roles, responsibilities, and how IBD care should be managed within primary and secondary care, particularly within the current NHS climate of change and uncertainty.

The quality of life in patients managed in primary care has been found to be similar to those managed in secondary care (Rubin, Hungin et al. 2004). A survey in the UK found that GPs wanted more specialist education and wished to extend their role within IBD care (Moody, Mann et al. 1993). Within the UK it has been reported that IBD is more prevalent in primary care than previously thought (Rubin 2000) but an Australian survey reported that GPs care for relatively few IBD patients on a regular basis and were in general uncomfortable with IBD management (Tan, Holloway et al. 2012). The Australian study also supported the role of an IBD nurse specialist adopting outreach support and responsibility for the majority of care.

7.7 Implications for practice and research

Involving GPs in IBD care is a natural progression within the NHS and this paper reports practical solutions to assist this. This study supports the idea that long term follow up for IBD in secondary care and primary care should be reviewed and, taking on board the GP recommendations, a restructure of services could be undertaken. Although GPs’ attitudes were overall positive, a number of conditions were proposed. These included the need for written information for the patient, establishment of a specialist nurse for community contact and a more integrated approach between hospital, specialist nurse, GP and patient. The simple act of GPs referring patients back into secondary care keeps GPs in the loop, helps maintain their skills, and encourages patients to include GPs in their care. Many of the recommendations would take little effort to implement but both secondary and primary care would need to work together and take responsibility for their successful implementation.

The trend of moving secondary care services into primary care is seen as the way forward (DH 2010) with varying outcomes (Powell 2002). Currently there are no IBD Nurse Specialist working in either an outreach capacity or employed by primary care. The heart failure model, which was used as a comparator by the GPs, needs to be explored further (Pearson and Cowie 2005).

The findings highlight barriers to the transition of care but also the willingness of GPs to be involved. There is a clear need to share responsibility and seek Gastroenterologists' views of how they could work more closely with GPs within an integrated framework of care.

Funding Body

The research was funded through an NIHR Clinical Academic Training Doctorate Fellowship awarded to Karen Kemp.

Ethical approval

Ethical approval was granted from the North West 2 Research Ethics Committee REC number 10/H1005/50.

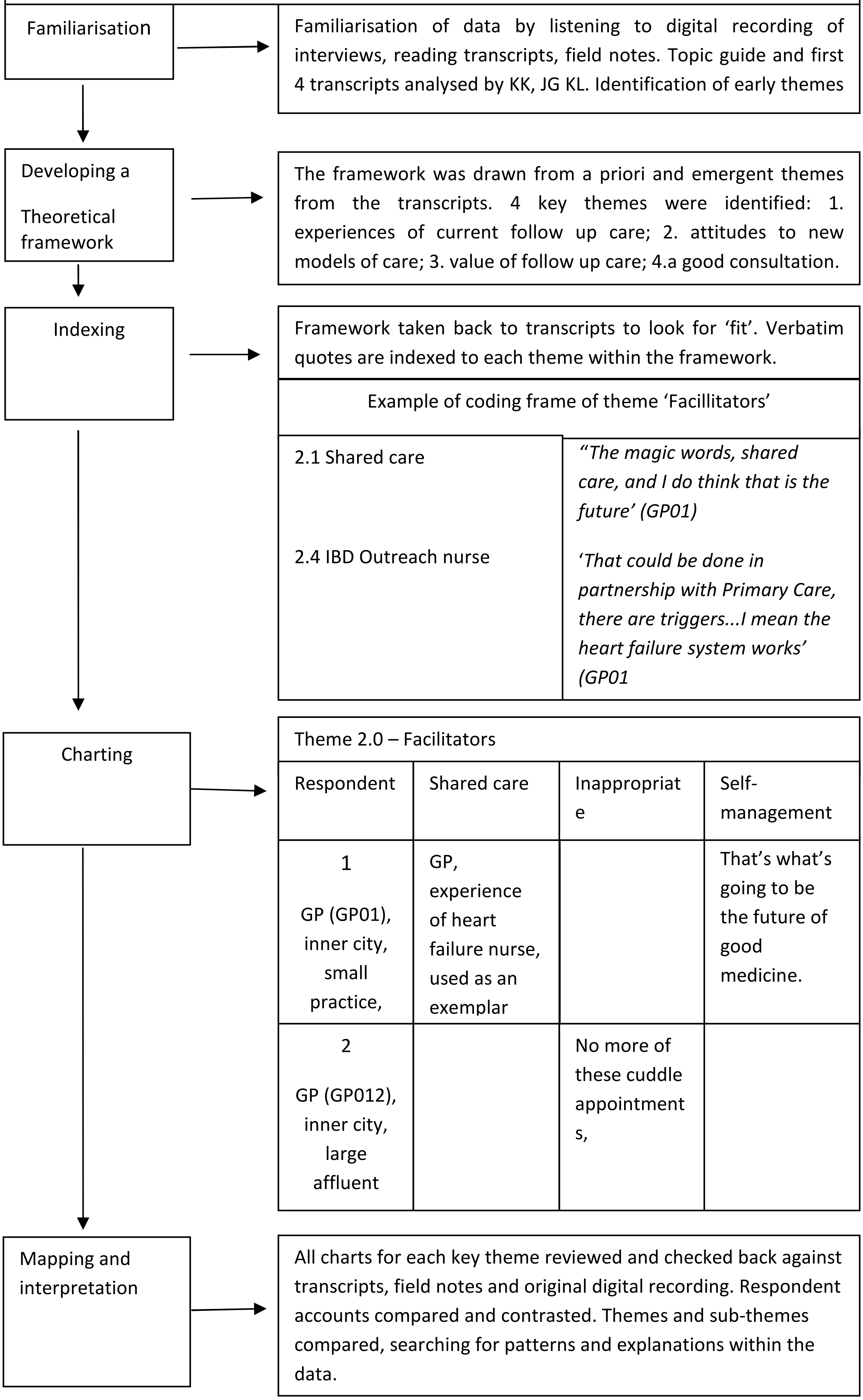
Competing interests

There are no competing interests.

Table 17: Developing framework themes - GPs

Early emergent themes	**Refined themes**	**Framework**
Attitudes towards secondary care	Policy Agenda	
Open access	Secondary Care	
Shred care	Low prevalence / low incidence disease	**Barriers**
Consortias and IBD	Poor communication	
External pressures	Quality Outcomes Framework	
Patient directing their care	Primary Care Management Plans	
Potential role of GP in care	Rapid access availability	
Secondary care role	Self-management	**Facilitators**
GP skills and knowledge	Shared care and communication	
Patterns of follow-up care	IBD Outreach nurse	
Role of IBD nurse specialist	Appropriate educational update	
Educational provision	Secondary care responsibilities	
Quality Outcomes Framework	Inappropriate follow-up care	
Self-management		

Figure 15: Framework Analysis example of ‘Facilitators’ theme



Familiarisation

Familiarisation of data by listening to digital recording of interviews, reading transcripts, field notes. Topic guide and first 4 transcripts analysed by KK, JG KL. Identification of early themes

Developing a

Theoretical framework

The framework was drawn from a priori and emergent themes from the transcripts. 4 key themes were identified: 1. experiences of current follow up care; 2. attitudes to new models of care; 3. value of follow up care; 4.a good consultation.

Indexing

Framework taken back to transcripts to look for ‘fit’. Verbatim quotes are indexed to each theme within the framework.

Example of coding frame of theme ‘Facillitators’

2.1 Shared care	*“The magic words, shared care, and I do think that is the future’ (GP01)*
2.4 IBD Outreach nurse	*‘That could be done in partnership with Primary Care, there are triggers...I mean the heart failure system works’ (GP01*

Charting

Theme 2.0 – Facilitators

Respondent	Shared care	Inappropriate	Self-management
1 GP (GP01), inner city, small practice,	GP, experience of heart failure nurse, used as an exemplar		That’s what’s going to be the future of good medicine.
2 GP (GP012), inner city, large affluent		No more of these cuddle appointments,	

Mapping and interpretation

All charts for each key theme reviewed and checked back against transcripts, field notes and original digital recording. Respondent accounts compared and contrasted. Themes and sub-themes compared, searching for patterns and explanations within the data.

Table 18: GPs’ Recommendations for IBD

GPs want to be more involved in the care of patients with IBD.
Well IBD patients do not require follow-up in secondary care, these can be undertaken in primary care. Complex IBD patients remain the responsibility of secondary care.
GP must be the first point of call when a patient relapses, the patient must not bypass the GP.
Secondary care should provide the GP with a primary care management plan for each patient, based on ‘triggers’ to guide the GP when to refer back to specialist clinic. The triggers must be developed by primary and secondary care.
The GP has access to a rapid referral specialist clinic in the event of a relapse and the patient presents as a follow-up and not a new referral. Access to the specialist clinic <1 week.
More emphasis on self management by the patient with open access but referral into clinic MUST be via GP and not patient initiated.
More emphasis on shared care and working together and communication.
Specialist IBD Nurse working in the community undertaking outreach clinics, following the model of heart failure nurses.
Regular ‘appropriate’ educational updates.
GP should be the main carer with support from secondary care in patients who are well or have mild disease.
Routine follow-up appointments must not be offered to the patient, patients should be directed to their GP.
Cancer surveillance remains the responsibility of secondary care

Paper 4

Developing a model of follow-up care for patients with inflammatory bowel disease using the MRC framework for the development of complex interventions: a description of the modelling phase

Kemp K, Griffiths J and Lovell, K

Prepared for submission

Title: Developing a model of follow-up care for patients with inflammatory bowel disease using the MRC framework for the development of complex interventions: a description of the modelling phase

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Author contributions: Kemp K designed and conducted the study. Griffiths J and Lovell K assisted to design and contributed significantly to each stage of the study. Griffiths J and Lovell K provided academic supervision throughout each phase of the study and Lovell K designed the modelling phase. All three authors read and approved the final manuscript.

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8.1 Introduction

Inflammatory bowel disease (IBD) is a chronic inflammatory disease of the gastrointestinal tract that is divided into two subgroups: Crohn’s Disease (CD) and Ulcerative Colitis (UC). They are characterised by periods of remission and relapse. Patients with IBD have predominantly been managed in secondary care and as it is a long term condition the common practice has been to follow-up these patients indefinitely. The aims of follow-up in IBD are to monitor the disease and drug therapy, to prevent flare-ups and so reduce the development of complications arising from flare-ups. People with IBD follow a traditional fixed scheduled appointment system but the fixed nature of this means that appointments are made months in advance, leading to a service which is inflexible, unresponsive and ultimately unable to match care with demand.

Follow-up care for IBD differs from that of many other healthcare situations due to the fluctuating needs of the patients. Several studies of follow-up care have explored and trialled self-management (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003) open access (Williams, Cheung et al. 2000; Rejler, Spangeus et al. 2007) and ‘virtual or tele-health (Krier, Kaltenbach et al. 2011; Cross, Cheevers et al. 2012; Hunter, Claridge et al. 2012) but none were developed from the patient perspective and there is no consensus as to which approach is the most acceptable and feasible for patients or general practitioners (GPs). A best evidence synthesis undertaken (Chapter 4) explored these different approaches to follow-up care and identified areas for further exploration such as why the quality of life (QoL) was no different in the control and intervention groups of the studies (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003), why a combined approach of self management and open access may be superior to open access alone or where tele-health fits in. There is also the potential for an integrated system which shifts the care of patients in remission into primary from secondary care.

There are no models of follow-up care for patients with IBD, which take into account the fluctuating nature of the disease and its chronicity, and there is also an absence of studies which have explored the patients’ views of an acceptable service, the role of primary care

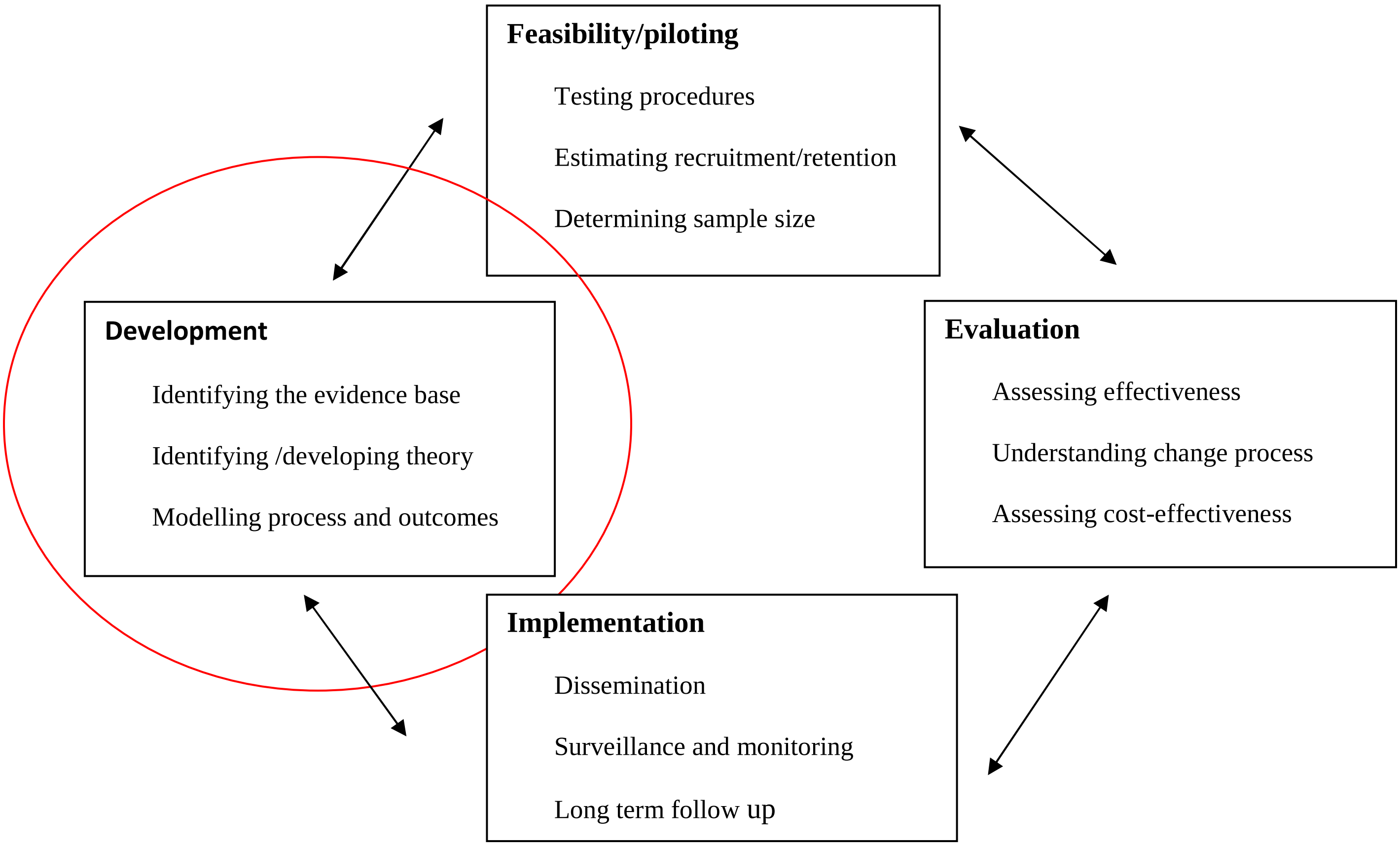
(GPs) in the management of these patients or maximising the potential role of the IBD Nurse Specialist. A service redesign of such scale should be effective, cost effective, feasible and acceptable to those receiving care and those delivering care. To ensure these characteristics a significant amount of preparatory work should be conducted prior to a full evaluation. The importance of such preparatory work has been highlighted by the MRC framework for the development of complex interventions (Craig, Dieppe et al. 2008). A model of follow-up care for IBD patients needs to be developed, one which is effective and takes into account the needs and preferences of patient and other stakeholders. A model which is acceptable to both users (patients) and stakeholders (GPs, Gastroenterologists, nurses, commissioners) is more likely to be implemented.

This paper reports a study in which the MRC complex interventions framework was used to guide the development phase of an acceptable integrated model of follow-up care for patients with IBD, later to be tested in a feasibility trial. The paper describes the processes undertaken to develop the intervention with emphasis on the description of the modelling phase of the MRC framework in which a stratified follow-up care model for patients with IBD was developed.

8.2 Developing the complex intervention

The MRC define a complex intervention as one that contains ‘several interacting components’ and a range of ‘dimensions of complexity’ (Craig, Dieppe et al. 2008). Theoretical and empirical work was used to identify the development phase of the framework, (see figure 16: MRC framework for complex interventions).

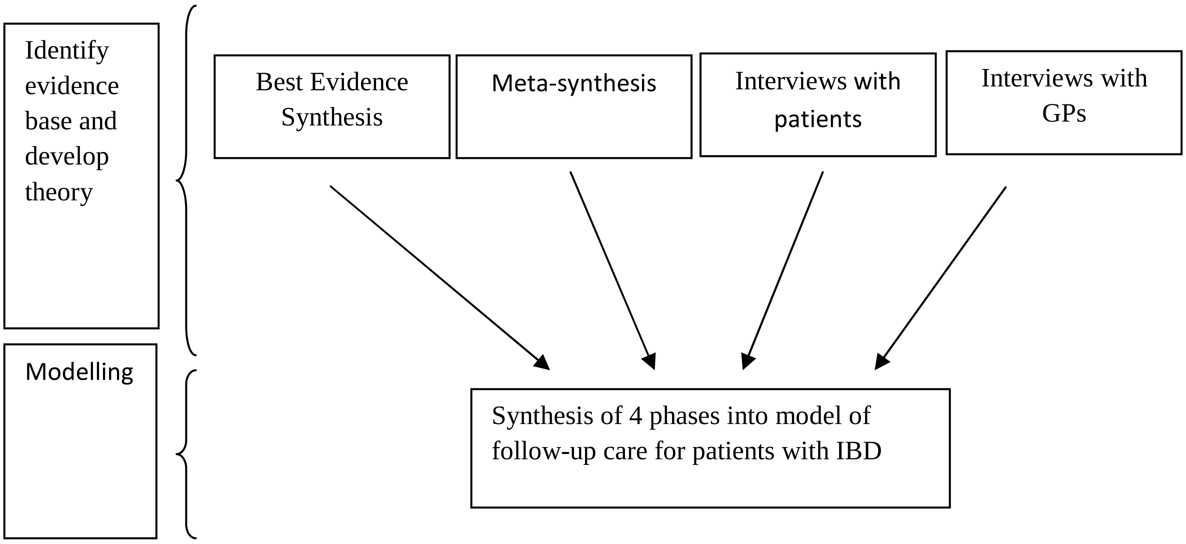
Figure 16: MRC Framework for development of complex interventions (Craig, Dieppe et al 2008) pg 8.



There is ambiguity however about how the modelling phase of the intervention should be carried out (Lovell, Bower et al. 2008). Several studies describe using the MRC framework and make reference to the modelling phase (Eldridge, Spencer et al. 2005; Hardeman, Sutton et al. 2005) but with no definitive way of carrying this out. Whichever approach is used, the modelling phase is a fundamental part of the process of developing the intervention. The aim is to identify the intervention components and how these interrelate (Hardeman, Sutton et al. 2005), base the intervention on this evidence and ensure that it is patient-centred (Lovell, Bower et al. 2008).

The methodology used here mirrors that used by Lovell, Bower et al (2008), Bradshaw, Wearden et al (2012) and Gask, Bower et al (2012). A series of separate but interrelated studies were carried out: (1) a best evidence synthesis to identify the evidence base of models used for follow-up in IBD (Slavin 1986); (2) a meta-synthesis to identify the health and social needs of patients living with IBD (Noblit and Hare 1998); (3) qualitative interviews with IBD patients to identify their needs and preferences of follow-up care; and (4) qualitative interviews with GPs to identify their current role and potential role in IBD within a primary care setting, (see figure 17)

Figure 17: Development of a model of follow-up care for patients with IBD



8.3 Identifying the evidence base

The evidence base drew from a best evidence synthesis and a meta-synthesis. Within the best evidence synthesis, 19 studies met the inclusion and exclusion criteria and were included in the synthesis. Of these 19, six were RCTs (Williams, Cheung et al. 2000; Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003; Elkjaer, Shuhaibar et al. 2010; Krier, Kaltenbach et al. 2011; Cross, Cheevers et al. 2012), one was a population based longitudinal design study (Rejler, Spangeus et al. 2007) and one a qualitative study (Cheung, Dove et al. 2002). Five were retrospective audits (Miller, Caton et al. 2002; Gethins, Robinson et al. 2007; Stansfield and Robinson 2008; Gethins, Duckett et al. 2011; Hunter, Claridge et al. 2012). The remaining six were abstracts of conference proceedings (Schilstra, Bouma et al. 2005; van Dullemen, Doorn et al. 2005; Castro, Cross et al. 2006; Duncan, Caulfield et al. 2010; Plener, Morgan et al. 2011; Jakobsen, Bager et al. 2012)

Of the papers reviewed in the best evidence synthesis there was a notable lack of patient involvement in developing models of care. Measuring patients' experience, needs and preferences are fundamental in the development of patient-centred care (Sofaer and Firminger 2005) and a model which is acceptable to them. Each of the studies demonstrated the value of their intervention but there were vital components missing within all of them. These included: the possibility of an integrated shared care system and how this would fit in; the knowledge and skills of GPs to enable integrated care; the needs and preferences of follow-up care from the patients' perspective, whether patients wanted their GP to be involved and if so how and to what extent; and how and to what degree GPs wanted to be involved.

The best evidence synthesis identified which models had been developed but did not explore the impact of living with IBD. Such insights into exploring the impact of IBD would help with identifying their needs and help in developing a more patient-centred follow-up care system (Sofaer and Firminger 2005). For this reason a meta-synthesis was undertaken to identify the health needs of patients with IBD (Kemp, Griffiths et al. 2012).

In order to understand IBD, tailor treatment and provide personalised care, capturing the patient experience is imperative. The meta-synthesis included qualitative studies exploring the experience of living with IBD from the patient's perspective. There was a need to synthesise the evidence to understand this experience before developing the model further. The value of the meta-synthesis was the interpretation of all of the synthesised studies to provide an inclusive representation of living with IBD: 'Pushed and pulled: a compromised life'. People living with IBD experience a constant conflict throughout their lives, they *push* to be normal but IBD *pulls* them back. Seven studies were identified for the meta-synthesis, indicating that this as an under-researched subject area. One of the main findings from the meta-synthesis was the unmistakeable burden of incontinence and its ongoing effects, even when the patient was in remission.

The best evidence synthesis and meta-synthesis formed the basis of the topic guides for interviews with patients and GPs. These were conducted to develop theory about potential approaches to follow-up care.

Permission to undertake interviews to develop the follow-up care model was granted from the North West 2 Research Ethics Committee REC number 10/H1005/50.

Semi-structured interviews were carried out with 24 patients and 20 GPs. The patients were selected from a large single Foundation Trust in the North West of England and the GPs from a range of rural and inner city, large and small, deprived and affluent practices across the North West of England.

The aim of the interviews with the patients was to explore their needs and preferences of follow-up care. The patients’ experience of follow-up care was explored and from this barriers and behaviours were identified which would impact on the final model of follow-up care. All of the patients experienced a difficult time during diagnosis, some taking up to ten years to be given definitive diagnosis. Many patients blamed their GP for this diagnostic delay and unnecessary suffering, querying the knowledge and skill of the GP. This led to a loss of confidence in the GP which in turn impacted upon the patient seeking out their GP for assistance with their IBD (see Paper 2 pg 148).

The aim of the GP interviews was to explore the current and potential role of the GP in IBD management. It emerged from these interviews that GPs were extremely frustrated with the barriers they faced, both financial and organisational, when trying to be involved with IBD patients. GPs wanted to be involved however and identified a range of recommendations about how this could be achieved which could be incorporated into the model of follow-up care, (see Paper 3 pg 172).

8.4 Modelling the intervention

Evidence from the best evidence synthesis, meta-analysis and key findings from the patient and GP interviews were used to create a matrix. Each column indicated the core components derived from the best evidence review, meta-synthesis, patient interviews and GP interviews which required synthesising and modelling. A series of questions about the components of the intervention were posed within the matrix: content of the intervention, mode of delivery, who should deliver the intervention, the setting of the intervention, how often the intervention should be delivered, feasibility of the intervention; and acceptability, what is acceptable follow-up care. The matrix can be seen in table 20, pg 204 (full version of this can be found in appendices of the thesis).

The matrix was used as the starting point for synthesising the evidence and theory and translating these into the main ingredients of the intervention. This was undertaken by a multidisciplinary group of healthcare professionals and a patient (see table 19: member of multidisciplinary group, pg 199).

Guided by the processes undertaken in previous studies (Lovell, Bower et al. 2008; Bradshaw, Wearden et al. 2012; Gask, Bower et al. 2012) the synthesis day was divided into two stages. The first stage was an overview of all of the evidence identified and the theory developed to clarify any ambiguity within the data. This second stage was an interactive discussion by the members of the multidisciplinary expert group, using the matrix to identify the main components of the model. The day was digitally recorded and transcribed verbatim to allow the researcher to review what was discussed and clarify any uncertain points. One academic supervisor helped to facilitate the meeting whilst the second academic supervisor also acted as ‘scribe’ to note any salient points. Summary of the synthesis of key components can be seen in table 21, pg 209. Figure 18, pg 210 displays the model that was arrived at, which was a stratified model of follow-up care for patients with IBD. Figure 19, pg 211 displays how patients move within the model.

Table 19: Members of multidisciplinary group

Contributor 1	Consultant Gastroenterologist, lead for IBD at Foundation Trust
Contributor 2	GP with a special interest in gastroenterology and member of Primary Care Society for Gastroenterology.
Contributor 3	Patient (male, age 52yrs) with Crohn's Disease
Contributor 4	Lecturer in Nursing
Contributor 5	Professor of Nursing, past experience of hosting research synthesis meetings

8.5 The developed model of care

It was clear from the synthesis that one approach would not meet all patients' needs. A complex, multi-layered intervention was developed to meet the needs of patients who fell into three categories of IBD: quiescent / mild; moderate; and severe complex disease.

Disease activity scores such as Crohn's Disease Activity Index or Ulcerative Colitis Activity Index may be used to categorise patients into mild, moderate and severe. Patients with IBD can be categorised further depending on age, disease severity and behaviour. The Vienna (Gasche, Scholmerich et al. 2000) and Montreal Classifications (Satsangi, Silverberg et al. 2006) place patients into 24 potential subgroups depending on disease location, such as stomach or small bowel, behaviour, such as structuring or penetrating, and age. Using these classifications to define and categorise patients would however have led to a model which would not be feasible because it would add too many layers and subgroups of patients.

The interface between primary and secondary care was addressed by recognising the barriers identified by the patients and the GPs, putting processes into place to overcome these and working with the facilitators identified by the GPs to put these into an acceptable, feasible model of follow-up care.

The concept of control was visible throughout the meta-synthesis and what patients needed to control for life to be acceptable. The need to control was inter-related with knowing their body and being able to identify triggers or a flare ups, having the skills to manage it and giving the patient a degree of ‘control’. These findings, combined with evidence from established models of care in the best evidence synthesis (Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003; Gethins, Duckett et al. 2011), placed the concept of guided self-management within all three layers of the model. Even if a category of patients made the decision not to self-manage, as uncovered in the patient interviews, it was felt that the skills learned from a self–management programme would benefit the patient and allow for some degree of control or ‘push’ into their lives.

There is a move within the NHS to integrate primary and secondary care for patients with long term conditions (DH 2010) and to reduce ‘inappropriate’ follow-up appointments (Institute for Innovation and Improvement 2007a). It was a contentious subject for the GPs who expressed a desire to be involved in the care of patients with a disease which has predominantly been managed solely in secondary care. There was little evidence for GP care or development within the models synthesised in the best evidence review, apart from one qualitative study which proposed that a number of recommendations needed to be put into place before open access or GP care could be realised (Cheung, Dove et al. 2002).

Patient experience of GP care, which emerged during the interviews, was reported as suboptimal (see Paper 2). It was important to address issues of continuity of care and the barrier to access for the patients in this layer of the model.

There was a requirement within the synthesis group to reach a consensus about what would be acceptable to patients and GPs in line with Department of Health policy. Patients were concerned about GPs’ lack of knowledge of IBD, which the GPs acknowledged. Facilitators identified to address this issue were the development of enhanced services with GPs (DH 2012) supported by the IBD specialist team, and detailed primary care management plans (see Paper 2, Table 18, GP recommendations for IBD, pg 188).

During the modelling phase it was evident that the role of the IBD outreach nurse at the interface of primary and secondary care would be instrumental in facilitating the movement of patients between the layers of the model, in continuity of care and in breaking down the barriers identified by patients and GPs. IBD Nurse skills and education would need to be advanced to fulfil such a role.

The concept of the ‘push’ within the meta-synthesis, the push to be normal and in control (Kemp, Griffiths et al. 2012), was combined with open access outlined within established models (Williams, Cheung et al. 2000; Robinson, Thompson et al. 2001; Rejler, Spangeus et al. 2007). Patient expressions of not wanting to be seen when well (see Paper 2), led to the classification of the middle layer of the model as ‘virtual’ care (van Dullemen, Doorn et al. 2005; Krier, Kaltenbach et al. 2011; Hunter, Claridge et al. 2012) and patient- initiated referrals for patients with moderate IBD disease.

The patients with severe complex IBD would remain under the management of the IBD specialist team until such a time when their disease was ‘controlled’ and the patients could then move down the layers of the model.

8.6 Discussion

The revised MRC complex intervention framework placed great emphasis on the importance of the development phase (Craig, Dieppe et al. 2008). There is caution against neglecting this vital aspect (Eldridge, Spencer et al. 2005). Inattention to this phase and lack of qualitative groundwork can lead to weak interventions and missed complexities which potentially affect outcomes (Rowlands, Sims et al. 2004).

This paper reports the methodology used to identify the main components or the ‘active ingredients’ (Craig, Dieppe et al. 2008) of a complex intervention of follow-up care for patients with IBD. Four seperate but interrelated studies were conducted and the findings synthesised to develop a theoretical and acceptable intervention driven from the patient and GP perspective.

The key tasks used in the modelling process described in this study were to collect the evidence and theory to inform the intervention. The strength of modelling the intervention was that unanticipated barriers and behaviours with the potential to compromise the model were identified, such as the patients' loss of confidence in the GPs and the GPs' frustration with the reimbursement system. The development of the model was systematic, synthesising evidence and developing empirical theory to determine the active ingredients.

This approach also has limitations. The MRC suggest the gold standard approach to identification of the evidence is to undertake a systematic review (Craig, Dieppe et al. 2008). Due to the lack of RCTs of effectiveness in the area of follow-up care, a best evidence synthesis was conducted instead. Modelling the intervention was also highly dependent on the consensus of the synthesis group to make decisions where there was conflicting needs from patients and GPs. Another limitation is that the views of a range of healthcare professionals such as consultant gastroenterologists, IBD nurses and commissioners, would also have been helpful and could have taken place prior to the modelling synthesis meeting. This was not possible due to time constraints but to strengthen the model further, there is a plan to elicit the views of gastroenterologists, GPs, patients, IBD nurses and commissioners in a series of multidisciplinary focus groups.

8.7 Conclusion

This paper outlines the steps taken in the first phase of the MRC complex intervention framework to develop a stratified model of follow-up care for adult patients with IBD. A criticism of studies using the framework is lack of transparency about how models are developed (Shepherd, Lewin et al. 2009; Mohler, Bartoszeck et al. 2012). This paper has provided one possible approach which systematically searches and synthesises quantitative and qualitative data, develops theory and models this into an intervention which can then be tested in a feasibility trial and if successful, an RCT.

Table 20: Matrix of key components for synthesis of the model of follow-up care

Component	**Research Evidence**	**Patient interviews**	**GP interviews**
Content?	**1.Open access** and care transferred to GP, guaranteed rapid access back to secondary care (RCT) (Williams et al 2000). **2**.GP supported **open access**, more written info required, IBD nurse and more integrated approach between hospital, GP patients and nurse (Cheung et al 2002) **3.Self management**, **patients initiated FU,** only UC, (RCT) (Robinson et al 2001) **4.Self management**, whole systems approach, structured programme with self help book, self referral. *Could not calculate if care shifted to GP* (RCT) (Kennedy et al 2003) **5.Self management** (Stansfield 2008, Gethins et al 2011) **6.Patient experience of open access**, mainly positive but security of fixed appointment important to some (Rogers 2004) **7.Patient and demand directed care**, telephone access to nurse in working hours, appointments scheduled to patients needs, emergency appt available daily, annual	**Don't wish to be seen if well** Must have access to GP rapidly Must have access to Sec Care rapidly and have confidence in this, even if just expert advice needed e.g. fertility and drugs. Separate 'crisis clinic' from well routine clinic. **Helpline 'crisis line' still accessible but more co-ordinated**. Self management in those that wish to do this. Continued contact with sec care – newsletter – if virtual clinics. Out of hours and weekend help line – 7 day availability. Access to counsellor / psychologist Patient-initiated referral (open access) **Do not want to be discharged.**	**Don't need to see patients if well.** GP 1st point of call during flare up. Written care plans /(Primary Care Management Plans (GP01). Supportive self management, GP must be included in plan. Access to expert as and when needed. Rapid follow up clinic daily. GPs general lack of awareness of IBD Nurses in local hospitals. Regular '**appropriate**' educational updates of IBD. Inconclusive re QoF for IBD.

	telephone review with nurse (Rejler 2007)		
Mode of delivery?	**1.Telemedicine** high satisfaction (Cross 2007, Cross 2009) **2.Telemedicine and self management** SMART solutions (Rosser 2009) **3.E-Health** UC only (RCT) (Elkjaer et al 2011) **E-homecare** (van Helden 2010) **4.Telephone clinics** (Miller 2002, Gethins 2007) **5.Virtual clinics –** paper clinics. Patients posted out questionnaires, blood forms, no FU given unless required from results of blood forms and responses to questionnaires (Porrett 2004, van Dullemen 2005, Hunter 2012)	Emails, paper questionnaires posted out, text, telephone clinics	The IBD nurse best placed to deliver self management training and manage any 'virtual' pathway to avoid patients lost in the system.
Who should deliver the intervention?	**1.GPs** manage pts with IBD (Rubin2000, Stone 2003) **2.GPs** want to be involved in IBD care (Moody 1993, Stone 2003)	Someone with knowledge and expertise. If GP, which is acceptable, still must be under care of Sec Care. GP and Secondary Care together using **written care plans or**	**Mixed views: GP** should be main carer with *support from Secondary Care* in quiescent, mild / mod IBD.

	3.GPs desire more specialist education (Moody 1993) more written information (Moody 1993, Cheung 2002). **4.No evidence** for IBD nurse at the interface of Primary / Secondary care Adapting **Heart Failure nurse model in primary care** (Managing chronic heart failure: learning from best practice' RCP 2005) **5.Shared care -** Insufficient evidence to demonstrate significant benefits from shared care apart from improved prescribing (Cochrane SR, Smith et al 2009)	**within a guided self management package.** Follow up must be of value, offer confidence, security, reassurance, hope, and outcome, the person delivering the intervention must be able to achieve this. Confidence needed that GP can manage IBD properly. IBD Nurse essential	**IBD Nurse Specialist** at the interface of Primary Secondary Care, similar to Heart Failure Nurse model (NSF Heart Disease) Patients should be discharged
Setting of the intervention?	**1.Specialists Outreach Clinics** improves access to specialist care, reduce waiting times, as part of a multi faceted intervention but may cost more (Bowling 2001, Cochrane SR Gruen 2009)**evidence is for consultants, not based on nurses. See Heart Failure Nurse Model of care.*	Mix of Primary and Secondary Care	Mix of Primary and Secondary Care
How often the intervention should be delivered?	1.IBD Standards (2009) 12 monthly review for all IBD patients. Does not state where the review should be.	Face to face 12 monthly	As prescribing responsible for reviews already. More than able to do 12 month review
Feasibility of the intervention	**1.Ten priorities for commissioners** Active support for self management Managing ambulatory care sensitive	Mix of Primary and Secondary Care. Electronic records between primary and sec care needed.	Mix of Primary and Secondary Care Self management.

	conditions (reducing hospital admission in exacerbations). **2.**Care co-ordination through integrated health and social care team (GPs as navigators as opposed to gate keepers) Managing emergency activity - urgent care. **3.QoF 2012-2013** – avoiding unnecessary follow up appointments, avoidable hospital admissions. **4.**British Society of Gastroenterology Commissioning Guide (2012) provision of 'an integrated and flexible IBD service' barriers must be removed e.g. tariffs. **5.**IBD Standards (2009) shared records and web based entry data to enable decision making.		Not re-referred as a new referral if needs to come back to sec care. Cancer surveillance during quiescent periods how will this be managed? Electronic records between primary and sec care needed. Enc patient to see GP first if problems. Create Locally Enhanced Service (LES) Directly Enhanced Services (DES) for IBD. Direct contact for help.
Acceptability – what is acceptable follow up?	1.IBD Standards (2009) Patients should be offered choice of follow up care. 2.BSG Commissioning Guide (2012) 'calprotectin should be available to GPs'	Follow up must be of value, offer confidence, security, reassurance, hope, and outcome. Patients want choice of follow up. More than 'medical model of care', cover all psychosocial aspects. Not to be lost in the system, forgotten. Most pts wish to be seen only when required, during flare up etc.	To review patient only when required. Avoid unnecessary follow ups and reduce cost. Stop offering routine OPDs for no reason '*cuddle appointments* (GP04). Cost effective. Mix of Primary and Secondary

		Many pts still wish 12 mth reviews with Cons in sec care. 12mth review **must not** post phoned. IBD MOT review (P016). Face to face must be with healthcare professional that knows the patient. Longer appointment times. If flare up and ref back to sec care, wish to see Cons, not nurse or registrar doctor. Mix of Primary and Secondary Care. Newly diagnosed more ‘needy’ and stay with sec care at beginning. Some type of connection maintained. Triage appointment system (see P003 recommendations). Email contact for non-urgent questions.	Care. Self management. Seamless movement between primary and secondary care based on triggers. Define triggers?? Stages of triggers?? Sec care offer an exacerbation service at designated trigger Primary Care and Secondary Care to develop this but calprotectin test in Primary Care needed Secondary care overall management of complex cases.

Table 21: Summary of key components of model of follow-up care

Patients were grouped into three categories: quiescent / mild; moderate; and severe. This dictated the arm of the intervention the patient would ‘sit’. Patients would move across the arms of the model as their disease and needs changed.

It was clear that one approach did not suit all patients and a variety of approaches were included. Patients wanted flexibility and choice. ‘Virtual’ care as an adjunct to patient-initiated consultations and self-management was identified as optimal approaches to meet the patients’ needs of follow-up care.

GPs wanted to be involved and recognised their on-going need for contact and support from secondary care but also the organisational funding system as a barrier. For this reason, only quiescent patients would be discharged, moderate and severe patients would remain under the jurisdiction of secondary care. This may change as the tariff reimbursement system changes with the NHS and annual tariff take effect.

Guided self-management was a vital level within each arm. Consensus from the ‘expert’ group was that all patients should attend a self-management programme even if they felt this was not an approach they could personally adopt. The benefits of attending outweighed those of not learning these skills.

Quiescent / mild patients would be discharged to a locally enhanced (LES) GP service, defined as GP service which delivers higher than specified standards. These would be supported and educated by the IBD specialist team. Patients discharged to the LES GP service would have a detailed primary care management plan (PCMP) and NOT be referred back on a new patient tariff. Rapid access to secondary care guaranteed within 7 days.

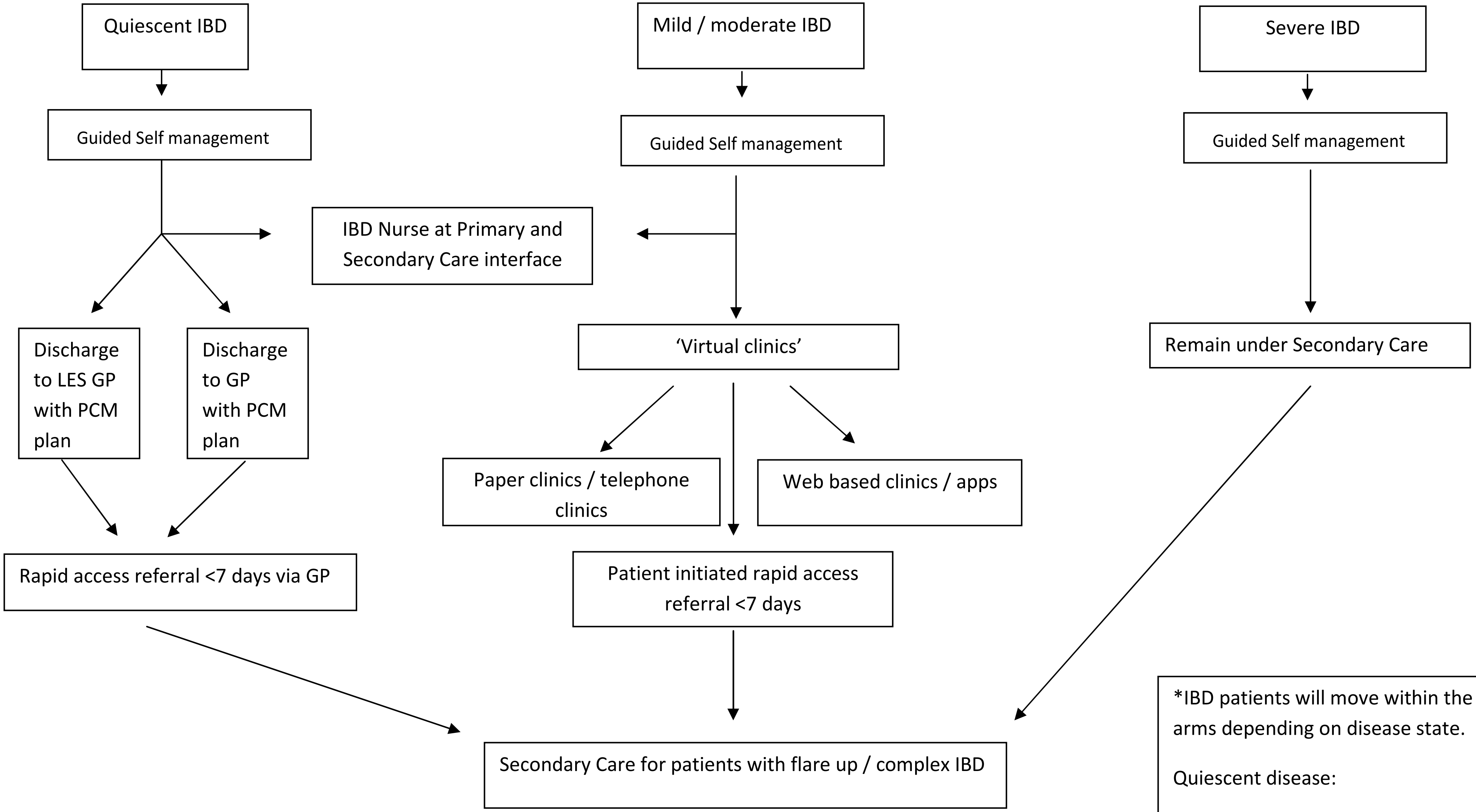
Moderate patients would remain under the care of the IBD team in secondary care but would be offered the flexibility of ‘virtual’ care. These would include paper clinics, telephone clinics and web-based tele-health. Face-to-face clinics would still be offered to patients who did not wish to enter ‘virtual’ care. Patients in this arm of the intervention would initiate self-referral into secondary care guaranteed within 7 days.

Patients with severe complex IBD would remain under secondary care, face-to-face follow-up. As their disease is controlled and the patient moves into moderate and quiescent disease, so the level of care is reduced accordingly.

Consensus ‘expert’ opinion: 12 monthly reviews for quiescent patients would take place by LES GP, the report forwarding to secondary care. Compulsory reviews, such as PBR Exclusion NICE drug reviews were a secondary care responsibility.
Colorectal cancer surveillance responsibility remains with secondary care.

IBD nurse would play a pivotal role bridging patients within a LES GP service to secondary care and overall management of patients cared for ‘virtually’.
All patients retain the right for secondary care specialist opinion.

Figure 18: Stratified Model of Follow up care for adult patients with inflammatory bowel disease



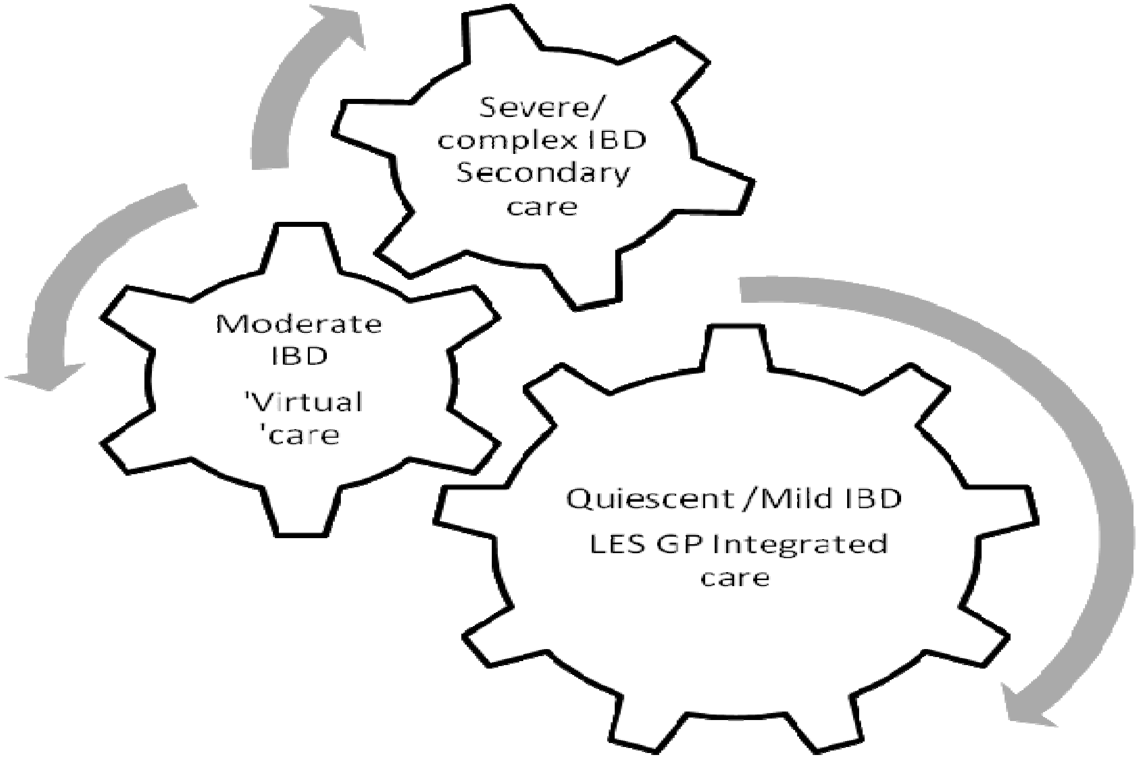
*IBD patients will move within the three arms depending on disease state.

Quiescent disease:

Mild/moderate disease:

Complex disease:

Figure 19: Patient moving between arms of model



Chapter 9

Discussion and Conclusions

9.1 Aims and stages of thesis

This thesis aimed to develop a model of follow-up care for inflammatory bowel disease (IBD) patients using the Medical Research Council (MRC) Framework for the development of complex interventions to guide the approach. To achieve this aim five key stages were completed.

1) Best evidence synthesis to identify and synthesise the evidence of other models of follow-up care, the content, how they worked and evaluate patient acceptability.
2) Meta-synthesis of qualitative studies to understand the health and social care needs of people living with IBD.
3) Qualitative interviews with IBD patients to explore patients' experience, needs and preferences of follow-up care.
4) Qualitative interviews with GPs to explore GP perspectives of IBD care, their role and responsibilities and identify how IBD care in a primary care setting could be facilitated.
5) Synthesis process which describes the method undertaken to develop the intervention with emphasis on the description of the modelling phase of the MRC framework in which a stratified follow-up care model for patients with IBD was developed.

The alternative thesis method been used and the thesis contains an introductory and methodology chapter and 4 papers which have either been published (2 papers), submitted (1 paper) or in preparation to submit to peer reviewed journals (1 paper). This final chapter provides a brief overview of the findings, recognises the strength, weaknesses and limitations of the overall study, discusses the recommendations from the research and how this fits into the wider body of evidence, and concludes with recommendations for future research.

9.2 Best evidence synthesis Chapter 4, pg 76.

This chapter provided a best evidence synthesis (Slavin 1986) of models of follow-up care. The synthesis systematically searched and comprehensively examined and critically appraised models of follow-up care in IBD. The synthesis found models of follow-up care which have been developed and in some cases, tested within an RCT. There are many which were audits or in abstract form but were considered useful additions to the body of literature. 19 studies were included in the best evidence synthesis, 6 RCTs, 11 audit and conference abstract proceedings, a population based longitudinal design study and one qualitative paper.

A range of follow-up care models were identified within the review. These included self-management, open access, a combined approach of self-management and open access, and tele-medicine including ‘virtual’ care and remote monitoring using telephone and paper clinics. It is noteworthy that no patient voice or perspective was reported in the development of these models, although some models reported levels of patient satisfaction following the new model of care. There is controversy surrounding the use of patient satisfaction questionnaires and what they actually measure (Sofaer and Firminger 2005) (see Best evidence synthesis, patient acceptability of follow-up care models). The studies included in the review encompassed a variety of strategies to increase the patient’s quality of life (QoL), symptom management and relieve pressure on secondary services. Each of the strategies was effective, some more so than others. However, there remain questions surrounding follow-up care efficacy. What is the possibility of an integrated shared care system and how would this fit in? What are the knowledge and skills of GPs to enable integrated care, taking into account the needs and preferences of follow-up care from the patients’ perspective? Did patients want their GP to be involved and if so how and to what extent, and how and to what degree did GPs want to be involved?

9.3 Understanding the health and social needs of people living with inflammatory bowel disease. Paper 1, pg 117.

Paper 1 (Chapter 5) provides a meta-synthesis of the health and social needs of patients with IBD. In order to understand IBD, tailor treatment and provide personalised care, capturing the patient experience is imperative. This was fundamental to the development of the model of follow-up care. The paper followed the principles of meta-ethnography, as outlined by Noblit and Hare (1998). Using a systematic search strategy, the meta-synthesis identified qualitative studies exploring the phenomenon of living with IBD. Six published and one unpublished thesis were included in the synthesis.

The meta-synthesis identified that people with IBD endure many daily challenges, including stress, pain, fatigue, and fighting for control. The meta-synthesis provided an in-depth exploration of living with IBD: 'Pushed and pulled: a compromised life', people living with IBD experience a constant conflict throughout their lives, they push to be normal but IBD pulls them back.

Although the best evidence synthesis described the models of follow-up and how they worked it did not address the real impact of living with IBD. The meta-synthesis met this objective.

9.4 An exploration of the follow-up up needs of patients with inflammatory bowel disease. Paper 2, pg 148.

Paper 2 (chapter 6) explored the patients' experience, needs and preferences of follow-up care derived from semi-structured interviews. Interviews with 24 patients sampled purposively and recruited from a single gastroenterology out-patient department of a large University Foundation Hospital Trust in the North West of England were conducted. All patients invited to be interviewed agreed to take part in the study.

The interviews were analysed using Framework Analysis (Ritchie and Lewis 2003). The main finding was that patients were frustrated with the traditional scheduled system, and wanted more choice and flexibility from their follow-up care. Self-management, patient-initiated appointments, integrated care, ‘virtual’ and tele-health, were identified as possible components of a complex follow-up care model.

In the self-management theme four groups of patients emerged during the analysis: (1) patients who embraced the concept of self-management and questioned why they had not heard of it prior to the interview, (2) patients who could perceive no advantages to self-management. This group of patients had experienced quite complex disease processes and were reluctant to self manage for fear of becoming unwell again. (3) patients who were willing to embark on a self-management programme provided that if they could not manage they could revert back to the traditional care system, and (4) patients who required more knowledge about their illness and bodily response to their disease before considering self-management.

All but one patient was in favour of a patient-initiated referral system and welcomed an alternative system which offered care and monitoring away from the hospital. All of the participants were under secondary care and none had experience of GP led IBD care. There were some misgivings about GP care with patients reporting a loss of confidence in their GPs’ knowledge. The concept of an enhanced GP, supported by the IBD team, was a more acceptable approach for the patients.

There was emphasis placed on the value of the face-to-face appointment and when it should be conducted. The value of follow-up care was about contact, connection, continuity, expertise and reassurance. When the patient did require a face-to-face consultation, it was the *content* that was important to them.

Understanding the views of patients and engaging them in decisions about treatment and services can help to improve the patient’s experience of care and to improve the patient’s management of their condition. This study identified patients’ follow-up care needs and preferences but it was clear that one approach would not suit all patients and that a variety of approaches should be considered.

9.5 General practitioners’ perspectives of inflammatory bowel disease management in primary care. Paper 3, pg 172.

Paper 3 (chapter 7) established the GPs current role and potential role within IBD management in primary care. 20 GPs, purposively sampled from large and small practices, rural and inner city, deprived and affluent from across the North West were interviewed. The GPs were self selected following recruitment from the Greater Manchester Primary Care Research Network (PCRN).

The semi-structured interviews were then analysed using Framework Analysis and two overarching themes emerged: barriers and facilitators to IBD management in primary care. GPs felt powerless to influence or change the reimbursement system within the NHS which they identified as the largest barrier to integrated care. GPs also reported a breakdown in communication between primary and secondary care, a lack of clarity in secondary care patient management plans for them to act upon.

There was a mixed response about including IBD in the Quality Outcomes Framework (QoF) which reflects the diverse national opinion of GPs towards this.

The key messages from this study was that GPs were frustrated with the current situation, they wanted to be more involved with IBD care, and were willing to explore new ways of working to ensure this. The GPs highlighted a range of recommendations about to how a more integrated approach to care could be achieved (see Paper 3, table 18, pg 188).

9.6 Developing a model of follow-up care for patients with inflammatory bowel disease using the MRC framework for the development of complex interventions: a description of the modelling phase. Paper 4, pg 191.

Paper 4 (chapter 8) is a descriptive paper synthesising the 4 stages outlined above to provide a model of a best evidence and acceptable follow-up care model for IBD. There is ambiguity about how to synthesise such evidence. The synthesis process outlined in this paper was taken from previous work of the researcher's academic supervisor and demonstrates how the stages can be synthesised using a pragmatic approach. This method also highlighted the importance of the development phase of the MRC complex intervention framework because in the different stages barriers and behaviours were identified that might have had a detrimental impact upon the model, such as the GP wanting more involvement in direct care yet the patient reporting a loss of confidence in the GP.

A synthesis group was established (Consultant Gastroenterologist, GP, patient and academic supervisors) to synthesis the phases of the best evidence synthesis, meta-synthesis, patient and GPs interviews. It was clear from the synthesis that one approach to follow-up would not meet all patients' needs. A complex, multi-layered intervention was developed to meet the needs of patients who fell into three categories of IBD: quiescent / mild, moderate, and severe complex disease. The resulting output from this exercise was a stratified model of follow-up for adults with inflammatory bowel disease (see Paper 4, figure 18, pg 210 and table 21, pg 209).

9.7 Strengths, weaknesses and limitations of the thesis

The focus of the study was the development of an acceptable integrated model of follow-up care for adult patients with IBD.

This study has successfully demonstrated how to use the MRC framework to develop an acceptable model of follow-up care for adult patients with IBD. Lack of evidence of the real impact of living with IBD identified this as an under-researched area, which needs addressing, to enable patient-centred care to be delivered at the right time by the right healthcare professional. It has highlighted the benefits of engaging with patients when developing new services (paper 2) and sought to identify barriers and facilitators to take the intervention forward to the next stage (paper 3).

The modelling process in paper 4 built upon previous work of Lovell, Bower et al (2008) and may be used as one approach for modelling within the MRC framework.

There are limitations to the study. The patients selected for interview in paper 2 were from a single tertiary centre in North West of England, which is a major hub for IBD care in the UK. The participants may have had more complex disease than patients managed in a small hospital and this may have reflected their follow-up care needs and preferences.

In addition, there were more patients with Crohn's Disease (CD) than ulcerative colitis (UC) which may have led to a biased sample, although evidence shows that there is no difference in quality of life between patients with CD and UC (Guthrie, Jackson et al. 2002). This limitation of the study may have been addressed by widening the sample to large and small hospitals across the UK. However, both small District General Hospitals and large Foundation Trusts are experiencing the same problem of overbooked clinics and a growing demand on specialist health services and it was felt that the single site would capture patient experience, needs and preferences.

The GPs in paper 3 were self selected and so may represent GPs who had a greater interest in IBD. However, the GPs were asked at the end of the interview why they chose to take part in the study and whether they had an interest in IBD. Only one GP had a special interest in IBD. The remaining GPs stated that they had participated for the following reasons: IBD was a long term condition and so part of their remit; a general interest in research; GPs wanted claim their continuing professional development (CPD) points as this study adopted by the Primary Care Research Network (PCRN) they were eligible for this; the researcher was willing to travel to them; and the interview offered a chance to discuss the challenges they were facing within the new commissioning system.

The PCRN invited 65 GPs across the North West to take part. 25 interested GPs contacted the researcher directly. Due to the recruitment strategy, the GPs were self-selected and purposively sampled to represent large and small, inner city and rural, and affluent and deprived areas. A limitation of this study was the inability to describe the total population of GPs approached by the PCRN or reasons why GPs chose not to participate.

There is no guidance on how to synthesise the development phase of the MRC framework for complex interventions so the approach used here, described in paper 4, is just one approach. The MRC also recommend that cost effectiveness analysis is incorporated into any complex intervention, but this was not possible in the time frame of this PhD study.

A limitation of this study is the lack of additional health care professionals' views in the development or the modelling of the follow-up care model. This was primarily due to time constraints within the PhD study period. The views of gastroenterologists, nurses, hospital managers and clinical commissioners would have strengthened the evidence for the intervention. This will be addressed and undertaken in future studies.

9.8 How this research fits into the wider body of evidence

This study was undertaken during a time of upheaval within England and the NHS. Models of care for long term conditions (LTCs) were identified as the main area for research by service managers, clinical leaders, patients and researchers advising the National Institute of Health Research (NIHR) Health Services and Delivery Research Programme (HS & DR) in 2012 (http://www.netscc.ac.uk/hsdr/files/adhoc/12_130commbrief.pdf.). The commissioning brief outlined the growth and cost to the NHS of people living with a LTC, and that current services are not organised to promote independence and provide the best quality of care for patients. They also identified a lack of integration between primary and secondary care.

Within any new service there must be a drive to offer patient choice and treat patients closer to home (DH 2010). Two key principles came from the DH (2010) ‘Equity and Excellence: Liberating the NHS’: that patients must have more control over the care they receive and that those responsible for patient care should have the freedom and power to lead services that deliver continued quality care. Embedded within this is the Quality Innovation Productivity and Prevention (QIPP) agenda whose central themes are self-management and shared decision making.

The Institute for Innovation and Improvement (Institute for Innovation and Improvement 2007a) framework consisted of ten high impact changes which included avoiding unnecessary follow-ups for patients, providing necessary follow-ups in the right care setting, applying a systematic approach to care for people with LTCs and a redesigning role in general practice (Institute for Innovation and Improvement 2007b). Within the NHS Outcomes Framework (2012/2013), Domain Two is about enhancing QoL with LTCs and within this, the concept of self-management and promotion of independence is emphasised. Domain Four is concerned with ensuring people have a positive experience of care, which has been updated for 2013/2014 into a positive experience of ‘integrated’ care (https://www.wp.dh.gov.uk/publications/files/2012/11/121109-NHS-Outcomes-Framework-2013-14.pdf).

Patients defined quality of care as patient–centred care. Quality encompassed having their physical and emotional needs met, receiving individualised care and being involved in their care and making decisions about their care. They also wished to be cared for by health care professionals who know them and have knowledge about their condition, who show respect and build a relationship with them by listening and anticipating their needs (Sofaer and Firminger 2005). All of these requirements are met within this model of follow-up for patients’ with IBD.

Examining the policy on LTCs in England, it is clear that the model of follow-up care for adult patients with IBD developed within this study reflects the national agenda. It takes into account patient experience, needs and preferences of care and patient involvement. However, there is a need to step back and question why the UK models covered in the best evidence synthesis have not been rolled out across the NHS (Williams, Cheung et al. 2000; Robinson, Thompson et al. 2001; Kennedy, Nelson et al. 2003). Although these were robust RCTs, the reason why they failed may be that they did not take into account the NHS reimbursement system and economic situation within the NHS. There were also ingredients missing from these, such as patient involvement and acceptability. IBD care and the NHS have moved on from these studies. Patient independence and self-management is important but the move towards tele-health and remote monitoring as an adjunct to these, have made the requirement of a model of follow-up care for adults with IBD essential to care.

9.9 Recommendations for practice:

The study has identified several recommendations for future practice:

- There is a deficit in the knowledge of GPs regarding IBD and this must be addressed. One approach is to develop locally enhanced services (LES) within GP practices. This would also assist in building the patients' confidence in seeking advice and care from their GP.
- The current reimbursement of care system is undergoing a review. The Year of Care programme for diabetes, referenced in Paper 3, has the potential to change the way patients with LTCs are managed, including tariffs for care. This was identified as a major barrier to more integrated care for patients with IBD. Lessons can be learned from other LTCs e.g. the heart failure model, and how the approach to follow-up care is being reorganised and reimbursed.
- There needs to be improved communication between primary and secondary care with a greater recognition of roles. For a truly integrated care, shared electronic records must be made a reality.

- There needs to be greater engagement with patients when developing and re-organising healthcare services. This needs to become normal practice as opposed to an exception to the rule for research studies.
- There needs to be greater recognition of the ‘chronicity’ of IBD and managing the perceived ‘well patient’ with a relapsing remitting illness. The meta-synthesis highlighted a range of issues which the perceived ‘well patient’ still experienced, such as the fear of incontinence and the impact this had on patients’ behaviour.
- The role of the IBD nurse has not been fully recognised or developed. Both patients and GPs supported the proposal of an IBD nurse at the interface of primary and secondary care, supporting the locally enhanced service GP. This would require further educational development for the IBD nurse into an advanced practitioner for IBD. Exploring the heart failure nurse as an exemplar would assist with the development of this role.
- There would need to be a robust recall system for colorectal cancer surveillance and other compulsory reviews, such as reaching the five year point of immunosuppression therapy and National Institute of Clinical Excellence (NICE) guidance.

9.10 Recommendations for future research

A number of recommendations for future research derived from this study can be made:

- A range of healthcare professional views need to be sought to add to the intervention and refine it further. This may be via interviews or focus groups of nurses, gastroenterologists, colorectal surgeons, GPs, hospital managers and commissioners.
- The refined intervention requires an economic modelling to test for cost-effectiveness. It would then undergo a feasibility trial and if successful, full RCT with cost effectiveness analysis.
- Evaluation of the role of the IBD nurse at the interface of primary and secondary care with measurement of patients and GPs acceptability.
- The main finding of the meta-synthesis was the impact of the fear of incontinence and behaviour of the individual as a result. There is no qualitative work exploring the impact of faecal incontinence on patients with IBD and this requires further enquiry.

9.11 Conclusion

This study, presented as an alternative thesis, documents the justification behind the development of a follow-up model for patients with IBD. It outlines the steps taken within the MRC framework for the development of complex interventions, the methodology used, the best evidence synthesis, meta-synthesis study, qualitative interviews with patients and general practitioners, and a synthesis day. The strengths, weaknesses and limitations are acknowledged within the study. The study concludes with a stratified model of follow-up care for adult patients with IBD which will be refined further through focus groups with other healthcare professionals and then a feasibility trial.

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RCD
Building Research Capacity

NHS
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Health Research

NIHR Trainees Coordinating Centre
Leeds Innovation Centre
103 Clarendon Road
Leeds LS2 9DF

Phone: 0113 346 6267
Email: jim.lithgow@nihrtcc.org.uk

1st October 2009

Re: Karen Kemp

Dear Karen,

Thank you for attending the recent interview for the Clinical Doctoral Research Fellowship. I am pleased to tell you that your application has been successful and approved for funding by the CNO and NIHR.

Please contact Jim Lithgow at the NIHR Trainees Coordinating Centre (NIHR TCC, formerly known as NIHR Coordinating Centre for Research Capacity Development) by email or phone before 14th October to confirm that you would like to accept the offer of this Fellowship.

Please note that uptake of the Fellowship and the associated funding is subject to the following conditions:

1) Awards are granted to individuals on the condition that any part of the Fellowship programme of work which requires ethical approval **can not be undertaken prior to obtaining the necessary ethical approval**. It is suggested that you begin the process of obtaining any required ethical approval if you have not done so already.

2) Contract-writing will require confirmation of the following details: Individuals will be required to confirm the Fellowship **start date** with the NIHR TCC Programme Manager (Jim Lithgow). This start date may differ from the date proposed in the original application but may not be later than 31st March 2010.

3) Individuals will be required to **confirm the details of funding** requested prior to contract documents being completed. Individuals may also be asked to re-submit Finance requests if their original finance forms are found to have errors or items that do not fit with the funding structure of this scheme. Also, any costs identified as NHS Service Support Costs will be met by local clinical research networks and will not be funded by this scheme.

Following this communication we will to write to you with feedback from the application and interview process. We will endeavour to send you this feedback as soon as possible. Please also find attached (below) a summary of the anticipated next steps of the contracting process should you decide to accept this offer.

Yours sincerely,

Dr. Jim Lithgow
Programme Manager

PTO: next steps of contract process

If you decide to accept this Fellowship offer, we recommend that you consider the following points regarding the award contracting process:

a) The NIHR TCC will be involved in communication both the award winner *and* the appropriate Finance Officer in the award winner's host institution. This Finance Officer is usually the person identified on the original application form. It is suggested that award winners make contact with the appropriate Finance Officer to establish understanding of the next steps and a clear line of communication between the individual, the NIHR TCC and the Finance Office to expedite the contracting process.

b) Once contracts are written, signatures will be required from the appropriate authorised signatory in the award winner's hosting institution (such as Head of Department, Head of Research and Development, Grants/Contracts Manager). Again it may be appropriate for individuals to contact this person prior to them receiving the contract documents.

A summary of the anticipated steps in the contracting process is as follows:

1) NIHR TCC reviews applications and finance forms.

2) NIHR TCC contacts award winner to request from them the following:

    i) confirmation of finance request details and/or re-submission of finance form.
    ii) confirmation of ethical approval status (if required)
    iii) confirmation of start date

3) NIHR TCC draws up contract ("Research Agreement"), including payment profile, and sends electronic copy to award winner and appropriate authority within host institution for checking and approval.

4) Once contract details are agreed, NIHR TCC sends 2 Paper copies of the contract to the authorising signatory of the host institution. Authorising signatory signs 2 copies of contract and returns them to NIHR TCC.

5) NIHR TCC requires confirmation of **Host Institution bank name, sort code, account number and a Payee Reference number** specific to the award winner for Fellowship payments (this should be obtained from the Finance Office).

6) NIHR TCC sends contracts to be signed by appropriate authority in the Department of Health.

7) Once signed, payment profile details sent to appropriate office to enable payments to be made to host institutions.

8) As part of monitoring NIHR research fellowships, you will be required at times to provide written reports on the progress of your fellowship. Details about these requirements will be sent at a later date.

NHS

National Research Ethics Service

North West 2 Research Ethics Committee – Liverpool Central
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7818
Facsimile: 0161 237 9427

24 August 2010

Mrs Karen Kemp
48 maple grove
Worsley
Manchester
M28 7FB

Dear Mrs Kemp

Study Title: **The development of an intervention of follow up care for patients with inflammatory bowel disease**
REC reference number: **10/H1005/50**

Thank you for your letter of 24 August, responding to the Committee's request for further information on the above research and submitting revised documentation. .

The further information has been considered on behalf of the Committee by the Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be *notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.*

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Investigator CV		
CV for Jane Griffiths		
Participant repy form	3	02 July 2010
Letter from NIHR - 01/10/2009		01 October 2010
External peer review		
REC application	3.0	02 July 2010
Covering Letter		02 July 2010
Summary/Synopsis	4	02 July 2010
Letter from Sponsor		02 July 2010
GP/Consultant Information Sheets	2	02 July 2010
Participant Information Sheet: Focus Groups - Healthcare Professionals	4	23 August 2010
Participant Information Sheet: Patient focus groups	4	23 August 2010
Participant Information Sheet: Patient interviews	4	23 August 2010
Participant Information Sheet: Patient observations	4	23 August 2010
Response to Request for Further Information		
Participant Information Sheet: Interviews - Healthcare Professionals	4	23 August 2010
Participant Information Sheet: Clinic observations - - Healthcare Professionals	4	
CV for Karina Lovell		
Participant Consent Form: Patient focus groups	3	02 July 2010
Participant Consent Form: Patient interviews	3	02 July 2010
Evidence of insurance or indemnity		02 July 2010
Letter from NIHR - 12/10/2009		
Participant Consent Form: Focus Groups - Healthcare Professionals	4	23 August 2010
Participant Consent Form: Interviews - Healthcare Professionals	4	23 August 2010
Participant Consent Form: Observations - Healthcare Professionals	4	23 August 2010
Participant Consent Form: Patient observations	4	23 August 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H1005/50 **Please quote this number on all correspondence**

Yours sincerely

Professor Sobhan Vinjamuri
Chair

Email: carol.ebenezer@northwest.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mohammed Zubair*
Lynne Webster

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20 October 2010

Mrs Karen Kemp
Lecturer/Nurse Practitioner
University of Manchester
Jean McFarlane Building
Oxford Road
Manchester
M13 9PL

Ref: R01325-Ltr 2-Kemp

Dear Mrs Kemp

PIN: R01325 (Please quote this number in all future correspondence)
CSP Reference: 47651/GM
Research Study: The development of an intervention of follow up care for patients with inflammatory bowel disease

Thank you for submitting the above study for approval.

We acknowledge that the University of Manchester has accepted the role of Research Governance Sponsor for this study.

We understand that this study has been adopted by the NIHR Portfolio.

I am pleased to confirm that the Research Office has now received all necessary documentation, and the Trust Director of Research & Innovation has given approval for the project to be undertaken. This approval is in relation to the documentation supplied to us below.

Approval is given subject to the attached conditions – please ensure you and all members of the research team are familiar with these before commencing your research.

Please note: You must tell your Divisional Research Manager – Manju Luckson

- the date that you intend to start recruiting to this study AND
- the date on which the first participant is recruited/consented

The Trust aims for its research projects to recruit their first participant within 30 days of the recruitment start date. If you do not tell us your actual recruitment start date, we will use this approval date. This information is important for monitoring Trust recruitment performance for internal and external assessment.

I would like to take this opportunity to wish you well with your research.

Yours sincerely

George Georgiou

Dr George Georgiou
Quality Manager

Encs **SSI Form – Fully Signed**

cc Mrs Manju Luckson, Divisional Research Manager for Acute, Rehab and Emergency Division & Specialist Medical Services Division – CMFT

Dr Simon Campbell, Consultant Gastroenterologist – CMFT

Documents Acknowledged/Approved

Document	**Version Number / Reference**	**Date**
NRES Approval	10/H1005/50	24 August 2010
Participant Reply Form	3	02 July 2010
Letter from NIHR – 01/10/2009		01 October 2009
External Peer Review		
Summary/Synopsis	4	02 July 2010
Letter from Sponsor		02 July 2010
GP/Consultant Information Sheets	2	02 July 2010
Participant Information Sheet: Focus Groups – Healthcare Professionals	4	23 August 2010
Participant Information Sheet: Patient Focus Groups	4	23 August 2010
Participant Information Sheet: Patient Interviews	4	23 August 2010
Participant Information Sheet: Patient Observations	4	23 August 2010
Participant Information Sheet: Interviews – Healthcare Professionals	4	23 August 2010
Participant Information Sheet: Clinic Observations – Healthcare Professionals	4	23 August 2010
Participant Consent Form: Patient Focus Groups	3	02 July 2010
Participant Consent Form: Patient Interviews	3	02 July 2010
Evidence of Insurance or Indemnity		02 July 2010
Letter from NIHR – 12/10/2009		
Participant Consent Form: Focus Groups – Healthcare Professionals	4	23 August 2010
Participant Consent Form: Interviews – Healthcare Professionals	4	23 August 2010
Participant Consent Form: Observations – Healthcare Professionals	4	23 August 2010
Participant Consent Form: Patient Observations	4	23 August 2010

Conditions of Approval:-

- The Project unique identification number (PIN) must be quoted in all correspondence with the Research Office.
- All research undertaken under this approval must be conducted in compliance with the Sponsor Agreement (if applicable) and in-line with the guidance given within the Research Governance Framework. Further guidance is available on the R&D web pages.
- All researchers involved in the study need to have received appropriate training covering aspects of Research Governance and good research practice. GCP Training is provided monthly by the Research Office. From January 2009 evidence of appropriate training has become mandatory.

  The Research Office must be informed of: (please forward copies of amended documents by email)
  - The actual start date of the project
  - Any changes to the protocol throughout the course of the project
  - Any amendments sent to the MHRA or Research Ethics Committee
  - Any changes to the management of the project
  - Any extensions to the project, and associated additional funding, if applicable
- The Research Office must be notified immediately of all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) via the Trust Incident Reporting system and/or by copy of official notification to the regulatory authorities (NRES, MHRA as applicable) Research Office fax: 276 5766
- All research taking place on CMFT Trust premises is subject to the Trust monitoring programme, either as part of the annual 10% audit requirement or "triggered" monitoring[1]. The Chief and/or Principal Investigator is required to make him/her self available for any monitoring visit, on a mutually agreed date.
- All Chief and/or Principal Investigators are required to complete and submit an annual self-assessment at the request of the Research Office.
- All Chief and/or Principal Investigators are required to provide recruitment (accrual) data to the Research Office on request.
- All Chief and/or Principal Investigators are required to comply with all other UKCRN/NIHR requirements for projects that are listed on the Portfolio.
- All Chief Investigators of Clinical Trials are required to sign the Trust's *Delegation of Duties* letter issued by the Research Office.
- The Research Office must be given a minimum three months' notice, in writing, if the Chief or Principal Investigator leaves the employment of CMFT Trust.
- The Research Office must receive immediate notification if the Chief or Principal Investigator is unable to continue to fulfil his/her duties as CI/PI for other reason e.g. long-term sickness
- Any evidence of fraud &/or misconduct must be immediately brought to the attention of the Research Office either via the Incident Reporting system, or by direct communication.
- All research undertaken under this approval must comply with all applicable legislation and guidance relating to but not limited to Clinical Trials, Research Ethics, Human Tissue, Gene Therapy, Data Protection and Health & Safety.

Failure to comply with any of the above may result in withdrawal of approval for the project and the immediate cessation of the research. Persistent failure to comply may result in disciplinary action.

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[1] Triggered monitoring may be as the result of a request to monitor from an external sponsor, a problem highlighted at a standard monitoring visit requiring more in-depth monitoring, or notification to the Research Office of suspected breach of Governance issues, or other concern.

THE UNIVERSITY OF MANCHESTER

Faculty of Medical and Human Sciences

PERMISSION TO SUBMIT A Ph.D. THESIS IN ALTERNATIVE FORMAT (SUITABLE FOR PUBLICATION OR DISSEMINATION)

We confirm that the following student in the Faculty of Medical and Human Sciences, has been granted permission by his/her supervisor to submit a Ph.D. thesis in alternative format approved under the regulations, including sections which are in a format suitable for submission for publication or dissemination.

Name: ____________Karen KEMP____________

Degree programme: _____________PHD Nursing____________

Registration Number: ___________________ 7316487__________________

School: ________ School of Nursing, Midwifery & Social Work

This form should be submitted with the thesis.

Signed: __________________________________ Date 18/11/11
Graduate Education Manager
Faculty of Medical and Human Sciences Graduate Office

TWO COPIES OF THIS FORM SHOULD BE GIVEN TO THE STUDENT, WHO SHOULD SUBMIT ONE COPY WITH THE THESIS AND RETAIN THE OTHER COPY. FURTHER COPIES SHOULD BE HELD BY THE FACULTY GRADUATE OFFICE AND BY THE SUPERVISOR.

NHS
Western Cheshire
Your partner for longer healthier lives
1829 Building
Countess of Chester Health Park
Liverpool Road
Chester, CH2 1HJ
Switchboard: 01244 650300

Direct Tel: 01244 650559
e-mail: phil.elliott@wcheshirepct.nhs.uk
website: www.wcheshirepct.nhs.uk

29th March 2011

Dear Karen,

Development of a model of follow up care for patients with inflammatory bowel disease

I write to confirm we have received the necessary documentation for the above study. The project has been submitted to the relevant research review groups and has been registered on our database. I am pleased to inform you that your project has been approved by Western Cheshire Primary Care Trust.

It is imperative that you inform the Primary Care Trust should any adverse events occur when carrying out the research. Should this arise, please contact myself immediately.

We would please request that recruitment to the study is uploaded to the National Institute for Health Research portal as soon as possible.

Primary Care Trust approval is given on the understanding that we will receive an update on progress every six months and, upon completion, an executive summary of your main findings. The aim of dissemination is to celebrate your research and discuss any practical implications for service delivery.

I wish you every success in your research. If you require any further information or assistance please do not hesitate to contact me.

Yours sincerely

Phil Elliott

Dr Phil Elliott
Research and Innovation Manager
Email: phil.elliott@wcheshirepct.nhs.uk

Chairman: John Church Chief Executive: Helen Bellairs
INVESTORS IN PEOPLE
POSITIVE ABOUT DISABLED PEOPLE

GM PC ReGrouP
Greater Manchester NHS
rimary Care Research Governance Partnership

NHS SalfoR+D
Acute & Primary Care Research

NHS SalfoR+D Director: Professor Bill Ollier
R&D Lead: Rachel Georgiou

Enquiries: Email: Salford-Regroup-RD@manchester.ac.uk
Tele: 0161 206 8343
Fax: 0161 206 4205

SalfoR+D web address: http://www.nhssalfordrd.org.uk/
ReGrouP web address: http://www.gmregroup.nhs.uk/index.html

20th July 2011

Mrs Karen Kemp
Rm 5.307, Jean Macfarlane Building
University of Manchester
Oxford Road,
Manchester
M13 9PL

Dear Karen,

Study Title: The development of an intervention of follow up care for patients with inflammatory bowel disease
REC Reference: 10/H1005/50
CSP Reference: 47651/GM
R&D Reference: 2011/066

Thank you for forwarding all the required documentation for your study as above. I am pleased to inform you that your study has been registered with NHS SalfoR+D and has gained NHS R&D approval from the following NHS Trusts:

- Ashton, Leigh & Wigan PCT
- Salford PCT

All clinical research must comply with the Health and Safety at Work Act, www.hse.gov.uk and the Data Protection Act. http://www.hmso.gov.uk/acts

It is a legal requirement for Principal Investigators involved in Clinical Trials to have completed accredited ICH GCP training within the last 2 years. Please ensure that you provide the R&D Department with evidence of this (certificate for completing the course). A list of GCP training courses can be obtained from the R&D Office.

All researchers who do not hold a substantive contract with the Trust must hold an honorary research contract before commencing any study activities related to this approval. The 'Research Passport Application Form'. This can be obtained from web addresses: http://www.gmregroup.nhs.uk/researchers/passports.html and http://www.hope-academic.org.uk/academic/salfordrd/Research%20Passports.html This form should be completed and returned, with a summary C.V and recent (within 6 months) CRB to the address shown above.

It is a condition of both NRES and NHS R&D approval that participant recruitment data should be forwarded on a regular basis. Therefore, progress reports must be submitted annually to the main REC and copied to the R&D office until the end of the study. http://www.nres.npsa.nhs.uk/applicants/review/after/progress.htm#annual.

Where clinical trials of investigational medicinal products are sponsored by Salford Royal NHS Foundation Trust or Salford Primary Care Trust, it is a condition of Trust approval that Chief Investigators submit quarterly progress reports (to include Annual Safety Reports at the appropriate time) to R&D. For clinical trials of investigational medicinal products hosted within Salford Royal NHS Foundation Trust and Salford Primary Care Trust, the local PI will be expected to submit bi-annual progress reports to R&D. It is also a condition of approval that delegated duties (as agreed within clinical trial agreements and trial delegation logs) are fulfilled by only those delegated to undertake a specific duty. This will be monitored by the Sponsor's Representative during routine monitoring of the trial. Persistent non-compliance with these requirements may result in removal of Sponsorship or Trust R&D Approval.

Any amendments to the study must gain full approval by the Ethics Committee and if appropriate, by the MHRA.

Please note, because the study has been adopted onto the NIHR Portfolio, and has been processed through CSP, all amendments must be submitted through the Lead CLRN. Please do not send any amendments to R&D directly, the Lead CLRN will inform us of any amendments to the study and will send any relevant information to us for our approval.

On completion of the study you are required to submit a 'Declaration of End of Study' form to the main REC, which should also be copied and forwarded to the R&D office at the address shown above.

Any serious adverse events or governance issues related to the research must be notified to the R&D office.

Yours sincerely,

Rachel Georgiou
R&D Lead

NHS
Halton and St Helens

Research and Development Department
Victoria House
The Holloway
Runcorn
WA7 4TH
Tel: 0151 495 5480

Mrs Karen Kemp
University of Manchester
Room 5.307 Jean Macfarlane Building
Oxford Road
Manchester
M13 9PL

Date: 22nd June 2011

Dear Mrs Kemp

Letter of access for research entitled 'The development of an intervention of follow up care for patients with inflammatory bowel disease'

This letter confirms your right of access to conduct research through NHS Halton and St Helens for the purpose and on the terms and conditions set out below. This right of access commences on 22nd June 2011 and ends on 12th January 2013 unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at NHS Halton and St Helens has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to NHS Halton and St Helens premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through NHS Halton and St Helens, you will remain accountable to your employer, University of Manchester but you are required to follow the reasonable instructions of Kirsty Pine, R&D Manager in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with NHS Halton and St Helens policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with NHS Halton and St Helens in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on NHS Halton and St Helens premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Where required by law, your HEI employer will initiate your Independent Safeguarding Authority (ISA) registration, and thereafter, will continue to monitor your ISA registration status via the on-line ISA service. Should you cease to be ISA-registered, this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity. You MUST stop undertaking any regulated activity.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

NHS Halton and St Helens will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

Kirsty Pine
Research and Development Manager, NHS Halton and St Helens

cc: HR department of the substantive employer

Liverpool NHS
Primary Care Trust

Research Governance
Liverpool & Sefton PCTs
Liverpool PCT
1 Art House Square
2nd Floor
61-69 Seel Street
Liverpool
L1 4AZ
Tel: 0151 296 7726
Fax: 0151 296 7676
Email: gabrielle.marr@liverpoolpct.nhs.uk
Main Switchboard: 0151 296 7000

13th May 2011

Dear Karen

Re: Development of a model of follow up care with IBD

I am pleased to inform you that your request to carry out the above research has been given approval by the Liverpool & Sefton PCTs Research Management and Governance Collaborative Chair.

As discussed and agreed the Research Sponsor for the project is the University of Manchester.

Please note that non-NHS researchers whose work involves NHS staff or patients, their organs, tissue or identifiable patient data require an Honorary NHS Contract or Letter of Access to be set up prior to commencement of such research. **I will therefore require a copy of the research team members research passports and supporting documentation to issue the letter of access before the research starts.**

In line with national policy, the Organisation will not give approval for any NHS research work which does not comply with Research Governance guidelines. (The Research Governance Framework for Health and Social Care is available from the DH website).

The Principle investigator is required to send a final report and a lay summary to the Organisation within 3 months of the completion date of the research project.

In particular, it is a condition of our approval that the PCT Research Department must be notified of:

- Commencement and completion of the study;
- Any significant changes to the study design;
- Any further decisions made by a Research Ethics Committee regarding this study, and copies of the relevant correspondence;
- Any serious adverse events on participants or staff;
- Any suspension or abandonment of the study.

Please sign and return the enclosed investigators agreement prior to starting your research.

I look forward to receiving a copy of your final report.

Yours sincerely

Gabrielle Marr
On behalf of
Liverpool & Sefton PCTs
Research Management &
Governance Collaborative

Encl. (1)

GM PC ReGrouP
Greater Manchester NHS
Primary Care Research Governance Partnership

NHS SalfoR+D
Acute & Primary Care Research

NHS SalfoR+D Director: Professor Bill Ollier
R&D Lead: Rachel Georgiou

Enquiries: Email: Salford-Regroup-RD@manchester.ac.uk
Tele: 0161 206 8343
Fax: 0161 206 4205

SalfoR+D web address: http://www.nhssalfordrd.org.uk/
ReGrouP web address: http://www.gmregroup.nhs.uk/index.html

19th April 2011

Mrs Karen Kemp
Rm 5.307, Jean Macfarlane Building
University of Manchester
Oxford Road,
Manchester
M13 9PL

Dear Karen,

Study Title: The development of an intervention of follow up care for patients with inflammatory bowel disease
REC Reference: 10/H1005/50
CSP Reference: 47651/GM
R&D Reference: 2011/066

Thank you for forwarding all the required documentation for your study as above. I am pleased to inform you that your study has been registered with NHS SalfoR+D and has gained NHS R&D approval from the following NHS Trusts:

- Manchester PCT
- Oldham PCT
- Stockport PCT

Oldham PCT have requested that as soon as you know which Oldham GP practices will be participating, please inform koserkhan@nhs.net of the GP names

All clinical research must comply with the Health and Safety at Work Act, www.hse.gov.uk and the Data Protection Act. http://www.hmso.gov.uk/acts

It is a legal requirement for Principal Investigators involved in Clinical Trials to have completed accredited ICH GCP training within the last 2 years. Please ensure that you provide the R&D Department with evidence of this (certificate for completing the course). A list of GCP training courses can be obtained from the R&D Office.

All researchers who do not hold a substantive contract with the Trust must hold an honorary research contract before commencing any study activities related to this approval. The 'Research Passport Application Form'. This can be obtained from web addresses: http://www.gmregroup.nhs.uk/researchers/passports.html and http://www.hope-academic.org.uk/academic/salfordrd/Research%20Passports.html This form should be completed and returned, with a summary C.V and recent (within 6 months) CRB to the address shown above.

It is a condition of both NRES and NHS R&D approval that participant recruitment data should be forwarded on a regular basis. Therefore, progress reports must be submitted annually to the main REC and copied to the R&D office until the end of the study. http://www.nres.npsa.nhs.uk/applicants/review/after/progress.htm#annual.

Where clinical trials of investigational medicinal products are sponsored by Salford Royal NHS Foundation Trust or Salford Primary Care Trust, it is a condition of Trust approval that Chief Investigators submit quarterly progress reports (to include Annual Safety Reports at the appropriate time) to R&D. For clinical trials of investigational medicinal products hosted within Salford Royal NHS Foundation Trust and Salford Primary Care Trust, the local PI will be expected to submit bi-annual progress reports to R&D. It is also a condition of approval that delegated duties (as agreed within clinical trial agreements and trial delegation logs) are fulfilled by only those delegated to undertake a specific duty. This will be monitored by the Sponsor's Representative during routine monitoring of the trial. Persistent non-compliance with these requirements may result in removal of Sponsorship or Trust R&D Approval.

Any amendments to the study must gain full approval by the Ethics Committee and if appropriate, by the MHRA.

Please note, because the study has been adopted onto the NIHR Portfolio, and has been processed through CSP, all amendments must be submitted through the Lead CLRN. Please do not send any amendments to R&D directly, the Lead CLRN will inform us of any amendments to the study and will send any relevant information to us for our approval.

On completion of the study you are required to submit a 'Declaration of End of Study' form to the main REC, which should also be copied and forwarded to the R&D office at the address shown above.

Any serious adverse events or governance issues related to the research must be notified to the R&D office.

Yours sincerely,

Rachel Georgiou
R&D Lead

GM PC ReGrouP Greater Manchester Primary Care Research Governance Partnership NHS

NHS SalfoR+D
Acute & Primary Care Research

NHS SalfoR+D Director: Professor Bill Ollier
R&D Lead: Rachel Georgiou

Enquiries: Email: Salford-Regroup-RD@manchester.ac.uk
Tele: 0161 206 8343
Fax: 0161 206 4205

SalfoR+D web address: http://www.nhssalfordrd.org.uk/
ReGrouP web address: http://www.gmregroup.nhs.uk/index.html

4th May 2011

Mrs Karen Kemp
Rm 5.307, Jean Macfarlane Building
University of Manchester
Oxford Road,
Manchester
M13 9PL

Dear Karen,

Study Title: The development of an intervention of follow up care for patients with inflammatory bowel disease
REC Reference: 10/H1005/50
CSP Reference: 47651/GM
R&D Reference: 2011/066

Thank you for forwarding all the required documentation for your study as above. I am pleased to inform you that your study has been registered with NHS SalfoR+D and has gained NHS R&D approval from the following NHS Trusts:

- Bolton PCT

All clinical research must comply with the Health and Safety at Work Act, www.hse.gov.uk and the Data Protection Act. http://www.hmso.gov.uk/acts

It is a legal requirement for Principal Investigators involved in Clinical Trials to have completed accredited ICH GCP training within the last 2 years. Please ensure that you provide the R&D Department with evidence of this (certificate for completing the course). A list of GCP training courses can be obtained from the R&D Office.

All researchers who do not hold a substantive contract with the Trust must hold an honorary research contract before commencing any study activities related to this approval. The 'Research Passport Application Form'. This can be obtained from web addresses: http://www.gmregroup.nhs.uk/researchers/passports.html and http://www.hope-academic.org.uk/academic/salfordrd/Research%20Passports.html This form should be completed and returned, with a summary C.V and recent (within 6 months) CRB to the address shown above.

It is a condition of both NRES and NHS R&D approval that participant recruitment data should be forwarded on a regular basis. Therefore, progress reports must be submitted annually to the main REC and copied to the R&D office until the end of the study. http://www.nres.npsa.nhs.uk/applicants/review/after/progress.htm#annual.

Where clinical trials of investigational medicinal products are sponsored by Salford Royal NHS Foundation Trust or Salford Primary Care Trust, it is a condition of Trust approval that Chief Investigators submit quarterly progress reports (to include Annual Safety Reports at the appropriate time) to R&D. For clinical trials of investigational medicinal products hosted within Salford Royal NHS Foundation Trust and Salford Primary Care Trust, the local PI will be expected to submit bi-annual progress reports to R&D. It is also a condition of approval that delegated duties (as agreed within clinical trial agreements and trial delegation logs) are fulfilled by only those delegated to undertake a specific duty. This will be monitored by the Sponsor's Representative during routine monitoring of the trial. Persistent non-compliance with these requirements may result in removal of Sponsorship or Trust R&D Approval.

Any amendments to the study must gain full approval by the Ethics Committee and if appropriate, by the MHRA.

Please note, because the study has been adopted onto the NIHR Portfolio, and has been processed through CSP, all amendments must be submitted through the Lead CLRN. Please do not send any amendments to R&D directly, the Lead CLRN will inform us of any amendments to the study and will send any relevant information to us for our approval.

On completion of the study you are required to submit a 'Declaration of End of Study' form to the main REC, which should also be copied and forwarded to the R&D office at the address shown above.

Any serious adverse events or governance issues related to the research must be notified to the R&D office.

Yours sincerely,

Rachel Georgiou
R&D Lead

Warrington NHS
Primary Care Trust

Mrs Karen Kemp
University of Manchester
Room 5.307 Jean Macfarlane Building
Oxford Road
Manchester
M13 9PL

Research Department
Warrington PCT HQ
Millennium House
930-932 Birchwood Boulevard
Millenium Park
Birchwood
Warrington
WA3 7QN
Tel: 01925 843711

Date: 4th May 2011

Re: The development of an intervention of follow up care for patients with inflammatory bowel disease (Rec Ref 10/H1005/50)

Dear Mrs Kemp

I write to confirm that NHS Warrington R&D Department has received the necessary documentation for the above study. The project has been registered on our database.

Approval is given subject to the attached terms. Please ensure you and all members of the research team are familiar with these terms before commencing your research.

We note you have received approval from NHS North West 2 Research Ethics Committee – Liverpool Central on 24 August 2010. As the study involves direct contact with staff, you will be issued with a letter of access.

We would publish a brief summary of your research findings on our Trust Intranet. We will refrain from publication of your research findings on NHS Warrington's intranet if you inform us in writing along with your executive summary submission.

I wish you every success in your research. If you require any further information or assistance please do not hesitate to contact the R&D Department on 0151 495 5480.

Yours sincerely

Cate Carmichael

Cate Carmichael

Copy to Sponsor – University of Manchester
File

Before starting the study, please sign both copies of this letter to confirm that you accept the responsibilities outlined above. Keep one copy in your study site file and return the other to the R&D Department.

Agreement Date: ______________________

Signature: ______________________

(Please sign & RETURN to the R&D Department, Victoria House, Holloway, Runcorn, WA7 4TH)
(Please sign and RETAIN this copy for your records)

Working Together for a Healthier Future

NHS
Wirral

Mrs Karen Kemp
University of Manchester
Room 5.307 Jean Macfarlane Building
Oxford Road
Manchester
M13 9PL

Old Market House
Hamilton Street
Birkenhead
Wirral
CH41 5FL

Tel: 0151 651 0011
Fax: 0151 652 1668
Safehaven Fax: 0151 651 2918

intouch@wirral.nhs.uk
www.wirral.nhs.uk

Date: 4th May 2011

Dear Mrs Kemp

Re: The development of an intervention of follow up care for patients with inflammatory bowel disease (Rec ref 10/H1005/50)

I write to confirm that NHS Wirral R&D Department has received the necessary documentation for the above study. The project has been registered on our database.

Approval is given subject to the attached terms. Please ensure you and all members of the research team are familiar with these terms before commencing your research.

We note you have received approval from NHS North West 2 Research Ethics Committee – Liverpool Central on 24 August 2010. As the study involves direct contact with staff, you will be issued with a letter of access.

I wish you every success in your research. If you require any further information or assistance please do not hesitate to contact R&D Department on 0151 495 5480.

Yours sincerely

Dr Will Sopwith
Head of Research and Development

Copy to Sponsor – University of Manchester
File

Before starting the study, please sign both copies of this letter to confirm that you accept the responsibilities outlined above. Keep one copy in your study site file and return the other to the R&D Department.

Agreement Date: ______________________________

Principal Investigator Signature: ______________________________

(Please sign & RETURN to the R&D Department, Victoria House, Holloway, Runcorn, WA7 4TH)
(Please sign and RETAIN this copy for your records)

NHS
National Institute for
Health Research

Clinical Research Network
Coordinating Centre

NIHR Clinical Research Network
Coordinating Centre
Fairbairn House
71-75 Clarendon Road
Leeds LS2 9PH

Tel: 0113 343 2314
Fax: 0113 343 2300
Email: info@ukcrn.org.uk
www.crncc.nihr.ac.uk

28th October 2010

Mrs Karen Kemp
Lecturer/Nurse Practitioner
University of Manchester
Jean MacFarlane Building
University of Manchester
Oxford Road
Manchester
M13 9PL

Dear Mrs Kemp

Re: The development of an intervention of follow up care for patients with inflammatory bowel disease (IRAS Ref: 47651)

Thank you for submitting your study via the National Institute for Health Research (NIHR) Coordinated System for gaining NHS Permission (NIHR CSP) for inclusion onto the NIHR Clinical Research Network Portfolio. I am pleased to confirm that the above study is eligible for inclusion on the (CRN) NIHR Portfolio. [The inclusion of the study on the NIHR CRN Portfolio allows access to NHS support in England via the NIHR Clinical Research Networks]

Recruitment data
Please note that recruitment (accrual) data must be uploaded every month as a condition of inclusion on the NIHR CRN Portfolio. Recruitment data is monitored by the Comprehensive Local Research Networks and it is regularly checked that studies record their recruitment data.

It is your responsibility to:

- Identify and forward (by email) the name and contact details of the person who will be responsible for uploading the recruitment data for your study. The named person is referred to as the ‘accrual contact’

- Ensure that the accrual contact uploads recruitment (accrual) data on a monthly basis. Reported accrual activity ultimately informs the allocation of funding for NHS support

- Confirm whether the study is open to new sites. This information is extremely important to the successful development of studies.

We will then:

- Enter the study on the NIHR CRN Portfolio upon the receipt of accrual contact’s details and confirmation of whether the study is open to new sites

- Forward accrual instructions on how to upload the data to the accrual contact.

Directors
Professor Peter Selby
Professor Janet Darbyshire

International Standard Randomised Controlled Trial Number (ISRCTN)
One of the Department of Health's policies is to encourage transparency and promote public access to information about research and research findings affecting health and social care. Accordingly, the Department of Health strongly encourages voluntary registration of both interventional and observational clinical research studies on its preferred public register International Standard Randomised Controlled Trial Number (ISRCTN) which is the World Health Organisation's primary registry for the UK and is administered by Current Controlled Trials Ltd.

The NIHR Clinical Research Network (CRN) Coordinating Centre has developed a process which enables automatic and seamless registration of all new UK Clinical Research Network (UK CRN) Portfolio studies via the UKCRN Portfolio database.

New **non-commercial studies with an interventional component included on the NIHR CRN Portfolio**, which are not currently registered with ISRCTN or ClinicalTrials.gov will be registered for 'free' if they choose to register via the new UKCRN Portfolio Functionality.

Observational, industry sponsored and devolved nations studies (i.e. studies without English sites) are encouraged to use the new UK CRN Portfolio functionality to register with the ISRCTN; however for these studies ISRCTN registration will incur a fee payable by the relevant organisation/company and invoiced directly from Current Controlled Trials Ltd.

A register link for ISRCTN will be provided once your study is entered on to the NIHR CRN Portfolio and you have been issued with your study ID number

Please do not hesitate to contact me should you require further information

With best wishes

Joanna Olliver

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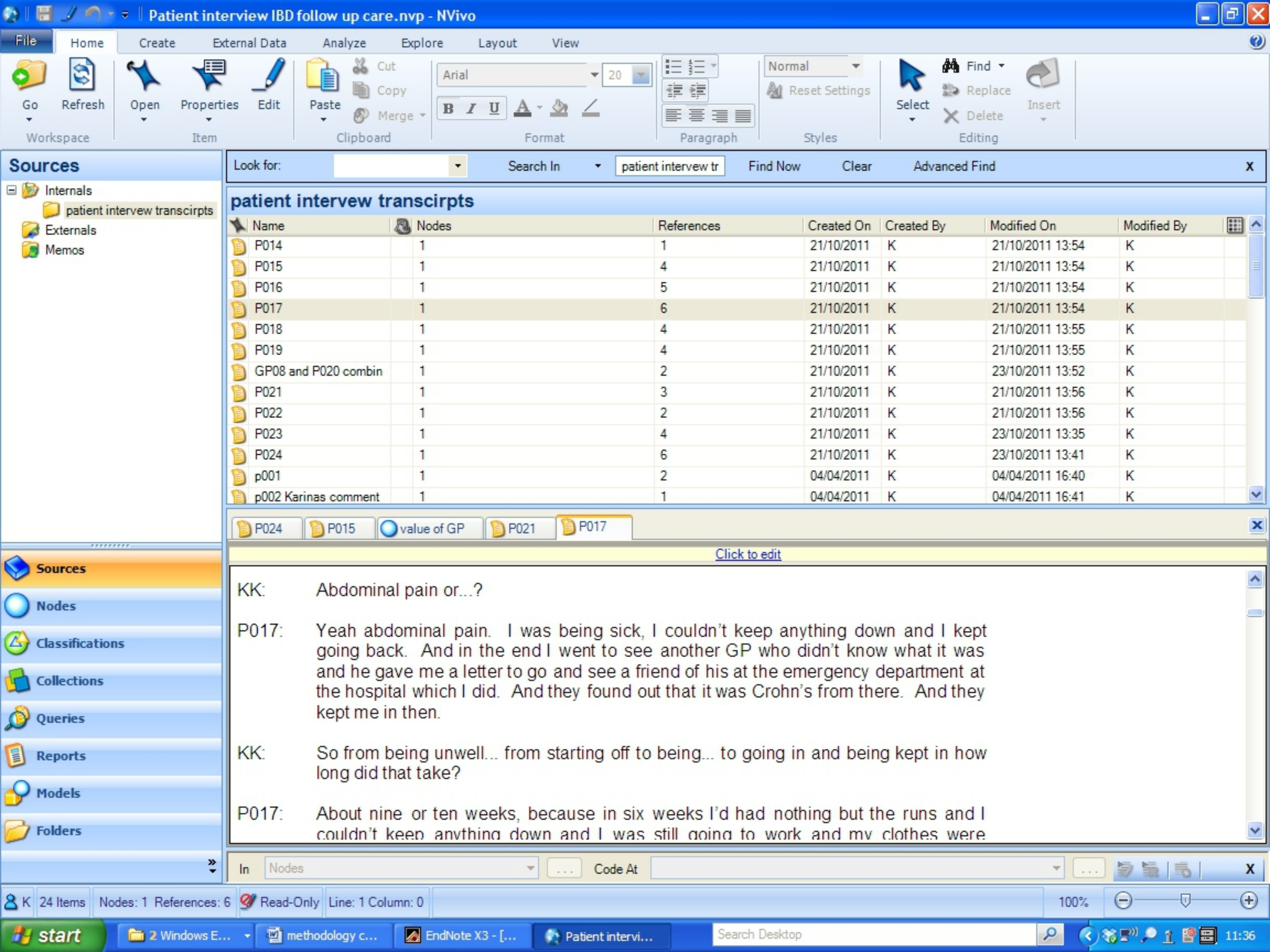


patient intervew transcirpts

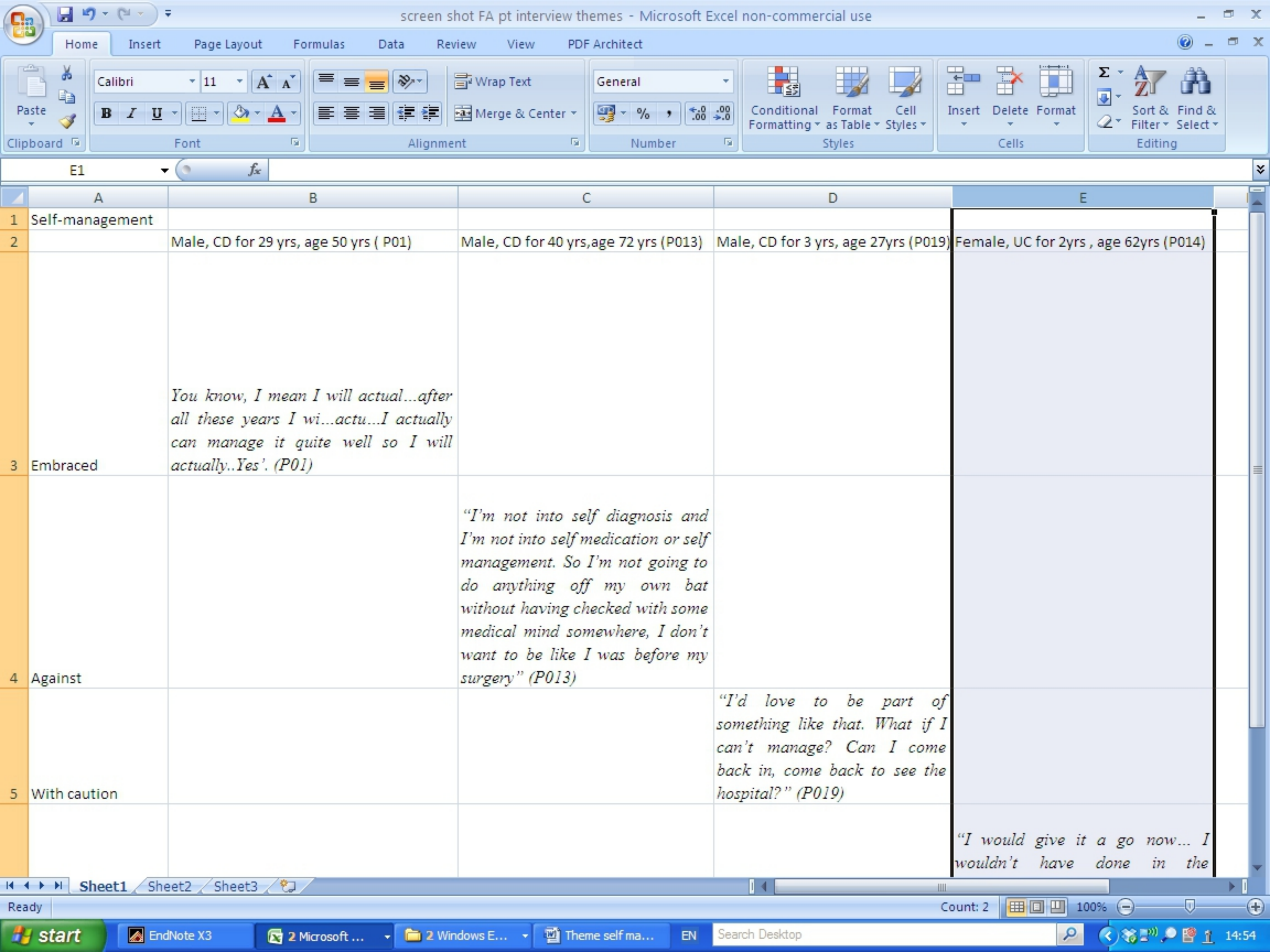
Name	Nodes	References	Created On	Created By	Modified On	Modified By
P014	1	1	21/10/2011	K	21/10/2011 13:54	K
P015	1	4	21/10/2011	K	21/10/2011 13:54	K
P016	1	5	21/10/2011	K	21/10/2011 13:54	K
P017	1	6	21/10/2011	K	21/10/2011 13:54	K
P018	1	4	21/10/2011	K	21/10/2011 13:55	K
P019	1	4	21/10/2011	K	21/10/2011 13:55	K
GP08 and P020 combin	1	2	21/10/2011	K	23/10/2011 13:52	K
P021	1	3	21/10/2011	K	21/10/2011 13:56	K
P022	1	2	21/10/2011	K	21/10/2011 13:56	K
P023	1	4	21/10/2011	K	23/10/2011 13:35	K
P024	1	6	21/10/2011	K	23/10/2011 13:41	K
p001	1	2	04/04/2011	K	04/04/2011 16:40	K
p002 Karinas comment	1	1	04/04/2011	K	04/04/2011 16:41	K

KK: Abdominal pain or...?

P017: Yeah abdominal pain. I was being sick, I couldn't keep anything down and I kept going back. And in the end I went to see another GP who didn't know what it was and he gave me a letter to go and see a friend of his at the emergency department at the hospital which I did. And they found out that it was Crohn's from there. And they kept me in then.

KK: So from being unwell... from starting off to being... to going in and being kept in how long did that take?

P017: About nine or ten weeks, because in six weeks I'd had nothing but the runs and I couldn't keep anything down and I was still going to work and my clothes were



	A	B	C	D	E
1	Self-management				
2		Male, CD for 29 yrs, age 50 yrs (P01)	Male, CD for 40 yrs,age 72 yrs (P013)	Male, CD for 3 yrs, age 27yrs (P019)	Female, UC for 2yrs , age 62yrs (P014)
3	Embraced	*You know, I mean I will actual…after all these years I wi…actu…I actually can manage it quite well so I will actually..Yes'. (P01)*			
4	Against		*"I'm not into self diagnosis and I'm not into self medication or self management. So I'm not going to do anything off my own bat without having checked with some medical mind somewhere, I don't want to be like I was before my surgery" (P013)*		
5	With caution			*"I'd love to be part of something like that. What if I can't manage? Can I come back in, come back to see the hospital?" (P019)*	
6					*"I would give it a go now… I wouldn't have done in the*

Topic Guide Patient Interviews

Aims and objectives

The overall objective is to explore the patient's needs of their follow up care, their experience of the current system and how they would wish it to be reorganised. Breaking down the key elements of the value and meaning of follow up care

This will involve exploring;

- Patients value of follow up care
- What role follow up plays in their management of the disease

Introduction

Aim: to introduce the research and set the context for the discussion

- Introduce self
- Introduce the study
- Talk through the key points
  - Purpose of the interview
  - Length of the interview
  - Voluntary nature of participation
  - Reasons for recording the interview
  - Confidentiality and how findings will be reported
  - Any questions they have

1. Background and personal circumstances

- Age, disease diagnosis, duration of disease
- Employment, impact of disease
- Managing their disease, social support, family support

2. Experience of follow up care

Need to define follow up care prior to this

- Experience of follow up care:

Probe positive and negative aspects of follow up care they have experience of, the setting, why good or bad, problems identified, why they feel this way, what might account for this

- How important is follow up care

- Ask participant to 'walk through' their follow up care routine

Probe what follow up care means to them, is it worthwhile, how do they feel following the consultation

- Are they involved in decisions about follow up care, are they give a choice, an alternative
- What role does follow up have in their life and disease management
- What role does the nurse have

Probe the qualities of HCP as a whole (not individuals)

- What role does the Consultant have
- What role does their GP have

3. The perceptions of patients with IBD of health care provision
4. Do you believe that follow care is helping you?
    - What are we doing wrong?
    - What needs are we not meeting for you?
    - Has their needs of follow up care changed over the years
    - What did they want from follow up care when first diagnosed
    - What do they want from follow up care now
    - Is follow up care system providing you with everything you need in terms of your IBD, such as health promotion,
    - How important is the actual contact?
    - What happens when they don't get a follow up appointment, or when they don't attend?
    - What are their coping strategies?
    - Do they ever talk to other patients whilst in the waiting room?
5. **Other follow up care interventions**

Probe their knowledge of other types of interventions, may need to outline types of follow up interventions, may need to offer scenarios if no knowledge of other interventions

1. What is their knowledge about guided self management

Probe do they fully understand what this is and what their own responsibilities would be, barriers to this, their expectation and responsibilities of the HCP in self management

2. How do they feel about managing their disease with no scheduled follow up

Probe their understanding, fears, how this would work, barriers

3. If you are unwell and try to manage your illness, at what point do you make that phone call to ask for help?

4. What are their thoughts on open access

Probe their understanding, fears, how this would work, barriers

6. Changes to the current follow up system

Probe each of these fully

5. What would you change about the current system and why
6. What specifics would you like to see changed
7. Discuss the setting and why
8. Discuss the time and why
9. Discuss the ‘who’ and why
10. Ask what their ideal consultation would be, what would they like to be asked?
11. Are we missing anything? I.e. psychological issues, health other than ‘IBD’ itself?

7. Summarise

Probe fully each aspect of their needs

- Can the patient sum up what their ideal follow up care pattern would look like
- I need to sum up what they have said, provide summaries throughout

8. Concluding
    - Is there anything the participant would like to add about their experience of follow up and what they would like to see changed
    - Thank participant for interview

GP Topic Guide

Aims and objectives

The overall objective is to explore the role and the views of the experience of diagnosing and managing patients with IBD. This will involve exploring;

- Their experience and perceived role in managing patients with IBD
- Their views on follow up care of these patients

Introduction

Aim: to introduce the research and set the context for the discussion

- Introduce self
- Introduce the study
- Talk through the key points
    - Purpose of the interview
    - Length of the interview
    - Voluntary nature of participation
    - Reasons for recording the interview
    - Confidentiality and how findings will be reported
    - Any questions they have
    - Why did you agree to be interviewed?
    - 'Other GPs interviewed have mixed feelings about their ability and confidence in managing patients with IBD, what are your thoughts?
    - Broaden out, how do they manage their own skills in IBD
    - Ask GP to talk about latest case, draw upon a particular example
    - What is the optimal way of managing these patients
    - Ask re family support , what role does the GP have in supporting the family of the pt with IBD, adolescent?

1. Background

- How many patients with IBD do they manage
- Why did they agree to be interviewed

2. Diagnosing patients with IBD

- How confident are they in diagnosing patients with IBD?

- What is the GP role in diagnosing patient with IBD

- What do you think GP involvement should be – diagnosis and management, just diagnosis and no management?

Probe this further, where does their role lie in IBD, what would they like it to be?

What skills do they need to diagnose or manage patients with IBD? What role would the IBD team play in this? Are they waiting until they are sure it is IBD before referring onto secondary care, will they refer early or late?

3. **Managing patients with IBD**
   - Do you manage patients with a flare up? If so how often do they manage IBD patients with a flare up?

Probe this in terms of what they do, do they treat or refer on, phone the secondary care, what do they do?

Do they think they should be involved with this, ask what their involvement is now, what they would like it to be, or not.

4. **Primary care roles in IBD**

What drugs do you think primary care should be involved in?

What do you perceive your role to be in 5 aminosalicylates? Immunosuppression or biological therapy? How much do you want to be involved in immunosuppression monitoring? Would it be just to monitor or would you be happy to administer?

If you do not think this is your role, whos role is this?

Probe re an IBD nurse in primary care

How should IBD be managed in primary care?

5. **Does the GP take part in any shared care?**
   - Are shared care protocols established?
   - Did the GP take part in the development of these?
   - If there are shared care protocols, do they use them

6. **Skills**
   - What skills are required to manage IBD patients?

Probe this in terms of it as a speciality, QoFfable, GP training, what has he or she undertaken in relation to IBD, their confidence in managing these patients and their perception of their competence in this area.

Probe further the role of GPs in specialities

7. **Views on secondary care and IBD**
   - How do you access secondary care if a patient with IBD attends the surgery?

- Do you contact anyone in secondary care if a patient comes to you with a flare up? If so who do you prefer to contact? Who is the most accessible? i.e nurse of consultant?

8. Role in follow up care

Probe what role they think they play or should play, is it in diagnosing and not in managing? Probe their knowledge of self management and what their involvement may be, are they aware of what open access is? What are their thoughts on open access?

Need to probe this further, what do they perceive their role to be, what are they willing to be involved in, where do they feel it is necessary to refer to secondary care, at what point are they unwilling to carry on.

8. New consortias

- Do you think your role will change in IBD within the new consortias?
- Cost?
- Man power?

3rd May 2012 Jean McFarlane Building, Room 2.325 10am – 3pm

Agenda for Synthesis Day

Attendees

Dr Simon Campbell, Consultant Gastroenterologist

Dr John O'Malley, GP

Ms Catherine Stansfield, Advanced Practitioner IBD,

XXXXX, patient

Academic supervisors: Professor Karina Lovell, Dr Jane Griffiths

10am arrival refreshments / coffee

10.15 Introductions

10.30 Overview of PhD study and aims of the day - Karen Kemp

10.45 Synthesis

12.30 Lunch

1.15 Synthesis

2pm Refreshments / coffee

2.15 Feedback of synthesis and discussion - Professor Karina Lovell and Dr Jane Griffiths

3pm Close

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National Institute for
Health Research

THE DEVELOPMENT OF AN INTERVENTION OF FOLLOW UP CARE FOR (ADULT) PATIENTS WITH INFLAMMATORY BOWEL DISEASE

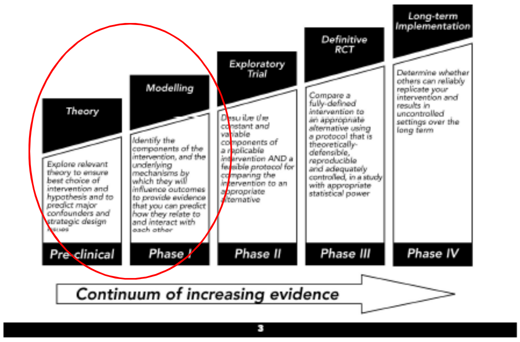
Background and rationale of the study

- Patients unhappy with FU care organisation
- Capacity issues in clinic
- Lack of evidence base to develop follow up care from patient perspective

Aims of the study to be undertaken

- To develop an acceptable, feasible and evidence based model of follow-up care for patients with Inflammatory Bowel Disease (IBD)

Medical Research Council Framework for the Development of Complex interventions (2000)



Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues

Identify the components of the intervention, and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other

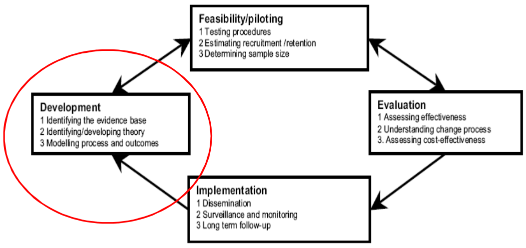
Describe the constant and variable components of a replicable intervention AND a feasible protocol for comparing the intervention to an appropriate alternative

Compare a fully-defined intervention to an appropriate alternative using a protocol that is theoretically-defensible, reproducible and adequately controlled, in a study with appropriate statistical power

Determine whether others can reliably replicate your intervention and results in uncontrolled settings over the long term

Up dated MRC guidance (2008)

Figure 1 Key elements of the development and evaluation process



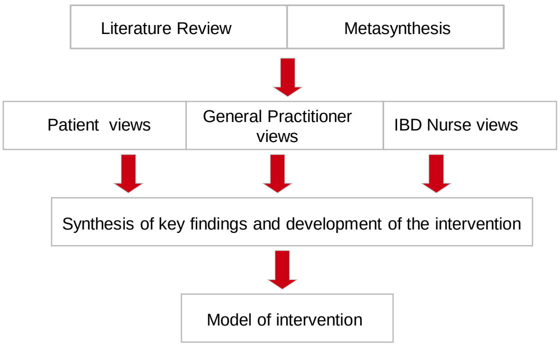
Feasibility/piloting
1 Testing procedures
2 Estimating recruitment /retention
3 Determining sample size

Development
1 Identifying the evidence base
2 Identifying/developing theory
3 Modelling process and outcomes

Evaluation
1 Assessing effectiveness
2 Understanding change process
3. Assessing cost-effectiveness

Implementation
1 Dissemination
2 Surveillance and monitoring
3 Long term follow-up

Study outline



Literature Review | Metasynthesis

Patient views | General Practitioner views | IBD Nurse views

Synthesis of key findings and development of the intervention

Model of intervention

Methodology

- Literature Review
- Metasynthesis
- Semi structured interviews with purposive sample of patients (users)
- Semi structured interviews with GPs, (stakeholders)
- Semi structured interviews with IBD Nurses
- Synthesis of findings
- Development of intervention

Evidence of organisation

- Open access (Williams 2000, Cheung 2002, Pearson 2005)
- Patient experience of open access(Rogers 2004)
- Self management (Robinson 2001, Kennedy 2003), Stansfield 2008, Gethins 2011)
- No difference in QoL, both self management group and control group worse off QUALYS, no adverse events (Richardson 2006)
- Patient and demand directed care (Rejler 2007)
- Telemedicine (Cross 2007, 2009,Rosser 2009)
- E-Health / E-homecare (van Helden 2010, Elkjare 2011)
- Virtual clinics (Porrett 2004, van Dullemen 2005, Hunter 2012)

Evidence – who should deliver

- GPs manage pts with IBD (Rubin 2000, Stone 2003)
- GPs want to be involved (Moody 1993, Stone 2003)
- No evidence for IBD nurse in Primary Care
- Shared care - insufficient evidence to demonstrate sig benefits (Cochrane Smith 2009)
- Specialist outreach clinics – improves access, reduces waiting time but may cost more (Bowling 2001, Cochrane Gruen 2009)* *evidence based on consultants not nurses*
- Heart Failure nurse model ('Managing chronic heart failure: learning from best practice' RCP 2005) NSF. Heart Failure nurse in Primary care running specialist clinics

Policy Drivers

- The Health Bill DH2010
- The NHS Outcomes Framework 2011
- QoF 2012 / 2013
- 10 NHS High Impact Actions DH 2010
- Transforming our Health Care System: 10 Key Priorities for Commissioners 2011
- 'Your health, your way' DH 2009
- Long terms conditions collaborative :High Impact Changes DH 2009
- 'Improving the health and well –being of people with long term conditions ' DH 2010
- British Society of Gastroenterology Commissioning Guide 2012
- *IBD Standards 2009*

Patient interviews – key findings

- Patients don't want to be seen when well
- Frustrations with capacity in clinics
- More flexible approach, at point of need
- Open access
- Must ensure rapid access back
- Self management
- Virtual clinics – web based, email, text, Apps, paper, phone
- Don't want to be discharged from 2nd care
- Accept GP care if still under 2nd care overall
- Safeguard - close relationship Primary and Sec Care
- 'Crisis line' but more co-ordianted
- IBD Nurse outreach clinics

GP Interviews – Key Findings

- *'tail wagging the dog'*
- Don't need to see pts when well (*cuddle appointments*)
- Support open access but must ensure rapid access
- Rapid access NOT on new pt tariff irrelevant of time frame
- Support guided self management
- Want to be involved in care
- Education specific to IBD
- IBD Nurse (heart failure model)
- Written care plans
- GP 1st point of call in flare up
- Cost effective
- Defined triggers for referral back as rapid FU and routine FU
- CRC remains 2nd care responsibility

IBD Nurse interviews

- Don't need to see patients if well
- Flexible clinics – evenings, Sat mornings, Drop in clinics don't work
- Self management at diagnosis
- Primary care with GP supported by Sec Care
- IBD Nurse in outreach clinics
- Self management with web based monitoring, GP 1st point of call, rapid access to Sec Care
- Careful selection of patients to go into this model
- Criteria defined by patient, GP, Cons IBD ,nurse
- Electronic records

Deliverables

- Provide clear and practical understanding of follow up care for patients with IBD
- Deliver an acceptable, feasible, best evidence based model of follow up care for patient with IBD
- Deliver the complex intervention in preparation for testing in next phase of MRC framework for the design of complex intervention to improve health within service delivery and organisation

Question 1

- What should be a different follow up model?

Question 2

- What is mode of delivery?

Question 3

- Who should deliver the intervention?

Question 5

- Where should the setting of the intervention be?

Question 6

- How often should the intervention be delivered?

Question 6

- Feasibility of the intervention?

Question 7

- Acceptability of the intervention?

What does the intervention look like?

Full matrix grid of synthesis of key components for follow-up care intervention

Component	**Research Evidence**	**Patient interviews**	**GP interviews**
Content?	**1.Open access** and care transferred to GP, guaranteed rapid access back to secondary care (RCT) (Williams et al 2000). **2.**GP supported **open access**, more written info required, IBD nurse and more integrated approach between hospital, GP patients and nurse (Cheung et al 2002) **3.Self management**, **patients initiated FU,** only UC, (RCT) (Robinson et al 2001) **4.Self management**, whole systems approach, structured programme with self help book, self referral. *Could not calculate if care shifted to GP* (RCT) (Kennedy et al 2003) **5.Self management** (Stansfield 2008, Gethins et al 2011) **6.Patient experience of open access**, mainly positive but security of fixed appointment important to some (Rogers 2004) **7.Patient and demand directed care**, telephone access to nurse in working hours, appointments scheduled to patients needs, emergency appt available daily, annual telephone review with nurse (Rejler 2007)	**Don't wish to be seen if well** Must have access to GP rapidly Must have access to Sec Care rapidly and have confidence in this, even if just expert advice needed e.g. fertility and drugs. Separate 'crisis clinic' from well routine clinic. **Helpline 'crisis line' still accessible but more co-ordinated**. Self management in those that wish to do this. Continued contact with sec care – newsletter – if virtual clinics. Out of hours and weekend help line – 7 day availability. Access to counsellor / psychologist Patient-initiated referral (open access) **Do not want to be discharged.**	**Don't need to see patients if well.** GP 1st point of call during flare up. Written care plans /(Primary Care Management Plans (GP01). Supportive self management, GP must be included in plan. Access to expert as and when needed. Rapid follow up clinic daily. GPs general lack of awareness of IBD Nurses in local hospitals. Regular '**appropriate**' educational updates of IBD. Inconclusive re QoF for IBD.
Mode of delivery?	**1.Telemedicine** high satisfaction (Cross 2007, Cross 2009) **2.Telemedicine and self management** SMART solutions (Rosser 2009)	Emails, paper questionnaires posted out, text, telephone clinics	The IBD nurse best placed to deliver self management training and manage any 'virtual' pathway to avoid patients lost in the system.

	3.E-Health UC only (RCT) (Elkjaer et al 2011) **E-homecare** (van Helden 2010) **4.Telephone clinics** (Miller 2002, Gethins 2007) **5.Virtual clinics** – paper clinics. Patients posted out questionnaires, blood forms, no FU given unless required from results of blood forms and responses to questionnaires (Porrett 2004, van Dullemen 2005, Hunter 2012)		
Who should deliver the intervention?	**1.GPs** manage pts with IBD (Rubin2000, Stone 2003) **2.GPs** want to be involved in IBD care (Moody 1993, Stone 2003) **3.GPs** desire more specialist education (Moody 1993) more written information (Moody 1993, Cheung 2002). **4.No evidence** for IBD nurse at the interface of Primary / Secondary care Adapting **Heart Failure nurse model in primary care** (Managing chronic heart failure: learning from best practice' RCP 2005) **5.Shared care -** Insufficient evidence to demonstrate significant benefits from shared care apart from improved prescribing (Cochrane SR, Smith et al 2009)	Someone with knowledge and expertise. If GP, which is acceptable, still must be under care of Sec Care. GP and Secondary Care together using **written care plans or within a guided self management package.** Follow up must be of value, offer confidence, security, reassurance, hope, and outcome, the person delivering the intervention must be able to achieve this. Confidence needed that GP can manage IBD properly. IBD Nurse essential	**Mixed views: GP** should be main carer with *support from Secondary Care* in quiescent, mild / mod IBD. **IBD Nurse Specialist** at the interface of Primary Secondary Care, similar to Heart Failure Nurse model (NSF Heart Disease) Patients should be discharged
Setting of the intervention?	**1.Specialists Outreach Clinics** improves access to specialist care, reduce waiting times, as part of a multi faceted intervention but may cost more (Bowling 2001, Cochrane SR Gruen 2009)**evidence is for consultants, not based on nurses. See Heart Failure Nurse Model of care.*	Mix of Primary and Secondary Care	Mix of Primary and Secondary Care
How often the intervention should be delivered?	1.IBD Standards (2009) 12 monthly review for all IBD patients. Does not state where the review should be.	Face to face 12 monthly	As prescribing responsible for reviews already. More than able to do 12 month review

Feasibility of the intervention	**1.Ten priorities for commissioners** Active support for self management Managing ambulatory care sensitive conditions (reducing hospital admission in exacerbations). **2.**Care co-ordination through integrated health and social care team (GPs as navigators as opposed to gate keepers) Managing emergency activity - urgent care. **3.QoF 2012-2013** – avoiding unnecessary follow up appointments, avoidable hospital admissions. **4.**British Society of Gastroenterology Commissioning Guide (2012) provision of ‘an integrated and flexible IBD service’ barriers must be removed e.g. tariffs. **5.**IBD Standards (2009) shared records and web based entry data to enable decision making.	Mix of Primary and Secondary Care. Electronic records between primary and sec care needed.	Mix of Primary and Secondary Care Self management. Not re-referred as a new referral if needs to come back to sec care. Cancer surveillance during quiescent periods how will this be managed? Electronic records between primary and sec care needed. Enc patient to see GP first if problems. Create Locally Enhanced Service (LES) Directly Enhanced Services (DES) for IBD. Direct contact for help.
Acceptability – what is acceptable follow up?	1.IBD Standards (2009) Patients should be offered choice of follow up care. 2.BSG Commissioning Guide (2012) ‘calprotectin should be available to GPs’	Follow up must be of value, offer confidence, security, reassurance, hope, and outcome. Patients want choice of follow up. More than ‘medical model of care’, cover all psychosocial aspects. Not to be lost in the system, forgotten. Most pts wish to be seen only when required, during flare up etc. **Many pts still wish 12 mth reviews with Cons in sec care**. 12mth review **must not** post phoned. IBD MOT review (P016). Face to face must be with healthcare professional that knows the patient. Longer appointment times. If flare up and ref back to sec care, wish to see Cons, not nurse or registrar doctor. Mix of Primary and Secondary Care. Newly diagnosed more ‘needy’ and stay with sec care at beginning.	To review patient only when required. Avoid unnecessary follow ups and reduce cost. Stop offering routine OPDs for no reason ‘*cuddle appointments* (GP04). Cost effective. Mix of Primary and Secondary Care. Self management. Seamless movement between primary and secondary care based on triggers. Define triggers?? Stages of triggers?? Sec care offer an exacerbation service at designated trigger Primary Care and Secondary Care to develop this but calprotectin test in Primary Care needed

		Some type of connection maintained. Triage appointment system (see P003 recommendations). Email contact for non-urgent questions.	Secondary care overall management of complex cases.

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BRIEF ARTICLE

Understanding the health and social care needs of people living with IBD: A meta-synthesis of the evidence

Karen Kemp, Jane Griffiths, Karina Lovell

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Author contributions: Kemp K designed the metasynthesis, conducted the search strategy, undertook the quality appraisal of included studies, conducted the main synthesis and data interpretation, and drafted the manuscript; Griffiths J and Lovell K contributed to the quality appraisal of studies to be included in the synthesis, contributed to the main synthesis and data interpretation, and contributed significantly to the draft of the manuscript; all three authors read and approved the final manuscript.

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Abstract

AIM: To undertake a metasynthesis of qualitative studies to understand the health and social needs of people living with inflammatory bowel disease (IBD).

METHODS: A systematic search strategy identified qualitative studies exploring the phenomenon of living with inflammatory bowel disease. Databases included MEDLINE, PsychInfo, EMBASE, CINAHL and the British Nursing Index *via* the OVID platform. Qualitative search filters were adapted from Hedges database (http://www.urmc.rochester.edu/hslt/miner/digital_library/tip_sheets/Cinahl_eb_filters.pdf). Qualitative empirical studies exploring the health and social needs of people living with inflammatory bowel disease were selected. Study eligibility and data extraction were independently completed using the Critical Appraisal Skills Programme for qualitative studies. The studies were analysed and synthesised using metasynthesis methodology. The themes from the studies allowed for common translations into a new interpretation of the impact of living with inflammatory bowel disease.

RESULTS: Of 1395 studies, six published studies and one unpublished thesis fulfilled the inclusion criteria. First iteration of synthesis identified 16 themes, 2nd iteration synthesised these into three main 2nd order constructs: "detained by the disease"; "living in a world of disease" and "wrestling with life". "Detained by the disease" is the fear of incontinence, the behaviour the patients display due to the fear, and the impact this has on the individual, such as social isolation and missing out on life events. All of these serve to "pull" the patient back from normal living. "Living in a world of disease" is the long term effects of living with a long term condition and the fear of these effects. "Wrestling with life" is the continued fight to thrive, the "push" to continue normal living.

CONCLUSION: The metasynthesis provides a comprehensive representation of living with IBD. The unmistakeable burden of incontinence is exposed and its ongoing effects are demonstrated. The combined overall impact of living with IBD is the tension these patients live with: "Pushed and pulled: a compromised life", people living with IBD experience a constant conflict throughout their lives, they push to be normal but IBD pulls them back. The impact of the fear of incontinence and behaviour of the individual as a result, requires further qualitative enquiry.

Key words: Inflammatory bowel disease; Metasynthesis; Qualitative; Incontinence

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INTRODUCTION

Inflammatory bowel disease (IBD) is a chronic inflammatory disease of the gastrointestinal tract that is divided into two subgroups: Crohn's disease (CD) and ulcerative colitis (UC). Characterised by periods of remission and relapse, bowel movements may be up to 20 times per day with associated faecal urgency and incontinence. IBD is also associated with extra intestinal manifestations, affecting joints, eyes, skin, bones and organs as a consequence of the disease process[1].

The disease often has a negative effect on the patient's emotional and social life, which are not always visually apparent[2]. Loss of bowel control, feeling dirty and smelly, producing offensive body odours, unfulfilled potential in the workforce and issues with sexual relationships, were concerns ranked highly in a patient survey of people with IBD[3]. One of the most prevalent concerns is fatigue[3,4]. Fatigue in people with IBD was found to be comparable to those suffering from cancer[5]. Fatigue affects the ability to work and socialise, confirming the disability associated with IBD[6]. Unemployment and sick leave is more common in IBD patients compared to the general population[7,8], with ability to work regarded as a global marker of the total impact of IBD[3].

People with IBD have a poorer quality of life than the general population[9-13] and are more likely to report increased levels of anxiety and depression with increased disease activity[14]. Evidence reveals that the disease continues to impact on the individuals psychological status even when in remission[9,15]. Overall, evidence suggests that the subjective experience of ill health associated with IBD does not always correlate with clinical disease activity.

The health-related quality of life (HRQoL) of people with IBD has been extensively evaluated with the development of two key disease specific tools: the Inflammatory Bowel Disease Questionnaire (IBDQ)[16] and the Rating Form for Inflammatory Bowel Disease Patient Concerns (RFIPC)[4]. The IBDQ was developed using survey methodology and measures subjective emotional and social functioning. The RFIPC was developed to measure neglected but important IBD concerns including disease related, body related, and inter/intrapersonal and sex related.

Whilst useful measures, the IBDQ and RFIPC fail to capture the essence of living with IBD from the patient's perspective[4,16]. For example, the RFIPC includes loss of bowel control as a concern but fails to encapsulate the real impact this has on the individual[17]. A study exploring concerns and worries of patients with CD identified other concerns and worries that were not captured within the RFIPC[18]. Objective indices within the tools do not fully summarize the patient's clinical symptoms, nor reflect the individual's experience of IBD[19-21]. Failure to capture the lived experience of IBD has been confirmed by the European Federation of Crohn's and Colitis Associations (EFCCA) patient survey[22] which reported that quality of life (QoL) and patient concerns were not taken into account when caring for patients with IBD, despite the plethora of studies highlighting this fundamental principle[23-25]. The EFCCA study identified that half of the patients surveyed were not questioned by their doctor about the impact of their symptoms on their QoL.

In contrast to quantitative measures, qualitative methods are more able to capture the essence of living with IBD from the patients perspective[26,27]. They can provide insight into the meanings, behaviours, experiences and beliefs of the participants with the aim of "drawing out understandings and perceptions and understand the linkages between process and outcomes"[28].

In order to understand IBD, tailor treatment and provide personalised care, capturing the patient experience is imperative. There are a number of small scale qualitative studies exploring the experience of living with IBD from the patient's perspective but there is a need to synthesis this evidence to further understand this before undertaking larger in-depth qualitative studies. The studies relating to IBD are small and often are not published in journals normally accessed by healthcare professionals responsible for managing these patients. Meta synthesis meets this need by the systematic selection, comparison and analysis of these qualitative combined studies and translating them to create new interpretations[28].

The qualitative meta synthesis is a set of techniques for the interpretive integration of qualitative research findings[29], it overcomes the limitations of small studies[30] and has the ability to promote a greater understanding in a particular area[31]. In this study, the purpose was to integrate and interpret the qualitative studies of the experience of living with IBD. Systematic reviews are accepted as the cornerstone of evidence based practice[32] and are based on reviews of effectiveness and of "what works". However there is now a move toward addressing the wider questions, such as why there is a problem in the first place and how it has come about. These questions need to be answered in order to develop patient centred interventions[33,34], implement studies of effectiveness and provide answers for the policy makers[31,33].

MATERIALS AND METHODS

Inclusion criteria

Qualitative studies which explored the phenomena of

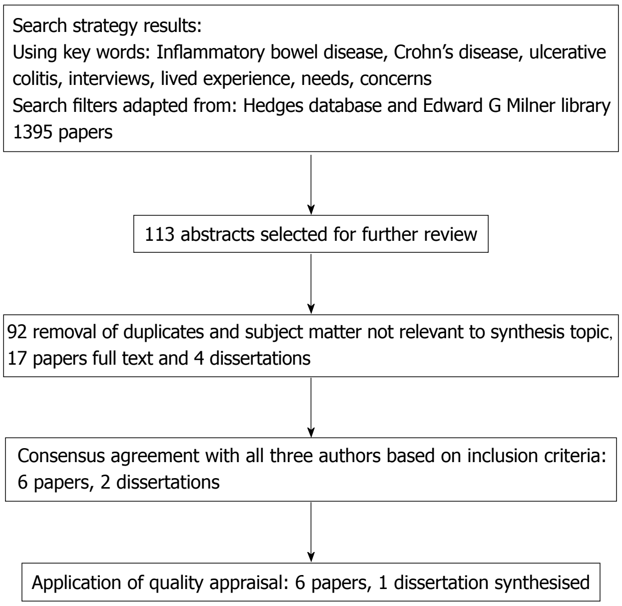

Figure 1 Flow chart summarising search strategy.

living with IBD from the patient's perspective were included in the synthesis. Additional inclusion criteria were studies restricted to English language only, published and unpublished studies and sample population adults > 16 years.

Exclusion criteria

The study focused on only one aspect e.g. living with a colostomy or diet, and mixed studies of irritable bowel syndrome and IBD.

Systematic search

Electronic literature searches were conducted in MEDLINE (1966-2010), PsychInfo (1967-2010), EMBASE (1980-2010) and CINAHL databases (1982-2010) and the British Nursing Index (1994-2010) *via* the OVID platform. Search filters developed by the Hedges database from McMaster University Health Information Research Unit and Kathryn Nesbit, Edward G Milner Library, University of Rochester Medical Centre, were adapted to aid the search (http://www.urmc.rochester.edu/hslt/miner/digital_library/tip_sheets/Cinahl_eb_filters.pdf). The search was conducted from the inception of the databases to August 2010. Web of Knowledge and CINAHL were used for citation searches, foot note chasing and journal runs. Author searches were also incorporated into the search of the literature from journals including Qualitative Health Research, Gastroenterology Nurse, and Inflammatory Bowel Diseases[35].

Of the 1395 papers generated by the preliminary search of all the databases combined, 1282 were excluded as they were irrelevant to the study question.113 abstracts were selected for further review, of which 92 were excluded based on duplication, quantitative methodology, and wrong subject matter. Four unpublished dissertations were identified within this and obtained, two excluded due to the quantitative methodological approach used[36,37], the remaining two were included for initial screening[38,39]. Full text papers were obtained for the remaining 17 papers. These 17 papers and two dissertations were then screened for initial inclusion using three screening questions: does this paper report on findings taken from qualitative work? Did the work involve both qualitative methods of data collection and analysis? Is this research relevant to the topic area?[40].

Of the 17 papers and two dissertations screened, 11 papers and one dissertation were excluded from the synthesis. The dissertation was excluded as no qualitative methodological analysis was undertaken[39]. The remaining papers were excluded based on: methodological approach used an online survey method[19]; paediatric age group[41]; subject matter focused on living with an ostomy[42]; narrative journey with no qualitative methodology[43]; participant responses used to validate commonly used indices[21] and six papers excluded as the subject group was a mixture of patients with IBD and irritable bowel disease and unable to distinguish between responses from each group[44-49].

The final selection of six papers[17,50-54] and one un published dissertation[38] were reviewed by all three authors. Data extraction forms were developed and data extraction, including study eligibility, study demographics, study characteristics, and themes, and data extraction were independently completed by three reviewers (Kemp K, Griffiths J, Lovell K).

The CASP[55] tool was used to quality appraise the papers and also to aid the interpretation and exploration process of the synthesis[56]. Further synthesis of the themes from the studies was agreed collectively at synthesis meetings to develop the new translations. The search summary is found in Figure 1 and full details of the search strategy are available from the authors.

RESULTS

Seven studies met the inclusion criteria. Summaries of the included studies are given in Table 1 and their corresponding demographics in Table 2. A list of excluded studies is available from the authors.

Characteristics of included studies

The seven selected studies were published from 1996-2010. Two were conducted in the United Kingdom[50,54], one in Sweden[52], one in Canada[51], one in New Zealand[53], and two in America[17,38]. All of the studies used in depth interviews[17,38,51-54] and one study combined interviews with focus groups[50].

A total of 86 patients with an age range was 16-83 years were included and only one reported one patient from an ethnic background[52]. Two studies focused on CD only[52,53], and one study UC patients only[17]. The remaining studies included people with both UC and CD. Patients were recruited from relevant national IBD charities[38,53], directly from outpatients clinics[17,52,54], media advertisements[51], and from a previous community

Table 1 Characteristics of synthesised studies

Ref.	Theoretical perspective	Sampling strategy	Recruitment setting	Data collection method	Analytical approach
Dudley-Brown[17]	Phenomenological	Convenience sample (n = 3)	Patients sampled from IBD outpatient clinic when attending for their scheduled appointment	In depth semi structured interviews	Coding and memo system used, grouped and transformed into an interpretive understanding of the phenomenology of living with UC, with the extraction of emergent themes
Daniel *et al*[51]	Phenomenological	Purposive sample (n = 5)	Patients recruited by an advertisement in national newspaper	In depth semi structured interviews	Kings Goal Attainment Framework used as theoretical framework; thematic content analysis of interviews to develop themes in line with this framework
Hall *et al*[50]	Grounded theory	Purposive sample (n = 31)	Recruited from a previous unconnected study, sampled by lowest quintile of UK-IBDQ, established low quality of life	In depth interviews and focus groups	Concurrent data collection and analysis to identify emerging themes; selective coding was used to enabled theoretical framework
Burger *et al*[38]	Interpretive phenomenological design	Convenience sample (n = 8)	Participants from mailing list of Indiana Chapter of Crohn's and Colitis Foundation of America, answered advert and recruited according to inclusion/exclusion criteria	In depth interviews, each participant interviewed 3 times	Thematic analysis, identification analysis and identification of paradigm cases used
Lynch *et al*[53]	Phenomenological	Purposive sample (n = 4)	Participants recruited from Crohn's and Colitis New Zealand	Semi structured in depth interviews	Thematic analysis from transcribed data, ongoing process of interpretation used to refine themes to describe nature of the experience
Pihl-Lesnovska *et al*[52]	Grounded theory	Theoretical sample (n = 11)	Patients recruited from the gastroenterology outpatient clinic	Unstructured in depth interviews	Constant comparative analysis used, saturation determined sample size; core category and related categories identified; two authors analysed all interview transcripts
Cooper *et al*[54]	Framework	Purposive sampling (n = 24)	Patients sampled from IBD outpatient clinic when attending for their scheduled appointment	Semi structured in depth interviews	Thematic content analysis using framework

IBD: Inflammatory bowel disease; UK-IBDQ: United Kingdom version of the McMaster Inflammatory Bowel Disease Questionnaire; UC: Ulcerative colitis.

Table 2 Demographics of synthesised studies

Ref.	Date	Country	Age range	Gender	Disease	Disease duration	Sample size
Dudley-Brown[17]	1996	United States	30-50 yr	1 female; 2 male	3 ulcerative colitis	1-10 yr	3
Daniel *et al*[51]	2001	Canada	18-24 yr	2 female; 3 male	IBD not specified	< 2 yr	5
Hall *et al*[50]	2005	United Kingdom	Not specified but all > 16 yr	19 female; 12 male	14 Crohns's disease; 17 ulcerative colitis	Not specified but all > 2 yr	31
Burger *et al*[38]	2005	United States	30-65 yr	6 female; 2 male	6 Crohn's disease; 2 ulcerative colitis	2-40 yr	8
Lynch *et al*[53]	2007	New Zealand	16-21 yr	3 female; 1 male	All Crohn's disease	< 18 mo	4
Pihl-Lesnovska *et al*[52]	2010	Sweden	29-83 yr	5 female; 6 male	All Crohn's disease	2-33 yr	11
Cooper *et al*[54]	2010	United Kingdom	30-40 yr	11 female; 13 male	12 Crohn's disease; 12 ulcerative colitis	1- > 10 yr	24

IBD: Inflammatory bowel disease.

based study[50]. The theoretical perspectives were mainly phenomenology[17,38,51,53] and grounded theory[50,52] with one study using framework[54].

Synthesis of the evidence

The three authors independently reviewed all of the studies. The emergent themes were subject to constant examination until an argument to explain the data of the combined studies was developed. The themes and findings of each study were compared with one another repeatedly to identify the 1st order constructs. This revealed the similarities and differences in the data, which led to 2nd order constructs and the interpretation of all of the synthesised studies. For example, study 1 may have had findings AB and C, study 2 may have findings AC and D, a new finding. The synthesis from studies 1 and 2 was compared to study 3 and so forth, until all of the papers were synthesised[29,57]. Early on in the synthe-

Table 3 Themes and concepts

1st order constructs	Ref.	2nd order constructs	Line of argument synthesis
Limitations/missing out on life events	[17,38,50-54]	Detained by disease ("pull")	"Pushed and pulled: a compromised life" Constant conflict between IBD and normal life results in a compromised life. Pushes to be normal but IBD pulls individual back.
Humiliation of incontinence	[17,50,51,53,54]	Fear of incontinence - unpredictability, humiliation	
Social isolation	[17,38,50,51,53,54]	Behaviour due to fear of incontinence - avoidance	
Unpredictability	[38,50-53]	Impact of behaviour - socially isolated, missing out on life events, limited life, relationship burden, feeling damaged	
Powerlessness	[17,38,53,54]	Fatigue	
Feeling damaged	[38,52-54]		
Impact on relationships	[17,38,50-54]		
Negative emotions	[17,50-54]		
Stress	[38,51-54]		
Fatigue	[38,50-53]		
A disease for life	[38, 51-53]	Living in a world of disease	
Fear of long term effects	[38, 51-53]		
Invisible disease	[38,50,53,52]		
Acceptance yet fight	[38,53,54]	Wrestling with life ("push")	
Knowing my body	[38,53,54]	Striving to thrive	
Control	[38,51-54]		
Maintaining normality	[38,50,52,53]		

IBD: Inflammatory bowel disease.

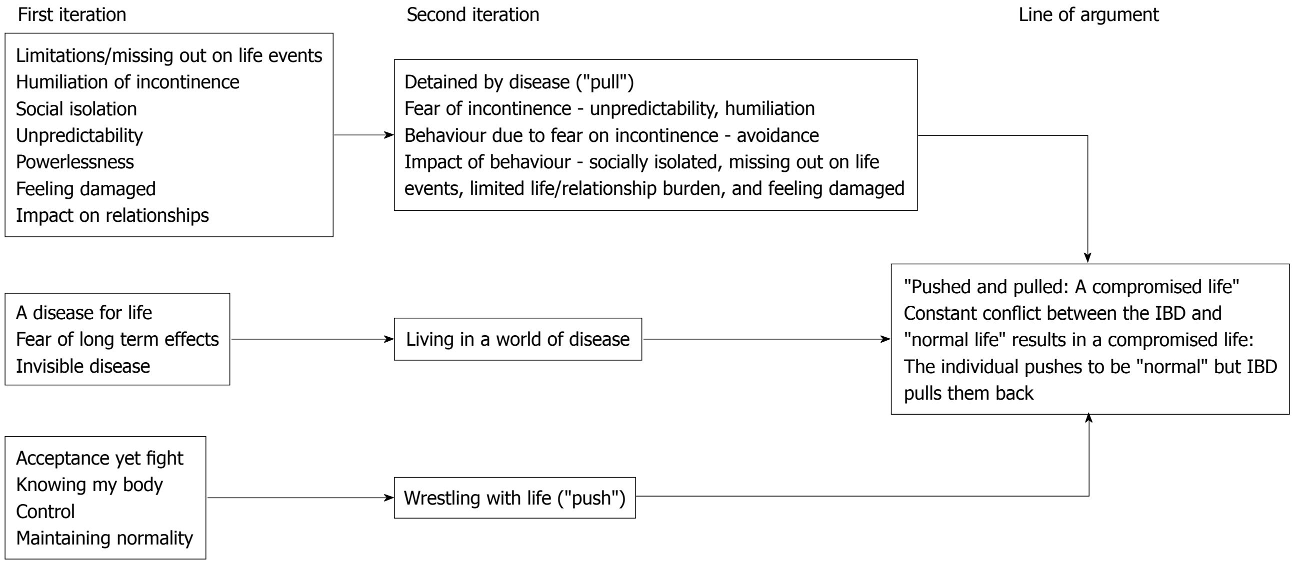

Figure 2 Relationship between synthesised studies. IBD: Inflammatory bowel disease.

sis it was clear that the relationship between the studies was mutual, all sharing common themes[58]. As the studies had a "reciprocal" arrangement, a new argument was developed. This process was followed systematically, starting with the oldest study first[17] in keeping with the model of "line of argument" synthesis[58]. The themes and concepts are illustrated in Table 3 and the relationship between them identified in Figure 2.

Results - synthesis of the evidence

The synthesis of the seven studies identified that people with IBD endure many daily challenges, stress, pain, fatigue, and fighting for control. The combined impact of living with IBD is the tension they live with. The meta-synthesis has provided an in-depth exploration of living with IBD: "Pushed and pulled: a compromised life", people living with IBD experience a constant conflict throughout their lives, they push to be normal but IBD pulls them back.

Living in a world of disease

A disease for life: Participants were acutely aware that they had been diagnosed with a long term condition with no cure. Facing and accepting the incurable illness was met with a variety of responses yet the need to get back to normal, but inability to do so, was a theme running through all of the studies.

Fear of long term effects: The fear of long term effects, of death and dying left people feeling powerless[52].

The risks of cancer development and passing on the illness to children added to the burden of living with the physiological aspects of the illness[38,52].

Invisible disease: A difficult aspect of living with IBD is its invisibility[17,38,52,53]. The studies detail how this concept affected the individuals. The lack of understanding from others doubting that they were actually sick as it was not visible, added to their feelings of anger and frustration, in particular with family members[51]. "My sister says I'm blowing this up...it's an act...I'm trying to get attention"[51].

Wrestling with life: Striving to thrive ("push")

Acceptance yet fight: A common theme throughout all of the studies was the individual's willingness and need to wrestle with their illness. Three of the studies discussed the acceptance of living with the illness yet continuing to fight it[38,52-54]. This can be interpreted as neither a submission to the illness nor as out and out combat but more where individuals made peace with their illness. "This is how I am...to me it's no different than saying I have a dog"[38].

Control: The concept of control is visible in all seven studies, whether this was trying to control the illness[50], controlling bowel urgency[38] or losing control[51]. Individuals fought to gain and maintain control and find a balance between what they could control and what they needed to control, for life to be acceptable[54]. Gaining "control" had a positive impact on the individuals, recognising "performance accomplishments"[54] and allowing them to feel "normal"[50]. However the cost of achieving this was a large trade off which was capable of wearing the individual down and losing its ability to continue to fight, fatigue becoming a significant problem[50]. Attempting to control their illness was their attempt to try to maintain "normality" for many people within the studies[38,50,52,53].

Knowing my body: Participants voiced the theme of "knowing my body", with accounts of knowing when their illness flared up better than their doctor. An increased awareness of their body led the individuals to try to identify triggers or patterns and recognise when their illness flared up. By learning about their own body the individual tried to gain some scale of control but often this concluded in them feeling helpless and misunderstood[53]. "He stated that he knew it was not his CD even though it was the physician's first inclination"[38]. Wrestling with life culminates with the individual pushing to be normal, accepting their illness yet striving to thrive and survive.

Detained by the disease ('pull')

Fear of incontinence (unpredictability, humiliation): All of the studies report the patient's fear of incontinence and how they try to live with this[17,38,50-54]. The fear appeared to be associated with past experiences of actual episodes of incontinence and remembering the humiliation this produced. Actual episodes were rare but the fear remained constant. Patients felt ashamed, not only of the actual incontinence but also of their ongoing fear. Some people reported the overwhelming shame of incontinence. Shame and humiliation was even experienced within the family unit, one grandmother describing the embarrassment should her grandchildren know that she cannot make it to the bathroom[38,51,54]. This fear of incontinence was all consuming for some patients and became a focus of living with IBD, over and above the physical symptoms. "It's terrible, but that's the biggest fear"[38].

Behaviour due to fear of incontinence (avoidance): The fear of incontinence and its unpredictability had a profound effect on the individual's behaviour. For many this fear led to an avoidance or curtailing of daily activities and impaired individuals work, social and leisure and private functioning[17,38,51].

Individuals used a range of coping strategies to either manage or avoid incontinence and included carrying potties and spare clothes, wearing nappies and identifying bathrooms prior to any travel[17,38]. Travelling anywhere required extra time and was dictated by the individual's bowel frequency and control. "Planning an escape route provided a sense of security even if it was not needed"[38].

The impact of this behaviour led to avoiding places and people. Studies describe patients only attending safe places[50] with a dependency on toilets[51] or avoiding public places all together[17].

Impact of behaviour (missing out on life events, socially isolated): The fear of incontinence, coupled with avoidance behaviour, was immensely detrimental to the individual's QoL. They became socially isolated very easily: had limited activity with family and friends[38]; became reclusive[50]; and missed out on life events[51]. The self enforced social isolation led to feelings of social inadequacy, lacking the necessary societal skills for everyday living[51]. "I've just missed a whole part of my life"[51].

Individuals expressed feeling damaged, a failure, weak and feeble with overwhelming feelings of anger, frustration and depression[50-53]. Unable to identify a pattern or trigger for their disease reinforced all of these negative emotions[17,38,53].

Stress was overtly discussed in five studies[38,51-54]. Triggers for stress ranged from the illness itself to outside factors such as the ability to work and financial concerns and manifested itself in the form of fatigue and exacerbations of their disease. Lack of understanding from family members and feeling redundant in the family home[50] left people feeling alienated from partners and family[51], and people reported complex emotions of "letting people down"[53].

Fatigue, tiredness and exhaustion contributed to people's feelings of frustration, stress and powerlessness[52]. Some people felt that fatigue was a sign of weakness[53] and was generally misunderstood by others[50] as it was not evidently visible, reinforcing the invisibility of the disease.

Detained by the disease became evident as the analysis of the studies revealed that the fear of incontinence, the behaviour associated with it and the resultant enforced social isolation, resulted in "pulling" the individual back from "normal" living.

Line of argument

A line of argument was derived from the synthesis of the seven studies[58]. The common translations from the studies were taken a step further and constructed into a new interpretation.

Line of argument synthesis: the ongoing factors identified by the qualitative studies impact on the individual's whole life with IBD leading to a compromised life: the individual pushes to be normal yet IBD pulls them back. The individual is in constant conflict, fighting to be normal with the impact of this resulting in constant tension within.

The synthesised studies revealed the fear and humiliation surrounding incontinence which resulted in severely reduced social interactions. Descriptions how the illness "intruded" into the participant's life and the constant "fight" for normality was evidenced throughout all of the studies. Phrases, including the "see-sawing of fears and hopes", illustrate the uncertainties and contradictions of living with IBD. Importantly, the individuals describe the courage required to break the social isolation resulting from bowel symptoms. All of these aspects of living with IBD are directly related to everyday life.

DISCUSSION

The aim of this metasynthesis was to provide an interpretation of the health and social needs of patients living with IBD by synthesising qualitative studies and key issues emerged. People with IBD endure many daily challenges including stress, pain, and fatigue and fighting to maintain normality. The combined overall impact of living with IBD is the tension these patients live with. The value of metasynthesis is the interpretation of all of the synthesised studies to provide an inclusive representation of living with IBD: "Pushed and pulled: a compromised life", people living with IBD experience a constant conflict throughout their lives, they push to be normal but IBD pulls them back.

Considering the plethora of evidence pertaining to the patient's QoL, symptom burden, and psychosocial factors related to IBD[3,10,12,25,59,60], there are few qualitative studies directly exploring the patient's beliefs and behaviours from the patient's perspective. Only seven studies were identified, six published and one unpublished thesis, the earliest undertaken in 1996 and the latest in 2010, during a 14 year time span. The studies amount to only 86 patient accounts of living with IBD.

People diagnosed with a chronic disease must adjust to the demands of the disease as well as to the treatments for their condition[61]. The disease may affect how the individual perceives him or herself and their relationship with others. The shifting perspectives model of chronic illness determined that life with a chronic illness does not follow a predictable trajectory but people experience a "complex dialectic between themselves and their world"[62]. This process of debate and argument, trying to cope with the disease is all encompassing; the individual with IBD lives in a world of disease, even when in remission.

Studies have identified the long term complications of IBD, such as bone problems and colorectal cancer[63]. These potential long term complications heighten the individual's fear of the disease. The uncertain nature of the illness and developing cancer were concerns ranked highly for people with IBD[4,23]. The fear of long term complications and dying are difficult discuss with others when outwardly the individual appears fine[38,51].

The issue of control is important within all of the studies. The ability to take control and the relationship with psychological functioning has been established in the literature. Personal control may be informed by self efficacy[64] or the Common Sense Model whereby the extent to which the individual believes that their illness is manageable and possible to control, becomes focal to their behaviour[65]. Individuals with IBD have been found to have significantly poorer psychological health than those without IBD[66] and the metasynthesis has illustrated that control and coping are important factors and assist the psychological well being in these individuals. Controllability and coping strategies were closely linked to knowing how their body reacted to their illness and identification of flare ups[38], maintaining normality and acceptance of IBD within the individual's life[50,52-54].

The unmistakeable burden of the fear of incontinence, the behaviour related to this fear and the impact of this behaviour on the individual, is exposed and its ongoing effects are demonstrated much more clearly by the metasynthesis. An early study identified urgency of defecation and the fear of incontinence as factors affecting the QoL in individuals with CD[54]. Behaviour due to fear and coping strategies, such as avoidance of public places, carrying potties when leaving the house[38], changing working schedules[21], have been identified in other studies, but the collective impact of this fear and behaviour reveals the true impact IBD has on the individual. The humiliation of incontinence and unpredictable nature of the disease leave the individual socially isolated and missing out on important life events. The reality that this fear and behaviour continues into disease remission compounds the stress, fatigue and debilitative nature of it.

All of the synthesised studies identified the issue of incontinence but the unmistakeable burden of this is exposed and its ongoing effects are demonstrated much more clearly by the metasynthesis, supporting the value of the metasynthesis and its ability to interpret studies into new translations.

There are limitations to the metasynthesis: the low number of people with IBD included in the synthesis;

the subjective nature of the synthesis; and grouping studies from various countries with different and changing health care systems over a period of 14 years and combining them and the advent of biologic drugs. The countries have similar socio-economic systems with developed healthcare resources but differ in terms of the financial aids required to access healthcare. Over the past decade the profile of chronic disease management has increased due to the aging population and the role of health care in the management of this area has changed dramatically with greater emphasis placed on self management. Early studies may be deemed outdated. However the methodology of the metasynthesis and the accounts of living with IBD in the studies remain important to capture the phenomenon of living with IBD.

Based on our analysis, we conclude that the fear of incontinence, the behaviour related to this fear and the impact of this behaviour on the individual, are perhaps the most significant issues to emerge from the metasynthesis. The findings highlight the daily challenges and tensions that individuals with IBD face, whether their disease is in remission or not. Evidence has found the incidence and prevalence of IBD to be increasing, indicating its emergence as a global disease[67]. Perhaps with the emergence of biologic therapies and gene identification, emphasis has been placed upon the acute aspect of IBD and the chronicity of the disease is forgotten.

The physical symptoms alone do not validate the subjective impact of living with IBD[3]. The psychological burden of living with IBD, QoL and specific psychological co morbidities are described as “un-promoted issues”: issues that are not always addressed in the medical literature[68]. Identification and clarity of these “un-promoted issues” can only be met by undertaking qualitative studies and health care professionals need to be aware of the influences these have on the individual when developing treatment strategies. More focused attention on the patient’s perspective of living with IBD is needed to provide patient centred care and structure health care services. The emergence of the immense impact of incontinence, fear and behaviour on the individual from this metasynthesis requires further qualitative enquiry.

COMMENTS

Background

The incidence and prevalence of inflammatory bowel disease (IBD) is increasing and it is being recognised as a global long term condition, with significant morbidity and cost. In order to provide patient centred care, an understanding of the impact of living with IBD, from the patient’s perception, is important. The Rating Form for Inflammatory Bowel Disease Patient Concerns and Inflammatory Bowel Disease Questionnaire are widely used measures to describe what it is like to live with IBD but these fail to capture the essence of this. There are few qualitative studies which fully demonstrate the impact of living with this condition. By using metasynthesis methodology, this study adds significant understanding of IBD and the impact of living with IBD, from the patient’s perspective.

Research frontiers

There is growing emphasis that the needs and preferences of patients must be addressed when developing and evaluating new models of care delivery. Incorporating patient preference, choice and experience is acquired through qualitative studies. Synthesising qualitative studies of IBD gives a profound insight into the disease. Capturing this evidence can lead to a greater understating of the condition and help to tailor treatments and provide personalised care.

Innovations and breakthroughs

Recent audits from the European Federation of Crohn’s and Colitis Association has demonstrated, on a large scale, the impact IBD has on the individual’s personal, work and social life. This audit highlighted some important considerations of IBD care in Europe, however, a more immersed understanding is required. This is the first metasynthesis of IBD and provides a comprehensive insight of what it is like to live with.

Applications

The findings from this study emphasises the impact incontinence has on the individual, even in remission. The fear of incontinence, the behaviour related to this fear and the impact of this behaviour on the individual, are the most significant issues to emerge from the metasynthesis, and requires further qualitative enquiry.

Terminology

IBD is a collective term for Crohn’s disease and ulcerative colitis. Qualitative studies typically use focus groups and/or interviews to gather data. Qualitative studies, from the patient’s perspective, are used to highlight the lived experience of a phenomenon. Metasynthesis is a method of identifying and bringing together (synthesising) relevant research evidence from a variety of qualitative studies. Metasynthesis methodology seeks to expand the understanding of patient experience.

Peer review

The enclosed metasythesis analyses the data from the literature regarding understanding the health and social care needs of patients with IBD. The paper is very well written. The Authors observed that the most significant issues were fear of incontinence, the behaviour related to this fear and the impact of this behaviour on the individual. This paper adds a lot of important information on health quality of life in IBD patients and help readers to understand the IBD more.

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An exploration of the follow-up up needs of patients with inflammatory bowel disease

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KEYWORDS
Inflammatory bowel disease;
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Follow-up care

Abstract

Background and aims: The rising incidence of inflammatory bowel disease (IBD) in adults and children has implications for the lifelong burden of disease and the provision of specialist services. Patients with IBD should have access to specialist care which is delivered according to their values and needs. Few studies have examined patients' views of follow-up care. The aim of this qualitative study was to explore patients' needs, preferences and views of follow-up care.
Methods: IBD patients were selected from a gastroenterology clinic in a UK Hospital and invited to participate in interviews which focused on needs, preferences and role of follow-up, their experience of follow-up, service delivery, and other models of follow-up care.
Results: 24 patients were recruited, 18 patients had Crohn's Disease, and 6 ulcerative colitis. Median age was 48.5 years (range was 27–72 years) and median disease duration 11.5 years (range 2–40 years). Four main themes emerged: (1) experiences of current follow-up care; (2) attitudes to new models of care, including self-management, role of general practitioner, patient-initiated consultations and 'virtual' follow-up; (3) the personal value of follow-up care; and (4) the 'ideal' consultation.
Conclusion: The main finding was that patients prefer a more flexible follow-up care system. 'Virtual' care as an adjunct to patient-initiated consultations and self-management, was identified as optimal approaches to meet the patients' needs of follow-up care. New models of follow-up care could improve the patients' experience of care, offer potential cost savings with reduction in face-to-face consultations and allow targeted care to those who need it.

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1. Introduction

IBD remains a challenging disease for healthcare services in its treatment, diagnosis and prognosis, assessment of disease activity and severity, and outcome of treatments.[1,2] Evidence suggests that the prevalence of IBD is rising in both adults[3] and children.[4–6] This is mirrored both in Europe[7] and North America.[8] This rise has implications for the substantial lifelong burden of this disease and the provision of specialists healthcare services.

Follow-up care for IBD differs from many other healthcare conditions. IBD is not only a life-long illness, it has a considerable spectrum of disease severity and complexity and a natural history characterised by periods of remission and relapse. In addition, the condition requires other active follow-up considerations when patients are clinically well for example colon cancer surveillance. The nature of the symptoms suffered by patients, reflecting the complexity of the disease, dictates that the follow-up facilities required are beyond those normally provided in general outpatients.[9]

As a chronic long term condition it has been recognised that patients with IBD should have access to specialised care.[10] The health care needs of patients fluctuate depending on the type of disease, and the care they receive during periods of remission and relapse. Factors such as the type of medical treatment they received, haematological monitoring required, level of support from primary care, and pattern of disease, such as penetrating, fistulising and number of flares per year, influence the follow-up care a patient with IBD requires or receives.

Traditionally patients are regularly followed-up and are not discharged from the gastroenterology service. In response to this, some IBD centres have implemented alternative services, such as telephone clinics and help lines to avoid unnecessary out-patient visits.[11]

In summary there is little evidence on which to base the provision of follow-up care for people with IBD. Such follow-up care, as with any long term condition, should be delivered according to patients' values, within a system that anticipates patients' needs and a service based on evidence.[12,13] Recent health care policy in the UK has emphasised the need to move long term conditions management from the hospital setting to primary care. However there has been a paucity of work which has explored IBD patients' perceptions of their follow-up care and which factors influence their needs and preferences for their care.

The study aimed to explore IBD patients' experience, needs and preferences of follow-up care.

2. Materials and methods

A qualitative study design was used to explore patients' needs and preferences for follow-up care.

2.1. Sample and data collection

Patients with IBD were purposively sampled from a University Foundation Trust in the UK. 24 patients were recruited from a gastroenterology clinic prior to their out-patient appointment, selected according to age, disease severity and duration to ensure diversity of sample and invited by post to participate in one-to-one interviews. All patients invited took part in the study. Inclusion criteria were: patients with an existing diagnosis of CD or UC; 18 years or older; and able to give informed consent. Demographic and clinical characteristics of participants are shown in Table 1. Interviews used a semi-structured topic guide and lasted approximately 1 h (range 40–60 min) (see Box 1 interview 1 topic guide). The interviews were digitally recorded and transcribed verbatim. Interviews continued until data saturation occurred.

2.2. Analysis

Interview transcripts were analysed using framework analysis.[14] Framework analysis is recommended when the objectives of the study are typically set in advance, in this case acceptable follow-up care based on patients' preferences. Framework starts deductively from pre-set aims and objectives, and data collection tends to be more structured than other approaches to qualitative data collection. The analytic process is more strongly informed by a priori reasoning.[15,16] There are five stages of data analysis within framework: familiarisation; identification of the thematic framework; indexing; charting; mapping and interpretation. Following familiarisation of the transcripts, the thematic framework was developed. The

Table 1 Demographics and patient characteristics.

Participant	Gender	Median age 48.5 years (range 27–72 years)	Disease	Median disease duration 11.5 years (range 2–40 years)
P01	M	50	CD	29
P02	F	54	CD	36
P03	F	50	CD	9
P04	M	38	CD	15
P05	F	60	UC	22
P06	F	60	CD	7
P07	F	40	CD	7
P08	F	31	UC	10
P09	F	48	UC	6
P010	F	27	CD	14
P011	F	57	CD	3
P012	F	31	CD	18
P013	M	72	CD	40
P014	F	62	UC	2
P015	F	44	CD	20
P016	M	58	UC	10
P017	F	48	CD	13
P018	M	68	CD	38
P019	M	27	CD	3
P020	M	49	CD	30
P021	F	47	CD	20
P022	M	41	CD	25
P023	F	24	CD	13
P024	M	41	UB	17

CD = Crohn's Disease; UC = ulcerative colitis; M = male; F = female.

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Box 1 Topic guide.

The overall objective was to explore the patient's needs of their follow-up care, their experience of the current system and how they would wish it to be reorganised. Breaking down the key elements of the value and meaning of follow-up care.

Review of history of diagnosis and disease (will be referred back to when describing follow-up care experiences)

Experience of follow-up care: Need to define follow-up care prior to this.

- Experience of follow-up care: Probe positive and negative aspects of follow-up care they have experience of, the setting, why good or bad, problems identified, why they feel this way, what might account for this.
- How important is follow-up care.
- Ask participant to 'walk through' their follow-up care routine.
- Has their needs of follow-up care changed over the years.
- What did they want from follow-up care when first diagnosed?
- What do they want from follow-up care now?
- Is follow-up care system providing everything needed in terms of your IBD, such as health promotion,
- How important is face-to-face contact?
- What happens when they don't get a follow-up appointment, or when they don't attend?

Other follow-up care interventions: Probe their knowledge of other types of interventions, may need to outline types of follow-up interventions, offer scenarios if no knowledge of other interventions

1. How do they feel about managing their disease with no scheduled follow-up?
2. If you are unwell and try to manage your illness, how do you do this? At what point do you make that phone call to ask for help?
3. What do you think about patient initiated appointments, open access?
4. What do you think about tele-health or 'virtual' clinics, remote monitoring?
5. Are there other ways of providing follow-up care?

Changes to the current follow-up system: Probe fully:

1. What would you change about the current system and why.
2. What specifics would you like to see changed.
3. Discuss the setting and why.
4. Discuss the time and why.

Box 1 (*continued*)

5. Discuss the 'who' and why.
6. Are we missing anything? i.e. psychological issues, health other than IBD?

The perceptions of patients with IBD of health care provision

Summarise: Is there anything the participant would like to add about their experience of follow-up and what they would like to see changed

framework was then applied to the transcripts and the verbatim data were rearranged to 'fit' within the framework to form charts. For example, the theme of self-management contained summaries of patient views and experiences of this (see Fig. 1). Mapping and interpretation of the data helped to define further concepts, create typologies, and find associations to explain the findings. Data were managed using NVivo 9.0.

2.3. Rigour

Rigour describes the 'trustworthiness' of the research.[17]The following steps were taken. Field notes reflected the conduct of the study.[18,19] Following the initial four interviews, transcripts were analysed by three researchers to ensure the topic guide was appropriate and that the data captured were within the scope of the study. Ongoing identification of themes was undertaken by three authors by reviewing transcripts and identifying emerging themes.

2.4. Ethics

Ethical approval was granted from the North West 2 Research Ethics Committee REC number 10/H1005/50.

3. Results

The main themes to emerge were: (1) experiences and views of the current follow-up system; (2) attitudes to new models of follow-up care, including self management, the present and potential role of the GP, open access, and 'virtual' follow-up (see Fig. 2); (3) the personal value of follow-up care, including the value of the IBD nurse specialist; and (4) the 'ideal' consultation.

3.1. Experiences of current follow-up care system

The patients were asked about their experiences and views of current follow-up care management. Patients reported that often the traditional system of scheduled, pre-fixed follow-up appointments was impersonal and inflexible.

Patients reported that 'when well' the traditional follow-up scheduled appointment was unnecessary and inconvenient. Most patients reported their frustration with this system, juggling their lives around what they felt were unnecessary, but with no alternative offered.

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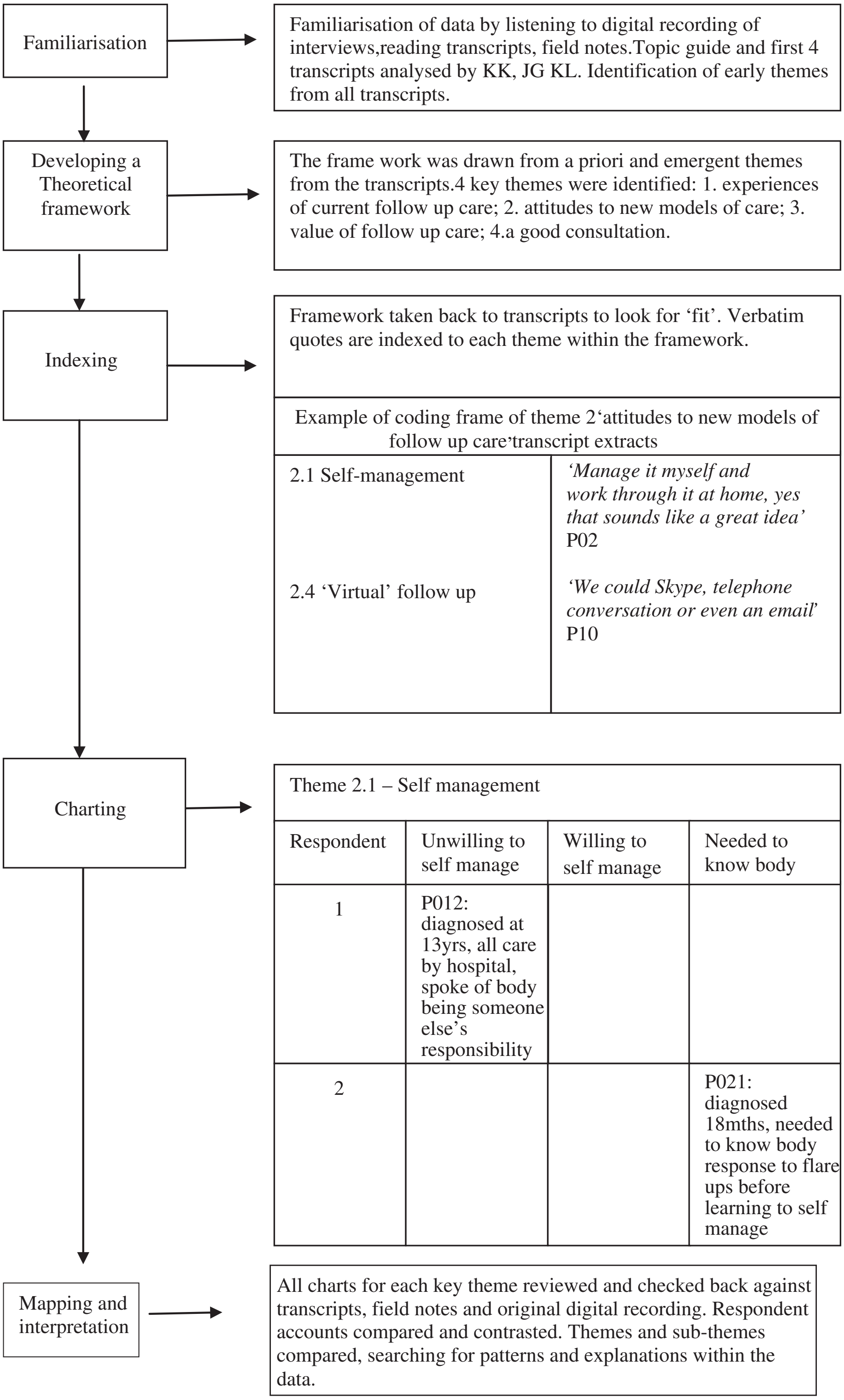

Familiarisation of data by listening to digital recording of interviews,reading transcripts, field notes.Topic guide and first 4 transcripts analysed by KK, JG KL. Identification of early themes from all transcripts.

The frame work was drawn from a priori and emergent themes from the transcripts.4 key themes were identified: 1. experiences of current follow up care; 2. attitudes to new models of care; 3. value of follow up care; 4.a good consultation.

Framework taken back to transcripts to look for ‘fit’. Verbatim quotes are indexed to each theme within the framework.

Example of coding frame of theme 2‘attitudes to new models of follow up care’transcript extracts	
2.1 Self-management	*‘Manage it myself and work through it at home, yes that sounds like a great idea’* P02
2.4 ‘Virtual’ follow up	*‘We could Skype, telephone conversation or even an email’* P10

Theme 2.1 – Self management

Respondent	Unwilling to self manage	Willing to self manage	Needed to know body
1	P012: diagnosed at 13yrs, all care by hospital, spoke of body being someone else’s responsibility		
2			P021: diagnosed 18mths, needed to know body response to flare ups before learning to self manage

All charts for each key theme reviewed and checked back against transcripts, field notes and original digital recording. Respondent accounts compared and contrasted. Themes and sub-themes compared, searching for patterns and explanations within the data.

Fig. 1 Framework analysis with worked example of theme ‘Attitudes to new models of follow-up care’.

"There's not really much point in being there and I could just be getting on with my work... its one of the things about having a chronic illness, means that you do have loads of doctors appointments, and so it's about juggling time off work for all of them”. [(P010)]

For some patients', reports of dissatisfaction with the system was more a reflection of their frustrations with their disease and lack of cure.

"I mean if I had my way now I would actually like to go and have somebody look at me and not send me away until they'd found out

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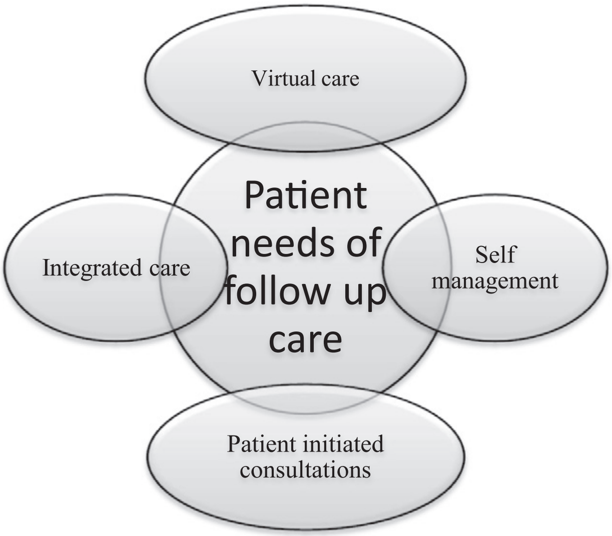

Fig. 2 Patient needs of follow-up care.

> what was wrong with me, what will make it all go away, do you know what I mean?"
>
> [(P015)]

3.2. Attitudes to new models of follow-up care: Self-management

Only two of the 24 patients had heard of self-management although many patients considered themselves to be managing their illness to some degree. The definition and process of self-management were explained to participants who were unclear about what it involved. Four clear groups of patients emerged:

(1) Patients who embraced the concept of self-management and questioned why they had not heard of it prior to the interview.

> "I think it would be really helpful… I think it's having an understanding and more awareness of what you can do, like treatments".
>
> [(P023)]

(2) Patients who could perceive no advantages to self-management. This group of patients had experienced quite complex disease processes and were reluctant to self manage for fear of becoming unwell again.

> "I'm not into self diagnosis and I'm not into self medication or self management. So I'm not going to do anything off my own bat without having checked with some medical mind somewhere, I don't want to be like I was before my surgery."
>
> [(P013)]

(3) One participant had been diagnosed with CD as a child and suggested that the responsibility for her body lay with the hospital.

> "I've been ill since I was so young… It has always been somebody else's responsibility…my body…and I'm not going to start now."
>
> [(P012)]

(4) Patients who were willing to embark on a self-management programme provided that if they could not manage they could revert back to the traditional care system.

> "I'd love to be part of something like that. What if I can't manage? Can I come back in, come back to see the hospital?"
>
> [(P019)]

(5) Patients who required more knowledge about their illness and bodily response to their disease before considering self-management. All of these patients had been diagnosed less than three years.

> "I would give it a go now… I wouldn't have done in the beginning nor a year ago, I was too needy, frightened to death actually. No I really needed the hospital at the beginning. It is just about learning to cope, learning how your body acts. But yes, now I would like to know about it".
>
> [(P014)]

3.3. Attitudes to new models of follow-up care: GP and integrated care

Patients with IBD are managed primarily in secondary care settings with some GP involvement within a restricted shared care protocol. There is a move to a more integrated care system with greater GP involvement yet it is unclear how IBD patients should be managed within primary care. Patients were asked about the current and potential role of their GP.

Many patients had experienced years of symptoms prior to diagnosis, in one case diagnosis took 10 years. This misdiagnosis, described by all participants, led to a loss of confidence in the GP for future care. This had an impact if they ever sought help from their GP in time of flare up or IBD related problems.

> "At the end of the day he is a GP, he's not a specialist and he doesn't know me."
>
> [(P012)]

Many patients reported that the lack of confidence in their GP and their GP's lack of knowledge of IBD, often acknowledged by the GP, was a barrier to seeking their help.

> "He said to me 'well actually you know more than me about this'… that's what my GP said to me."
>
> [(P005)]

> "It's the trust, and the knowledge thing okay..he's not a specialist…it's not his field is it, he's a general practitioner."
>
> [(P016)]

A number of patients stated that they were not aware they could seek help from their GP. They always referred back to secondary care and had no experience of GP led follow-up care.

> "I'm just blinkered to oh, Crohn's, hospital, yes."
>
> [(P021)]

Patients reported that they would be happy to increase the level of input from their GP but felt strongly that such

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care should be within an enhanced service under the direction of the IBD team. Patients were reluctant to be discharged from the IBD team completely but would accept reduced face-to-face contact in order to remain under the overall care of the IBD team.

3.4. Attitudes to new models of follow-up care: Patient initiated consultation

The patients were asked whether direct access to hospital review initiated by them, would be acceptable, as opposed to the traditional follow-up scheduled appointment. Often referred to as open access care, all but one patient was in favour of this approach. The only caveat was the fear that during a flare up the patient would be unable to re-access hospital care.

> "I know in myself what my triggers are… If I am well do I really need to take half a day off work to be seen? I am wasting time for you guys, but I'm also wasting my time, as long as I can be seen when I run into problems yes, this sounds a great idea."
>
> [(P019)]

Great emphasis was placed in the role of the nurse helpline within follow-up, often referred to as a 'lifeline' by the patients.

3.5. Attitudes to new models of follow-up care: 'Virtual' care

Patients reported a fear of being discharged from the IBD team but wanted to explore other models of care. This included tele-health and remote monitoring. All patients found this approach acceptable because it meant that they were not discharged from their IBD team but did not need to be seen when well.

> "Anything that takes me away from the hospital system all of the time. I suppose its finding that balance between feeling well and not coming in to hospital, knowing that you are monitoring me, and being poorly and suddenly needing to see you."
>
> [(P019)]

3.6. The personal value of follow-up care

Despite wanting to explore other innovative follow-up care approaches, patients valued their follow-up care, even when well. All of the patients reported that follow-up care was about contact, connection, continuity, expertise and reassurance. The personal value of follow-up care was based on the relationship the patient had with their nurse and consultant, and the confidence they had in their knowledge of IBD.

> "It reassurance that I am doing OK, I don't think I could have done without it… It's my security blanket."
>
> [(P015)]

> "Continuity, that's what it is all about for me, my nurse, my doctor, they know me, they look out for me. I would have moved away from here but for them."
>
> [(P021)]

All patients valued the IBD nurse, who was central to the IBD team, a liaison, and a constant identity in the hospital system. The patients were asked about the proposal for an IBD outreach nurse at the interface of primary/secondary care and were strongly in favour of this.

3.7. The 'ideal' consultation

Patients' views of an 'ideal follow-up consultation' were focussed on being treated as an individual rather than 'just someone with IBD'. They wanted to be listened to by a confident and knowledgeable practitioner, asked about how their illness was affecting them, and provided with a plan of action and goals.

> "I suppose you need two minutes to pour your soul."
>
> [(P020)]

> "nobody's actually said, "You know, how are you actually coping with it?" and I think…I mean it's bound to have affected me in some ways because it's a real drain on your emotions but nobody…although they talk about, you know, the physical side of it nobody's actually said, "How is it affecting you emotionally?"
>
> [(P011)]

4. Discussion

This study addressed patients' needs and preferences of follow-up care. Patients wanted to be consulted and involved in changing services or implementing new models of care so that these are aligned to their needs. The most striking finding from this study was that patients wanted a change in their traditional follow-up and wished to explore other models of care but their views had not previously been sought. Patients were frustrated with the traditional scheduled follow-up system and wanted to be seen only when unwell, except for compulsory reviews such as colorectal cancer screening. Alternative approaches to follow-up care were met positively, with some conditions placed upon them, including their need to remain under specialist care. Patients placed value on the expertise of the gastroenterologist or IBD nurse and the relationship they developed. Their 'ideal' consultation comprised of being listened to by a knowledgeable practitioner and helped to devise a plan of action.

4.1. Self-management

Patients felt that they were 'self-managing' their illnesses to some degree but many were unclear that 'self-management', in addition to health promotion and lifestyle, was a guided, supportive, IBD specific programme to help them manage their illness. The concept of self-management required explanation and patients held very strong views about whether this was the right way forward or not. This study discovered four categories of patients, three of which were willing to enter into self-management programmes. It was evident from this study that patient selection is paramount to the success of self-management in IBD. Some patients needed more time to recognise how their body reacted to their disease whilst some

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did not want to self manage in any form. The emergence of these categories perhaps reflects the complex nature of IBD and how it impacts on the individual, both physically and psychologically.

Self-management has been implemented in many IBD studies and has resulted in reduced consultation rates and reduced costs.[20,21] Self-management led to earlier treatment interventions for a flare-ups and reduced the risk of potential complications related to the relapse.[20,21] Self-management in other long-term conditions has been shown to improve health outcomes for patients[22] and the Year of Care Programme for diabetes may be a model of care that could be used with IBD patients.[23]

However, questions remain about the concept of self-management such as its effectiveness for patients with IBD and its effect on the quality of life.[20,21] One reason for this is that self-management is not well defined and encompasses a wide range of initiatives.[24]Any self-management programme must be compatible with other systems of care for those patients that cannot, or do not want, to self-manage.

4.2. Patient-initiated consultations/open access

The problem with the fixed appointment system and the rigidity of the outpatient structure means that patients' reviews may not coincide with an actual or impending relapse in their illness trajectory. The patients in this study suggested that patient-initiated consultations would offer some degree of control. One of the main fears identified was not being able to get back into secondary care to be reviewed during flare-ups, which has been identified in previous studies.[25] Patients wanted confidence in the system otherwise they would default to presenting themselves to emergency departments. Also not all patients wished to self-refer and relied heavily on face-to-face contact.

Patient-initiated access challenges the traditional follow-up schedule and reduces the volume of unnecessary care whilst directing support to where it is needed most. Patient-initiated access has been studied as a stand-alone service[25] or combined with self management.[20,21,26] Patient-initiated access has been shown to reduce costs which, expectedly, were related to the reduction in hospital appointments.[20,21] However, evidence has found no difference in quality of life in patients who entered the patient-initiated referral with self-management compared to the traditional model of care[20,21] suggesting that more research is required into this combined approach.

4.3. Potential role of GP

The patients in this study had little involvement with their GP. One of the key reasons for not seeking GPs' help was their lack of knowledge of IBD. Patients identified the following acceptable ways of integrating follow-up care with their GP: the GP service must be enhanced to ensure equitable treatment with secondary care; the use of patient care pathways; care management plans; clear guidance interlaced with 'triggers' for rapid referral; increased shared care; and the integration of services facilitated by an IBD outreach nurse. There are currently no IBD nurse outreach services in the UK but evidence from the heart failure specialist nurse may be used as a comparator. Moving the heart failure nurse into an integrated role between primary/secondary care, has led to a co-ordinated multidisciplinary primary service for patients with heart failure, linking directly back into secondary care during exacerbations.[27]

The prevalence of IBD has been found to be higher in primary care than previously identified. Although studies in the UK have found that GPs play an important role in IBD care,[28,29] with care shared equally between gastroenterologists and the GPs,[30] none of the participants in this study reported consulting their GP. There is some thought that the payment-by-results system, implemented in the past decade in the UK, has changed this and patients are predominately managed in secondary care.[31] However, GPs need relevant education and support if they are to share IBD care with gastroenterologists.[28] GP knowledge has been reported in other studies.[32] The proposition of developing an enhanced GP service, enhanced by educational and practical support from the IBD team, was acceptable to all of the patients and would assist in addressing patients' confidence in GPs' knowledge.

4.4. Tele-medicine

All but one study participant welcomed the use of tele-medicine into their follow-up care, many preferring the use of smart phones and web portals instead of the landline telephones. Patients who were self-confessed 'techno-phobes' welcomed the idea of 'paper' clinics, or remote monitoring,[33,34] the use of postal questionnaires to remotely monitor symptoms and quality of life. 'Virtual' care or tele-medicine, as an adjunct to patient-initiated consultations and self management, was identified within this study as an optimal approach to follow-up care.

The term 'virtual clinic' encompasses tele-medicine[35,36] e-health via the internet,[37] tele-consultations (virtual outreach)[38] and telephone clinics.[11] These approaches to follow-up care offer the patient an alternative way of being reviewed and monitored away from the hospital setting, often at home.[39] Recent developments in technology have led the way for an explosion in tele-health through which therapy can be delivered at any time and in any place.[40]

4.5. The value of follow-up care and the 'ideal' consultation

Participants wanted alternative approaches to their follow-up care but held strong views about the value of the face-to-face consultation and its 'ideal' content. Patients wanted to retain an albeit reduced level of specialist management and face-to-face consultation when needed. During these they required 'time' to talk about their disease and 'continuity'. The value of follow-up care and the 'ideal' consultation reflect the trustworthiness and the depth of relationship between the patient and gastroenterologist or patient and nurse.

These views mirror the findings of the Impact Survey, where patients stated that they did not discuss an important matter with their gastroenterologist and they wished they would ask more probing questions.[41] So if patients value the relationship they have with their gastroenterologist/nurse, to what extent do they really want new methods of follow-up care? When probed, there was greater emphasis on the *content* of the

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face-to-face consultation when part of an alternative model of follow-up care, as previously reported by European Federation of Crohn's and Colitis Association.[42] This 'continuity' and 'knowledge' referenced by the patients are in keeping with the core conceptual framework of the patient–doctor relationship,[43] and the 'continuous healing relationship', a relationship which is vitally important and can be sustained not just by face-to-face visits.[44]

4.6. Implications for practice

There is concern in the UK that services for patients with long-term conditions, including IBD, are not organised to promote independence. There is silo working in primary and secondary care.[45] The integration of primary and secondary care may be brought together formally through the development of models of care which can be applied to any healthcare setting. All countries are being compelled to provide cost effective care in partnership with patients to meet their needs. The growing prevalence of IBD across all countries[3] is impacting the ability of specialist services in all countries to achieve this. Self-management, tele-medicine and 'virtual care' are types of follow-up interventions not specific to the UK, with The Netherlands,[33] Denmark[37] and America[35] adopting 'virtual IBD care'.

Patients are now being encouraged to contribute to the planning and development of health services and measuring patient experience is central to this.[46–48] Understanding the views of patients and engaging them in decisions about treatment and services can help improve the patient's experience of care and improve the patient's management of their condition within any healthcare setting or country. Engaging patients can also link the commissioning decision to the needs of the service user rather than the service and assist in the commissioning of them.[49,50]

This study has identified patients' follow-up care needs and preferences. It is clear that one approach does not suit all patients and a variety of approaches should be considered. Patients want flexibility and choice. The lesson to be learned from previous research and the findings of this study are that patients' must be involved in the development of health service delivery and have confidence in the new approach. However, the views of gastroenterologists and other healthcare professionals must be sought prior to changing the follow-up care system to determine if the change would be acceptable and feasible. Reducing face-to-face consultations must be weighed against the impact it may potentially have on specialist medical training. Appropriate follow-up care within IBD contributes to patients disease outcomes. It is essential for drug reviews, disease assessment to help identify early complications of IBD, and reduce the development of complications as well as the psychosocial assessment of patients. The suggestion from patients within this study is that well patients can be reviewed by an enhanced GP or 'virtually' and complex patients should remain within a face-to-face specialist care system. Any new model of follow-up care must be subjected to rigorous testing with outcomes measured such as symptoms, functioning, patient reported outcome measures and acceptability.

There are limitations to this study. Qualitative research cannot be said to be generalisable but its strength lies in the *transferability* of knowledge to other contexts.[51,52] The sample comprised more patients with CD (18 CD, 6 UC) and these patients may have had more complex healthcare management than patients with UC, resulting in more follow-up care attendances. However studies have found no difference in quality of life in both CD and UC.[53] The hospital is a major hub for IBD care in the UK and the cohort was taken from a large tertiary centre. The participants may have had more complex disease than patients managed in a small hospital and this would reflect their follow-up care needs and preferences. However, both small District General Hospitals and large Foundation Trusts are experiencing the same problem of overbooked clinics and a growing demand on specialist health services. The option for more nurses or gastroenterologists to meet this demand is unlikely to be the way forward. The answer lies in new ways of working.

5. Conclusion

Studies of self management,[20,21] patient-initiated consultations[25] and tele-health in IBD measured patient satisfaction but no patients were involvement the design of the interventions. There are challenges when engaging patients in developing healthcare services but there are clear benefits to changing the traditional secondary care based approach to follow-up care for patients with IBD. This study is the first to provide a unique insight into patients' perceptions of how follow-up care should be planned and delivered. It is clear that some needs are unmet and patients want change. The recommendations from patients outlined in this study: the need *not to be seen* when well; 'virtual' care as an adjunct to patient-initiated consultations, self management, integrated care with GP and IBD outreach nurses, were identified as optimal approaches to meeting their needs. These would form a complex model of follow-up care but one that could improve the patients' experience of care. New models of care offer potential cost savings with the reduction in face-to-face consultations and allow targeted care to those who need it at point of access, the patient with complex disease or during a flare-up.

Conflict of interest statement

We confirm that the article, related data, figures, and tables have not been previously published and are not under consideration elsewhere. Dr. Campbell and I have acted as speakers or advisor for the Abbott UK, MSD, Shire Pharmaceuticals, Warner Chilcott, Dr. Falk Pharma. Dr. Campbell has also received unconditional educational grants. Professor Karina Lovell and Dr. Jane Griffiths have no conflict of interest to declare.

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The manuscript, related data, tables or figures, has not been previously published nor under consideration elsewhere.

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