

**The development, implementation and evaluation of a web-based care
package, designed to facilitate self-management and engage patients
with inflammatory bowel disease**

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Abbreviations

ADE – Adverse Drug Event
ASA- Amino-salicylate
CCM – Chronic Care Model
CD – Crohn's Disease
CRC- Colo-rectal Cancer
EHR- Electronic Health Record
EPR – Electronic Patient Record
GI – Gastro-Intestinal
HbA1c – Glycosylated Haemoglobin
HBI- Harvey Bradshaw Index
HCP- Healthcare Professional
HRQL- Health Related Quality of Life
IBD – Inflammatory Bowel Disease
ICT- Information and Communication Technologies
IHCA- Interactive Health and Communication Applications
LTC – Long Term Conditions
NHS- National Health Service
NRES- National Research Ethics Service
PAM – Patient Activation Measure
PFG- Patient Focus Group
PHR – Patient Held Record / Personal Health Record
PSC- Primary Sclerosing Cholangitis
PWP – Patient Web Portal
QoL- Quality of life
RCT – Randomised Controlled Trial
SCCAI- Simplified Clinical Colitis Activity Index
SMD- Standardised Mean Difference
SMI- Self-Management Intervention
SUS- System Usability Score
TNF- Tissue Necrosis Factor
UC – Ulcerative Colitis
UK- United Kingdom

Abstract

Introduction

There is an urgent need to find new ways of improving the quality and safety of healthcare whilst achieving efficiencies of service. E-health technologies offer exciting opportunities to support patients in managing chronic disease. Following continuous advances and increasing use, the Internet provides an ideal platform to empower patients. Previous studies have demonstrated that people taking a more active role in managing their health, experience improved outcomes.

Based on these principles and funded by Crohn's and Colitis UK, a new web-based care package was designed for adults with inflammatory bowel disease. Specifically 'My IBD Portal' aimed to provide greater access to information, improved communication and encourage greater engagement. Following its implementation at a single centre NHS Trust, the new IBD patient portal was evaluated in the clinical setting.

Methods

Following a literature review and significant patient involvement, 'My IBD Portal' was designed and implemented within a single centre setting. The system was evaluated over a 6-month period using a pre-post observational designed study. The primary objective was to examine patient experience. Usage, usability and satisfaction were measured. Secondary objectives included assessing factors that predicted use, analysed using logistic regression models. Changes in IBD knowledge, patient engagement, medication adherence and health utilisation were also explored using univariate analysis and multiple regression models.

Results

183 participants enrolled in the 6-month observational study. 63.4% of participants visited the IBD Portal more than once and were defined as users. In total there were 2080 individual visits to the Portal. The mean number of logins was 11.4 (SD 21.5) and median 3 (IQR 1-12). The mean duration of each visit was over 5 minutes. Individual use was highly variable. Approximately a quarter of participants never or only once used the IBD Portal, with an equal proportion visiting over 10 times. Satisfaction amongst users was high. 98% of respondents were either satisfied or very satisfied. 90% perceived the IBD Portal supported their management and 32% felt it helped with treatment decisions. An overwhelming majority expressed a desire to continue using the IBD Portal after completion of the study. Viewing test results (23%) was the most common section visited, followed by clinic letters (21%). 29% of participants reported sharing their access with a partner or family member. The qualitative data supported the quantitative findings. Many users expressed considerable benefit from online provision to their IBD health record.

Comparing users to non-users, logistic regression modeling showed active disease was significantly associated with use. Changes in health outcomes were explored using both univariate and regression analyses. Following multiple regression modeling, an increase in patient activation was significantly associated with Portal use ($p < 0.02$). A positive trend was observed in perceived support ($p = 0.06$). Improvements in IBD knowledge and medication adherence were not observed. Health utilisation was greater amongst users with more frequent outpatient and helpline contacts observed.

Conclusion

Design and implementation of an IBD Portal within the NHS setting is feasible. Technological, human and organisational factors need to be carefully considered during development to support adoption. The IBD Portal was used by a majority of participants and was perceived to support their care. Following adoption in other NHS clinical settings, a cluster randomised controlled study would provide the optimal study design to complete the evaluation process.

Declaration

No portion of the work referred to in this thesis has been submitted in support of an application for another degree or qualification of this or any other university or institute of learning.

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I would firstly likely to thank the charity Crohn's and Colitis, UK which has funded the entire project.

Thanks to the many patients who gave up their time to participate in the development of the project and who gave honest and helpful feedback that will benefit further development of the service and hence more patients in the future.

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Dedication

This thesis is dedicated to my wife Anne and daughters Ella, born at the beginning of this long journey and Jessica born close to the end! They have loved and supported me throughout this long journey.

The Author

I graduated from Nottingham University in 2001. Following 2 years in Australia, I completed my medical SHO training in Nottingham. Originally from the North-West of England, I moved back to do my Specialist Registrar training in gastroenterology around Greater Manchester.

I was passionate to do research in the exciting area of e-health, as I have many ideas and hopes as to how modern technology can and should benefit patients. My interest started following frustration with the lack of information provision and access to results for patients. After rotating to Salford Royal, a dynamic Trust with an excellent IT system, the opportunity arose to develop a patient-specific IBD portal. I have dedicated many hours to try and develop an excellent service for patients. I am delighted to say that since commencing this project, the system is planned to be adopted in Scotland, a clear indication of its potential!

I have now accepted a post as a Consultant Gastroenterologist at the Royal Devon & Exeter NHS Foundation Trust and I hope to enjoy a stimulating career in Gastroenterology specialising in nutrition and IBD.

1.0 Introduction

1.1 Background to the project

This aim of this thesis is to describe the methods used to develop and assess the impact of a novel web-based care package, designed to support patients living with inflammatory bowel disease (IBD). The original concept for this project was set out in 2011. Using the Chronic Care Model as a framework for re-designing the delivery of care, the web-based package 'My IBD Portal' has been constructed, implemented and evaluated in a clinical setting during the 2 years of this project. Despite the simplicity of the concept, its development and implementation proved to be far more complex and challenging than ever imagined! This first section summarises the rationale for this project.

1.1.1 Rationale

Inflammatory bowel disease (IBD) is the name of a group of long-term conditions (LTCs), affecting the small intestine and colon. Ulcerative colitis (UC) and Crohn's disease (CD) are the commonest types described. Recent estimates suggest up to 620,000 people in the UK may be affected by these conditions. [1] This rising prevalence not only has lifelong implications for each individual but also places an increasing burden on the provision of healthcare services. Most patients are managed in secondary care and are seen regularly through a follow-up cycle of scheduled appointments. Given the unpredictable nature of the disease, this traditional model of care often does not meet the needs of patients, at the crucial times when disease is active. As a consequence, both the quality and efficiency of care may be sub-optimal, impacting its potential effectiveness. [2]

Over the last twenty years significant research has evaluated strategies to optimise the management of chronic disease. This work is leading to a gradual change in healthcare interactions, from the traditional paternalistic methods to a more modern approach, focused around the needs and preferences of patients. The aim is to transform the healthcare delivered from a reactive to proactive system, helping people to support themselves. A

growing body of evidence underlines this change. [3] People who take an active role in managing their care experience better health outcomes. [4]

At the same time as progressive health policies aim to deliver a more integrated model of care, there is an ongoing digital revolution, leading to a significant increase in the use and technical capabilities of Information Technologies (IT) and in particular the Internet. This setting provides an exciting opportunity to develop innovative IT-related health services, aiming to support and engage people in managing their health.

This project evolved from these concepts. IBD predominantly affects young people, the majority diagnosed in their teens or twenties. The author wanted to create a web-based care package that leveraged the power of digital technologies to further support patients in managing their disease. Worldwide, very few studies to date have attempted to develop and evaluate novel IBD web-based applications and there are no reports in the UK literature.

Following an outline of the concept and an explanation of its potential, funding was secured for two years to develop this web-based care package. This funding, provided by Crohn's and Colitis UK, has enabled the development and evaluation of 'My IBD Portal' at Salford Royal Foundation NHS Trust (SRFT). Throughout the projects' design has been the intention to ensure this new system could be adopted across other NHS Trusts. The timing of this project also coincides with significant government and local policymaker initiatives, aiming to make better use of IT to deliver patient-centred care. [5]

This thesis is presented in the traditional format and describes the background literature, theories and processes the author has used to develop the web-based care package. It is hoped the work will help inform future IT-related patient-focused projects, both in IBD and other chronic diseases.

A major part of the work undertaken was developmental and structural, occupying the first 12 months of the project. The next 12 months were used to evaluate the service following approval of a pilot study.

Chapter 1 provides an introduction to the project. Section 1.2 providing a contextual background to chronic disease management and recent theories to improve the quality of care. Section 1.3 provides a background to IBD and its management. Section 1.4 reviews methods of service delivery within IBD. Section 1.5 outlines the theories and evidence for the use of e-health technologies in supporting chronic disease management.

Chapter 2 describes the methods used for developing the intervention and its evaluation. Section 2.1 reviews the factors affecting the design and implementation of web-based systems and documents the development of 'My IBD Portal'. Section 2.2 describes the methods used to assess its impact.

Chapter 3 presents the results of the study. Finally, Chapter 4 concludes with the discussion, limitations and future recommendations.

1.2 Concepts in chronic disease management

1.2.1 Contextual background to long-term conditions

Over the last century there has been a major shift in the pattern of disease epidemiology, from predominantly acute to chronic illness. Healthcare systems are continuously attempting to adapt to meet this challenge and to cope with the rising prevalence and complexity of chronic disease.

Long-term conditions (LTC) are described as “*those conditions that cannot be cured at present but can be controlled by medications and other therapies*” and by definition includes inflammatory bowel disease (IBD). The diagnosis of a LTC often has a profound impact on people’s lives and often there is no return to ‘normal’. [6]

At present there are an estimated 17 million people in the UK living with at least one LTC, representing over 30 percent of the population. As the population ages, this figure is expected to rise. People with LTCs are intensive users of healthcare, accounting for over 52% of GP consultations, 65% of hospital outpatient appointments and over 72% of inpatient bed days. [7] Policymakers see the need to improve the treatment and management of chronic disease as the most important challenge facing the NHS. [8] As a result, considerable emphasis has been placed both from a government policy perspective and in research, to examine strategies to improve the delivery of care in the UK and worldwide.

Over the last two decades, health services research has demonstrated that most healthcare systems are designed primarily for acute illness. Despite significant progress in both therapeutic and behavioural interventions, many patients with LTCs still do not fully reap the benefits of these advances. This ‘gap’ in the quality of care, has been attributed to a number of factors. These include the burden of ever increasing demand, the rising complexity of managing multiple conditions, poor organisation and constraints in using modern Information Technology (IT). These all contribute to unsafe and inefficient care.[9]

A seminal report from the Institute of Medicine (IoM) highlighted this 'chasm' in the range of quality of care delivered and recommended several objectives to consider when re-designing services. [10] The basic aims to improve care were summarized using the 'STEEEP' vision shown in figure 1 below.

Figure 1. STEEEP Vision

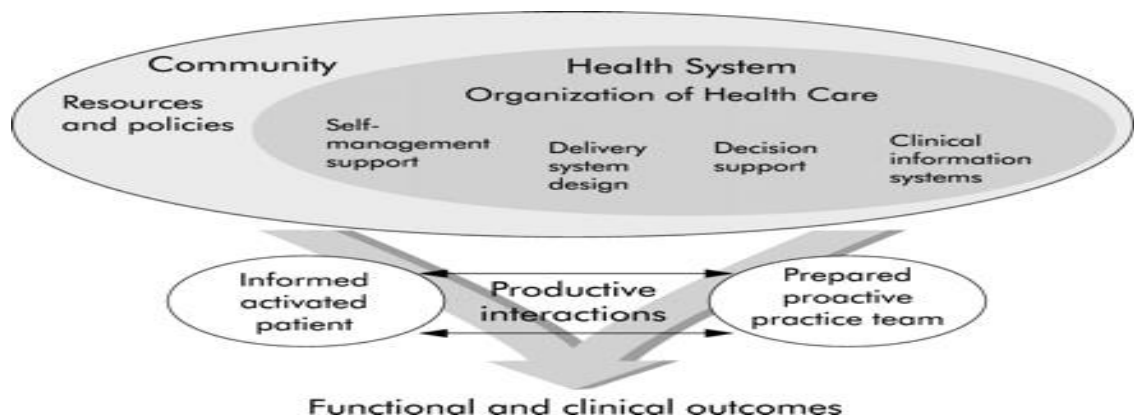
The delivery of care needs to be:

- **Safe:** avoiding injuries to patients from the care that is intended to help them.
- **Timely:** reducing waits and sometimes harmful delays for both those who receive and those who give care.
- **Effective:** providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.
- **Efficient:** avoiding waste, including waste of equipment, supplies, ideas and energy.
- **Equitable:** providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.
- **Patient-centred:** providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.

The IoM report highlighted the need to provide an integrated model of care with the patient at the heart of a responsive service. The optimal service needs to be flexible and able to adapt to meet individual needs and preferences. Decision-making should be informed using current evidence-based guidelines and shared with patients. To achieve this, patients' medical records need to be transparent and accessible, with the ability to exchange information freely to facilitate communication.

To help deliver these aspirational aims, Wagner et al. in 2001 described the Chronic Care Model (CCM) shown in figure 2 below. [11] The CCM provides a framework for changing the model of care to improve outcomes in chronic disease management.

Figure 2. Wagner's Chronic Care Model [11]



The model focuses on developing a proactive service, supporting patients to manage their disease. The original framework has influenced health policy worldwide and aims to achieve its goals through a combination of effective team care and planned interactions, strengthening patient-provider communication and leading to improved outcomes.

In the original model six inter-related principles were described to be of central importance:

- Healthcare organisation- Creating a culture and mechanisms that promote safe, high quality care.
- Community resources- Mobilising community resources to meet the needs of people with LTCs.
- Self-management support- Empowering and preparing people to manage their health and healthcare.
- Delivery system design- Planning and coordinating care using a multi-disciplinary approach with close follow-up to assess response to treatments.
- Decision support- Interventions directed at improving the knowledge and skills of providers, promoting care that is consistent with research evidence and patient preferences.
- Clinical information systems- Organising patient and population data to facilitate efficient and effective care.

The evidence synthesized to design the framework was predominantly from studies evaluating the individual impact of each of these six elements. [12] Following its publication, numerous prospective studies have reported using the framework to help re-design services. These evaluations have involved a wide variety of LTCs, in different sized organisations across the world. Not all reports have been positive.

A recent systematic review has shown that interventions using a multi-component approach have had greater success in improving the processes and outcomes of care. [3] Integrating all six components is often difficult and many of the elements overlap. The three elements associated with the most significant impact are changes to the delivery system design, supporting self-management and introducing clinical information systems. The next section of this thesis will review each of these elements in more detail.

1.2.2 Delivery system design

The delivery system design is the component that refers to the organisational structure of the healthcare team and how they interact with patients. At a national level over the last 30 years, there have been significant changes made in the NHS on how the delivery system is designed and people work within the team. These changes are constantly evolving but central themes have been redefining the roles of primary and secondary care and attempts to focus care around the needs of patients, commonly referred to as 'patient-centred' care.

Health policymakers are attempting to move services from secondary care to the community, where it is thought to be cheaper. The traditional model of long-term patients seeing a specialist consultant in a hospital clinic with repeated scheduled follow-up is changing. There has been an increased role for nurses in delivering outpatient care and a multi-disciplinary approach to managing complex cases advocated. A focus on integrating or coordinating care is emphasised, in an effort to reduce duplication and increase safety. The most recent organisational change is the centralisation of services. Concentrating services in specialist centres may improve outcomes but is often met with resistance from patients that want to maintain local secondary services. [13]

There has also been significant focus on the approach to consultations. The aim is to move away from a problem-focused and reactive approach, where healthcare providers (HCPs) make all the decisions, to planned and collaborative appointments, where informed patients are actively involved in decisions about their health. This is often referred to as shared-care or shared decision-making. [14]

To achieve this goal, patients require access to accurate information about their condition. A challenge for patients is determining what sources are credible and which should be ignored. Attempts to bridge this divide are on-going. Guidelines have been set to produce high-quality information. Still many available resources are inaccurate or biased with direct or covert pharmaceutical industry involvement. [15]

To optimise care, patients need active follow-up to assess disease control, monitor adherence and change treatments. Many appointments are still scheduled routinely in secondary care but processes to eliminate unnecessary follow-up are a focus of primary care groups. Follow-up need not be face-to face but tailored to the individual, with telephone and email possible viable alternatives. [16]

To enable these changes and develop a more integrated model of care requires a cultural change. Embedding these changes into routine practice is often difficult and depends on the context, setting and circumstance. The hope is that services designed around the needs of patients will be more effective and efficient, leading to decrease health utilisation in the long-term.

After implementing changes to the design of services and in developing more productive clinical interactions, requires patients to support themselves away from the healthcare setting. This is commonly referred to as 'self-management' and a growing body of evidence shows facilitating this key element, improves the quality of chronic care. [17]

1.2.3 Self-management

It has been estimated that as much as 80% of care for people with LTCs is undertaken by themselves and their families without healthcare support. [18] Self-management includes taking medicines, exercising, eating well, watching for changes, coping when symptoms worsen and knowing when to seek professional help. Supporting self-management involves educating people about their condition and motivating them to care for themselves better. [19] To enable self-management, patients require information and encouragement to help them understand, maintain control and monitor their condition, taking appropriate action when needed. [20]

Various theories of self-management have been developed in the fields of behavioural science. The most widely referred to is Bandura's self-efficacy model. [21] Self-efficacy is a measure of one's own competence to complete tasks and reach goals. [22] People with high levels of self-efficacy, (those who believe they can perform well), are more likely to view difficult tasks as something to be mastered. People with low self-efficacy find tasks harder and something to avoid.

When applied to the health setting, self-efficacy beliefs are thought processes that determine whether a health behaviour change will be initiated, how much determination will be applied and how long this effort will be sustained. Self-efficacy belief suggests that patients are empowered and motivated to manage their health, when they feel confident in their ability to achieve the changes. [23, 24] Consequently, many interventions designed to support self-management focus on building people's confidence in managing their condition and providing the tools to maintain this.

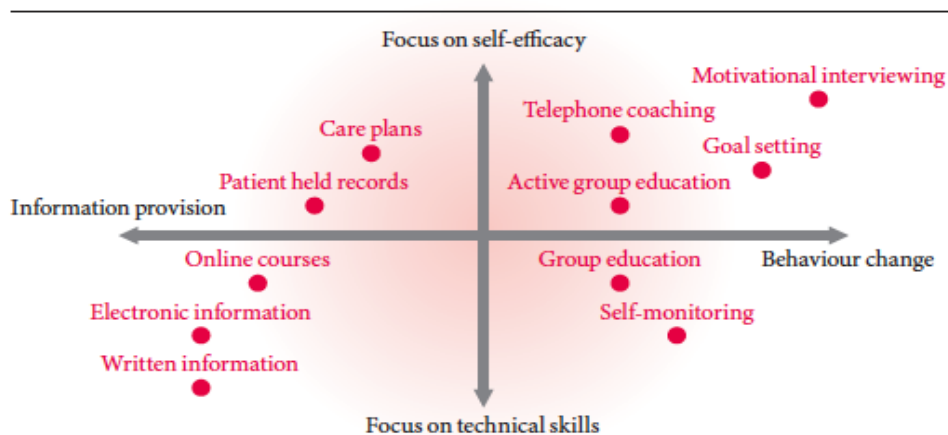
1.2.3.1 Evidence-base for the effectiveness of self-management

The literature describing self-management has grown dramatically over the last twenty years. A challenge in reviewing the many reported studies is the large variation in the quality, approaches, timescale and population targeted. [25, 26] Furthermore, given its broad aims, numerous strategies have been tested. These can be simplified into the following components:

- Information provision (e.g. written and electronic information leaflets)
- Focusing on technical skills (e.g. self-monitoring)
- Focusing on self-efficacy (e.g. goal setting)
- Behavioural changes (e.g. motivational interviewing)

Studies in this field of research have grown rapidly. A recent review identified over 600 published papers assessing the impact of self-management in a variety of LTCs. To review this evidence-base for self-management, De Silva et al. conceptualised the various approaches as a continuum, from more passive (e.g. providing information) to active interventions (behavioural change). They separated the multiple strategies tested into discrete entities. [27] Their aim was to assess the impact of each component on supporting self-management. (See Figure 3).

Figure 3. The effectiveness of strategies to support self-management [28]



The review showed that initiatives focusing upon supporting behavioural change provided the most positive outcomes. Overall, the systematic review concluded that self-management

can lead to improvements in patients' quality of life, clinical outcomes and health service use. [28]

1.2.3.2 Limitations of self-management

As previously described, strategies to support self-management have been tested in a multitude of different LTCs and health policymakers are keen advocates. However the question remains; why are self-management techniques not adopted more in routine clinical practice?

In addition, repeated NHS patient surveys clearly indicate that responders would like a greater role in managing their health. Patients would like more information about their condition, treatment options and support to gain confidence. [29] Despite these demands, repeated studies show a dichotomy between these perceived patient needs, against difficulties in engaging people to self-manage and change health behaviours over the long-term.

To illustrate the barriers of introducing self-management strategies within the NHS, the Expert Patient Programme (EPP) provides a carefully studied example. This Government-funded educational programme for generic LTCs, was developed using the theories of behavioural science and was evaluated in a large multi-centred randomised controlled trial (RCT) in primary care. The EPP was delivered by trained lay people and aimed to provide generic skills to support people in managing their health, gain confidence and improve quality of life. The programme involved a 6-week self-care skills course and any patient with a LTC was invited to attend. 629 recruited patients were randomised to the EPP or a waiting list control and its impact was measured at 6-months. The outcomes of the study were largely disappointing. The only positive outcome reported being an increase in self-efficacy. [30] Qualitative work revealed a lack of engagement from both patients and HCPs. These findings were not unique to this study. Other studies have reported high attrition rates and HCP concerns about their capacity and time to adequately support patients. Numerous

studies show significant difficulties in incorporating self-management techniques into routine care. [31] [32]

Another significant concern is engaging 'hard-to-reach' patients. Patients with poor literacy, those lacking support networks and those of lower affluence are often the patients that require the most support to manage their condition. This group stand to benefit most from such interventions. This theory is best explained by the inverse care law, described in 1971 by Tudor-Pick. The law states that "the availability of good medical care tends to vary inversely with the need for it in the population served. This inverse care law operates more completely where medical care is most exposed to market forces, and less so where such exposure is reduced". [33]

Against this principle, one could argue that if specific healthcare interventions decrease the costs or utility of the service, even in only a sub-set of the target population, more resources would be available for those most in need of care and support. This would provide a net benefit to all, even if the more active participants gain the most.

1.2.4 Clinical information systems

Central to all productive healthcare interactions between healthcare professionals (HCPs) and patients is timely and relevant information. Data are required to provide insights into current models of care and are needed to measure the impact of changes to services. Currently many healthcare providers in the UK still rely on paper-based records that often are hard to locate, poorly organised and illegible. They focus upon the 'biomedical' record and often do not collect 'psycho-social' data that are highly relevant. Methods of collection are reactive and only document past events, preventing the ability to plan care in the future. This makes it extremely difficult to manage and organise patients with LTCs who require frequent monitoring and continual support.

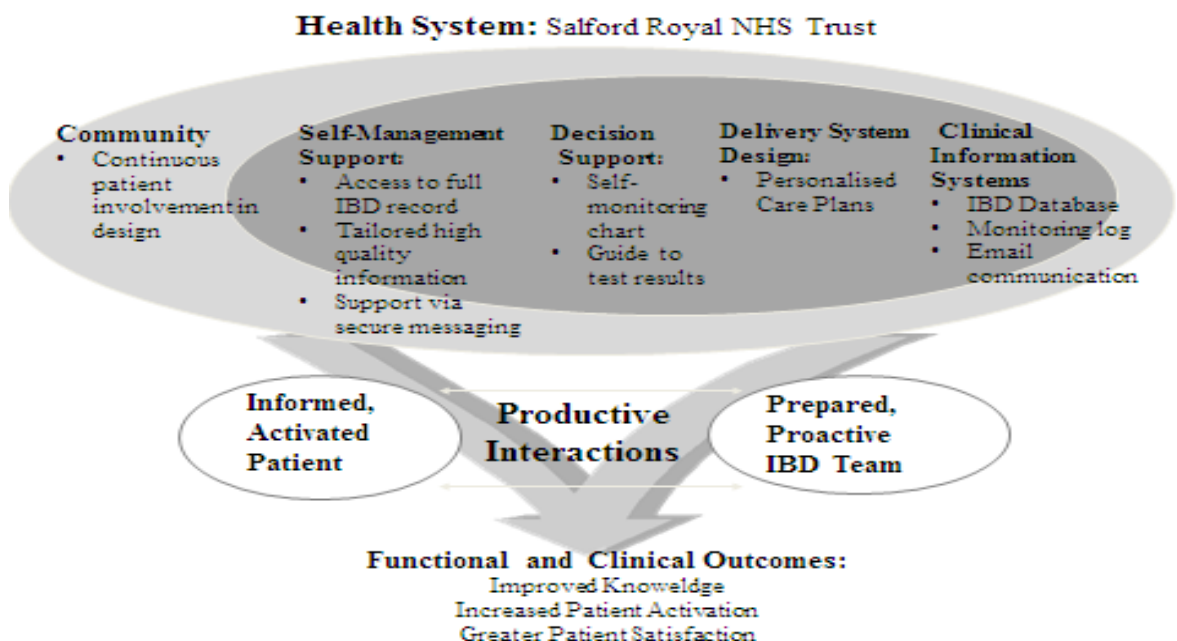
Information technology, including the Internet, holds enormous potential for transforming the delivery and quality of care. Given the complexity of the NHS, there are significant

challenges for its implementation. In the healthcare setting, adoption has been painfully slow compared to the revolution that has swept nearly every other aspect of society and industry. Gradually, new IT systems are being developed to enable data to be used more intelligently, creating a more efficient and safer healthcare service. [34]

1.2.5 Summary

This section provides a background on the theories and evidence for managing chronic disease. It highlights the need to engage patients in managing their health and the potential use of information technology to enable aspects of this change. Using the principles of the chronic care model and within the constraints of time and funding, the authors' aim was to create a web-based care package, enabling patients to be actively involved in managing their IBD. Figure 4 below highlights the components the author proposed to use in 'My IBD Portal' and how they relate to the concepts of the CCM. The next section provides a background to inflammatory bowel disease and reviews published studies that have attempted to re-design the delivery of care for this condition.

Figure 4. Using the CCM framework for redesigning IBD services



1.3 Inflammatory bowel disease

1.3.1 Background

Inflammatory Bowel Disease (IBD) comprises a group of chronic inflammatory conditions affecting the gastro-intestinal (GI) tract. The two commonest forms are Crohn's disease and ulcerative colitis (UC) and together latest estimates suggest up to 250,000 people in the UK are affected. [35] Both of these lifelong conditions follow unpredictable courses, with periods of relapse (flare-ups) and remission. Unusually for LTCs, they commonly present in the teenage years or twenties, affecting men and women equally.

The aetiology of IBD remains unknown but theories suggest that interactions between genetic susceptibility, the immune system and environmental triggers play a significant role. Each disease can vary considerably in their extent and severity. [36] The clinical effects of both UC and Crohn's disease are quite similar due to the effects of inflammation and ulceration within the gastro-intestinal tract. These cause abdominal pain, diarrhoea, fatigue, anaemia, bleeding and weight loss. IBD can also cause extra-intestinal manifestations in up to 40% of cases affecting the skin, eyes, liver and joints. [37]

1.3.2 Crohn's disease (CD)

Crohn's disease at present cannot be cured and is characterised by transmural inflammation, affecting any part of the GI tract from the mouth to anus. The disease process most commonly affects the distal ileum and colon and is not necessarily continuous, presenting often with skip lesions interspersed with normal tissue. The inflammation can affect all layers of the intestinal wall, leading to penetrating and stricturing phenomena. [35]

Its prevalence varies geographically. In the UK Crohn's disease affects around 145 people per 100,000 and its incidence is rising. [38] The disease is most commonly diagnosed at a crucial time in people's life, when establishing careers and raising families. Cases presenting in childhood (25%) often follow a more severe course. The burden of the disease has clear implications both at an individual and economic level. [39]

1.3.3 Ulcerative colitis (UC)

Ulcerative colitis prevalence is higher, reported to be 243 per 100,000 and incidence appears stable. In contrast to CD, UC only causes inflammation within the mucosal lining of the colon and rectum. [38] The hallmark of UC is continuous inflammation extending proximally from the rectum.

In around 10% of IBD cases affecting the colon, it is not possible to distinguish between these two sub-groups of disease. These cases are described as IBD unclassified (IBD-U) and this terminology changes to indeterminate colitis, if it is still not possible to distinguish the cause of colonic inflammation after surgical colectomy.

1.3.4 Risk of cancer

IBD is associated with an increased risk of cancer. This is primarily related to colo-rectal cancer (CRC). Risk increases with the extent of disease in the colon, severity of inflammation, a family history of CRC and disease duration. In patients with extensive Crohn's colitis the risk is similar to that of UC after adjusting for extent and duration. Up to 5% of IBD patients are also diagnosed with primary sclerosing cholangitis (PSC). This inflammatory condition affects the bile ducts within the liver, causing fibrosis and narrowing. Its presence significantly increases the risk of CRC, as well as cholangiocarcinoma and hepatocellular carcinoma.

To decrease the risk of CRC in the UK, surveillance colonoscopies for patients with colonic inflammation beyond the rectum is recommended after 10 years following diagnosis and annually in those with PSC. [40]

1.3.5 Medical therapy

Currently, there is no cure for IBD and nearly all patients require long-term continuous treatment. 5-aminosalicylates (5-ASAs), corticosteroids, thiopurines, methotrexate and monoclonal antibodies (anti-TNFs) are the main medical therapies used to either induce or maintain remission. Truelove and Witts first demonstrated the clinical effects of steroid

drugs to induce remission in the 1950s. [41] Since this time, further immunosuppressive drugs with better efficacy and lower side effect profiles have been introduced. Most of these drugs require regular blood monitoring and dose adjustments during periods of relapse. Although highly effective in maintaining remission, around 30% of patients are intolerant or fail to respond to prescribed medication. [42]

Currently most clinicians use a 'step-up' approach to treatment. Therapies with the least risk of adverse events are prescribed first, escalating step-wise to the more potent immunomodulators and then monoclonal antibodies if required. The balance of the therapeutic benefits versus their risk of harm needs to be assessed for each individual patient. Some clinicians advocate a 'top-down' approach using the more potent anti-monoclonal antibodies in the initial stages of treatment. The aim is to induce and maintain 'deep remission' with complete resolution of inflammation, both from a clinical and endoscopic perspective. Recent studies postulate this approach may alter the natural course of the condition when evaluated in the controlled setting. [43] However, universal use of monoclonal antibodies is not feasible given the potential side effects and the costs of this class of drug.

1.3.6 Medication adherence

Another major factor affecting the clinical effectiveness of treatment is medication non-adherence. Studies estimate this occurs in around 30-45% of IBD patients on long-term treatment. [44] Non-adherence to IBD medication increases the frequency of flare-ups and is associated with higher overall healthcare costs. [45] Multiple factors are associated with non-adherence including male gender, being single, employment status, disease type, severity and duration. Other possible factors include medication type, frequency of dosing and route of administration. Patients' attitudes, perceptions and beliefs surrounding their health are also linked to levels of adherence. It is often difficult to identify but its effect on both health outcomes and resource utilisation is likely significant. [46, 47]

1.3.7 Surgical therapy

If medical therapy fails patients require surgery. [48] Up to 50% of CD patients need surgery within 10 years of diagnosis and 70% over the lifetime of their disease. The lifetime surgical risk in UC is estimated to be between 20-30% and around 50% of patients with chronic relapsing UC require colectomy. [49]

1.3.8 The impact of living with IBD

The impact of living with IBD can be profound, disrupting education, employment, social and family life. Given the unpredictable nature of flare-ups, many patients' lives do not return to normal, even during periods of remission. Severe symptoms of bowel urgency, loss of control, abdominal pain, faecal incontinence, fatigue and changes to body image can have profound psychological and emotional effects. [50] Associated complications such as arthritis, perianal disease, fistulae, abscesses and skin problems can also contribute to a poor quality of life. Many of the symptoms are invisible to others. Unemployment and time off work are more common than in the general population. [7,8] There are increased levels of anxiety and depression in people with increased disease activity. [14]

It is imperative that patients have access to effective management to limit the potential constraints of the disease. Effective care can attenuate relapses, prolong remission, treat complications and vastly improve quality of life.

1.3.9 Healthcare costs

The vast majority of people with IBD are diagnosed from an early age, requiring continuous healthcare throughout their life. As a result, the lifetime medical costs associated with care are comparable to other major LTCs such as diabetes.

The few studies evaluating costs in the UK show a wide variation in estimates. The most recent study based on 2008 prices, estimated costs between £631 - £762 per patient per year. [51] Other studies have estimated costs as high as £3000 per patient per year. Around 50% of these costs are related to the inpatient care of the small proportion of patients, requiring intensive medical treatments during severe flare-ups or surgery. Indeed a study

showed costs were over 20 times higher for hospitalised patients and 2-3 times higher for outpatients experiencing a flare-up compared to those with inactive disease in remission. [52]

These studies estimate that drug costs account for around 25% of total health costs. The emergence of monoclonal antibodies and the future development of new biological treatments are likely to further increase this proportion of expenditure in the future. New therapies offer hope to people with severe disease who currently run out of medical options. From a cost-benefit analysis these newer drugs may alter the progression of disease and decrease the overall costs of managing complications over the long-term.

Extrapolating the current data suggests the annual expenditure in the NHS for IBD is between £470 million and £800 million. [53] These figures provide a strong argument both from a clinical and economic perspective to optimise services, enabling early treatment of disease flare-ups and effective maintenance of remission.

1.4 Models of IBD care delivery

1.4.1 Background

The model of care for IBD differs from many other LTCs given the unpredictable nature of the disease. Traditionally, most NHS Trusts adopted a service-centred model of care, with repeated scheduled hospital appointments with no or little provision during flare-ups. This model was organised due to a perceived need for continual follow-up, a lack of trust in primary care and a belief that patients expected to see the specialist. This fixed nature of scheduled clinic has been shown to be inflexible, unresponsive and failing to meet the preferences or needs of patients. Clinic appointments did not correspond to times of disease activity and provision of urgent slots created significant pressure on capacity. Dissatisfaction decreased clinic attendance, leading to an inefficient use of time and resources. [54]

Ideally an IBD service needs to be able to adapt to changes in disease activity. A majority of patients run a relapsing/remitting course. Around half of all patients with IBD are in remission each year and only around 5-10% of patients have continuous symptoms that do not respond to therapies. [35]

Patients with frequent relapses, and those who are non-responsive or have complications, require more intensive care and support compared to those with infrequent flares or long-term remission. A multi-disciplinary approach is advocated, particularly involving a wide range of specialists, as well as primary care. To optimise the effectiveness of treatment, patients are increasingly seen as a vital part of this team. They need to be well informed, know how to access services and agree to management plans. Previous studies showed many IBD patients perceive insufficient information and a lack of control over their lives. [55]

1.4.2 Current model of care

At present the majority of IBD patients are managed in secondary care. NHS Trusts serving a population of 250,000 manage approximately 50 new outpatients a year and provide follow up to 700 patients. It is estimated around 200 patients remain in primary care or receive no follow-up at all. [56] Many patients report a delay in their initial diagnosis. This can affect their relationship with primary care. In the UK, the median size of a GP practice is 6500 patients, meaning practice lists contain around 20-30 IBD patients. Many GPs are happy to devolve some or all care to specialist HCPs due to the complexity of cases, the potential risks of new potent therapies and continual updates to best practice. [57]

The organisational structure of IBD care has changed in the majority of NHS Trusts, predominantly with the introduction of specialist IBD nurses. This role has enabled GI physicians to provide expert care along with meeting the increasing demands of other GI commitments. With the introduction of payment by results, increasing demand for endoscopy and the Government 2-week wait and 18-week targets, there are increasing pressures placed upon consultant physicians' time. The role of the specialist IBD nurse aims to meet the needs of patients; providing expert clinical care, dealing with administrative tasks and supporting education of patients and fellow professionals. [58] Latest reports from the national IBD audit have shown a significant increase in access to specialist IBD nurses. At present over 78% of the population is covered. Despite this rise, there are significant local variations, with only 21% of NHS Trusts provided the recommended standards of cover and 41% of GPs reporting an inability to get patients reviewed within 7 days of a flare-up. [59]

Despite the invaluable role of IBD specialist nurses in delivering care and their widespread adoption, there is little published evidence to support their usefulness. Studies in other LTCs have shown specialist nurses to be cost-effective and reduce hospital admissions. Within IBD only two studies in the UK have evaluated their effectiveness. Nightingale et al. used a pre-post retrospective audit to evaluate the effects of introducing an IBD specialist nurse service. The study showed a reduction in hospital visits (38%), inpatient stay (19%), increased remission (6%) and improve patient satisfaction. Ease of access to information

was also noted. From a methodological perspective of the study design it is difficult to generalise the findings. As well as the introduction of the IBD nurse, a number of other components were introduced including new treatment guidelines, a dedicated helpline, information sheets and urgent access clinics. Despite the limitations of the methodology, the pragmatic study showed significant impact of a multi-faceted approach to IBD care. [60] The only RCT published evaluated the effectiveness of nurse led counselling service over a 12-month period. The counselling package consisted of information provision and a psychological intervention of stress management and relaxation techniques. None of the outcomes measured including HRQL, disease activity, mental health scores or coping strategies, were significantly changed. [61]

1.4.3 Alternative approaches to IBD care

A number of other strategies to improve the model of care have been published in the literature. Using the CCM framework these can be broadly be categorised into changes to the delivery system design and self-management support. A plan to introduce a national clinical information system for IBD has commenced (National IBD Registry) but its roll-out is in the early phases of development. Reported interventions combining multiple components of the CCM, appear to demonstrate greater effects. A review of the main studies is provided below.

1.4.4 System delivery design changes in IBD

1.4.4.1 Open access

Williams et al. redesigned their IBD service to discharge mild and stable patients back to primary care but offered urgent 'open-access' back to the secondary care if required. [62] They designed a non-inferiority RCT study comparing this service versus the traditional fixed hospital appointment model. The authors hypothesised that follow-up care through open access and shared-care would be no worse than standard secondary care and measured the outcomes of quality of life (QoL), total resource use, GP and patient preferences. 180 mild and stable IBD patients were randomised and a shared-care guideline adopted. The study found no difference in QoL, fewer outpatient consultations but no cost advantage. Both

the patients and GPs preferred the flexibility provided by review on request. However, there were reported difficulties in providing urgent appointments highlighting the need to ensure adequate capacity. Given the study only targeted a subset of the IBD population the cost effectiveness of this model is difficult to determine.

1.4.4.2 Telephone support

Telephone helplines may offer an effective service to improve access for advice and support. Despite their increasing use in service delivery, the published literature in IBD on their effectiveness is sparse. Miller et al. measured the effects on introducing a telephone follow-up service in IBD in a one year pilot study. Routine appointments were replaced by a nurse-led telephone support service. 150 participants enrolled and consultations were performed using a structured questionnaire. Only 23/150 patients required a clinic review because of worsening symptoms and they concluded that the service reduced unnecessary follow-up, provided rapid help during periods of relapse and promoted individualised care. [63] Other audits have revealed that when introduced, use of the telephone helpline is high, with patients contacting frequently during relapses. [64] In addition, a high number of calls are received from patients wanting general advice. Consequently, the telephone helpline may play a significant role in enabling patients to manage their disease without the need for GP or hospital follow-up. [65]

1.4.4.3 Virtual care

'Virtual' care has been evaluated in a number of studies. This service is designed to monitor patients remotely away from the hospital setting. Van Dulleman et al. described a system for follow-up using scheduled IBD paper-based questionnaires and blood tests. [66] Following their return, written advice was provided by the IBD team. This service was facilitated by an IBD specialist nurse. The pre-post designed study recruited 427 IBD patients over a two year period and was based in Groningen, Netherlands. 87% of questionnaires were returned and completed correctly. They reported a 33% reduction in outpatient visits during the two-year observation period with no adverse events or deterioration in patient's disease. They estimated a cost saving of €53,000 over the study period. Patient selection and clear

information were deemed significant factors to determine patient satisfaction. Female patients, those with better emotional functioning and perceived control were more satisfied with this method of service design. There were significant limitations to this study. No methods were reported on patient selection, disease activity or the outcomes measured to extrapolate their findings. The attrition rate also appears very low compared to other studies collecting questionnaire data over a prolonged period.

Hunter et al published evidence on a similar service set up in Southampton, UK. [16] This retrospective study provided data on patient selection. Inclusion criteria were IBD patients with disease established over two years and stable symptoms for greater than a year. Those with PSC were excluded. Patient consent was requested for enrolment. The intervention consisted of a questionnaire, information sheet and blood tests posted 2-months prior to their annual follow-up appointment. Checks were made to ensure no surveillance tests were needed. Following its introduction into routine practice, the authors reported over 20% of their IBD cohort were followed-up using this 'virtual' service. 12% of patients failed to respond to the intervention. Only 20% of patients required face-to-face consultations. Satisfaction was measured in a small sub-set of the population (20%). Over 90% of those responding preferred the intervention versus routine follow-up. The authors proposed this high level was due to less interference with work and social lives. Furthermore, non-attendance at appointments was reduced from the reported 10-20% to 3.5%.

1.4.5 Self-management in IBD

As highlighted earlier, there are a variety of approaches to support patients to self-manage their illness. The vast majority of studies have involved patients with diabetes, asthma or arthritis. In common with these other LTCs, people with IBD face similar challenges and disruption to their lives. This includes learning to cope with taking regular medication, managing symptoms, as well as dealing with the physical and psychological consequences of chronic disease. Despite this, only a few studies have evaluated self-management techniques in IBD. This may be due to the unpredictable nature of the disease, as well as the lack of measured end-points such as the glycosylated haemoglobin (HbA1c) in diabetes

and peak –flow readings in asthma. [67] The current focus in IBD is symptom management, although this concept may change with the development of newer surrogate biological markers and prognostic indicators, such as faecal calprotectin.

1.4.5.1 Information provision

The majority of published studies evaluating self-management in IBD have focused upon information provision only. [67-70]. Although health information is more widely accessible, many patients with IBD still rely on HCPs to provide information. [71] This mechanism of delivery is often ad-hoc and fragmented. There are significant variations in the resources used with many derived from drug companies and falling short of the recommended standards. [72-74] The National Patient Association, Crohn's and Colitis, UK (CCUK) produce high quality resources to the recommended standards but many people assume they need to be members for access. Less than 20% of patients attending IBD clinics are members of CCUK, meaning this resource is potentially under utilised. [75] Studies that have been performed purely on educational-based interventions have shown increases in disease-related knowledge. None of the evaluated studies have demonstrated improvements in either behavioural or psychological outcomes. This is consistent with the literature that shows that despite the clear role for information provision, on its own it provides little or no improvement in either behavioural, clinical or resource-use outcomes.

1.4.5.2 Guided self-management

As in other LTCs, studies using a greater number of self-management techniques in IBD have shown the most promise. [67] Robinson et al. in 2001 designed a randomised controlled trial (RCT) assessing the impact of 'guided self-management and patient directed follow up in patients with stable UC. In this study 203 patients in remission were randomised to receive personalised self-management training in clinic and open access to hospital appointments versus standard care. The intervention involved a change to the consultation process, with the development of a guided self-management plan agreed with patients whilst attending clinic. The aim was to assist patients in recognising flare-ups and to enable them to initiate self-treatment if a flare-up occurred. Following the consultation a written action

plan was agreed. Patients were asked to use a telephone support line if symptoms had failed to respond within one week or if symptoms deteriorated.

Following 12 months follow-up, patients in the intervention group had less hospital visits (0.73/year) versus (2.45/year) the control group. There was a similar decrease in primary care visits and a significant reduction in the time to treat relapses. Despite the study's focus on guided self-management, the study clearly also changed the service delivery design, including additional telephone support and the use of open access to appointments.

Kennedy et al. further developed this work and evaluated a 'whole systems' approach to IBD self-management. This consisted of training GI Specialists in patient-centred consultations and the use of disease-specific guidebooks. Patients were encouraged to write care plans on managing relapses and follow-up was arranged at the request of the patient. This intervention was evaluated in a large multi-centred cluster randomised trial over a 1-year period in both UC and Crohn's disease patients. The trial involved 700 patients across 19 hospitals. Outcomes measured included quality of life, health resource use and acceptability. The intervention resulted in fewer hospital visits. There were no effects on quality of life scores. Participants in the intervention group felt more able to cope with their condition and 74% indicated a preference to continue with the system. Further qualitative interviews revealed the effectiveness of the guidebook in facilitating improvement in family communication away from the healthcare setting. Difficulties with time constraints in adopting a shared-decision approach within the consultations were highlighted.

Despite these positive findings, these more complex self-management packages have yet to be adopted routinely in clinical practice. The barriers may be related to HCPs' reluctance to pass control to the patient; concerns that the organisational infrastructure is not in place to effectively provide a more flexible service; time limitations; or related to patients in reality preferring to remain passive recipients of care. [76] This is despite repeated questionnaires highlighting patients' interest in becoming more actively engaged in their health.

1.4.6 Clinical information systems

Providing healthcare is complex, requiring accurate decision-making based on interpreting clinically relevant information. As IBD patients require lifelong care, paper-based medical records for these patients are voluminous. Finding relevant data in these records can be slow and inefficient, leading to duplication of tests and concerns with safety. Introducing a clinical information system or Registry offers many theoretical advantages. In other LTCs, registries have been shown to improve patient care. [77, 78] Easy access to aggregate data not only facilitates audit and research, there is potential to use collected data to improve the day-to-day management of individual patients. The latest National IBD audit reported 53% of NHS Trusts operated some form of electronic database but with significant variations in function. [59]

Steps are in place to develop a national IBD registry. Despite the potential benefit, there is limited published evidence of the impact of IBD registries. Rejler et al. reported the introduction of an IBD registry in their cohort of patients in Sweden. [79] Its development was part of a wider process to redesign their IBD service, from the traditional model to a 'patient and demand' directed service. To enable this change they initiated a computerised IBD registry, to collect data on all individual patients on a population-based level. Data were continuously collected at all points of contact. With its introduction in 2001 further organisational changes were made. These included an IBD specialist nurse, virtual care with annual remote follow-up and patient initiated access to clinic. The authors explicitly used the CCM framework to help reshape their service. To evaluate the impact of these changes they measured a variety of outcomes longitudinally. These included a quality of life measure (Short Health Scale), Haemoglobin levels (Hb), patient satisfaction and hospital admissions. They used quality improvement tools to set goals and coeliac patients as a control group. The study recruited 466 patients over 4 years. In their analysis they excluded 72 patients with other co-morbidities and another 56 who dropped out of annual telephone follow-up. The study reported a decrease in unplanned hospital admissions and annual increases in patients with Hb above 120g/L. Patients were satisfied with the service and QoL measures improved. Despite these positive findings, there are limitations in interpreting the outcomes.

The results were not calculated on an intention-to-treat basis and the retrospective nature of the study risks significant bias. The coeliac comparator group does not match the needs of IBD patients and the outcomes measured have not been validated in an IBD population. The authors highlight the benefit of using a registry to monitor the quality of care across the IBD population. The data led to a cycle of continuous internal control and feedback, helping benchmark their standards and compare their levels of care to other institutions.

1.4.7 IBD standards

Rejler et al. retrospective study does highlight the potential of using the CCM to redesign IBD services and the need for improved and validated outcomes. These broad objectives are similar to the IBD standards, first published in 2009 and recently updated in 2013. [39, 53] In an attempt to address the challenges in delivering quality IBD care across the UK, a working group was commissioned to recommend standards. The principles of these reports are very similar to the CCM and highlight that an ideal IBD service should be knowledge-based, involve local and national networks, meet specific minimum standards and use modern IT. The document highlights six key themes to enable this:

- High quality clinical care- High quality, safe and integrated clinical care for IBD patients based on multi-disciplinary team working and collaboration across NHS organisational structures and boundaries.
- Local delivery of care- Care for IBD patients delivered as locally as possible, but with rapid access to more specialised services when needed.
- Patient-centred care- Care should be responsive to individual needs and offer a choice of care strategies where possible and appropriate.
- Patient Education and Support- IBD care should empower patients to understand their condition and its management. This will allow them to achieve the best quality of life possible within the constraints of their IBD.
- Data, Information Technology and Audit- An IBD service that uses data, IT and audit to support patient care effectively and to optimise clinical management.
- Evidenced-based Practice and Research- An IBD service that is knowledge-based and actively supports service improvement and clinical research.

1.4.8 Patient needs and expectations

Since the original IBD Standards report in 2009, further work has been published exploring patients' needs and preferences for their IBD care. In all of the previous studies described, there was no explicit patient involvement in the redesign of services. Kemp et al. used qualitative methods to discover patient perspectives on service delivery. [2] The author examined patient views on the current model of care and proposed changes to the service. 24 IBD patients were recruited in a tertiary centre setting. A number of themes were explored. The studies found that many patients desired a more flexible model of care. Most patients found that the traditional model of follow-up was unnecessary and inconvenient. Very few had heard of the term self-management but on further explanation, most were willing to adopt the principles in their care. A group of patients were clear that did not want to be active participants in their care and with responsibility left entirely for HCPs. Most patients were willing to adopt open access but needed confidence in its organisation. Many patients lacked trust in primary care and the majority wanted to remain followed-up in secondary care. All but one participant welcomed the use of incorporating virtual care into their follow-up. Many stated a preference for using health information technologies instead of the landline telephones. 'Virtual' care or e-health, as an adjunct to patient-initiated consultations and self-management, were identified as an optimal approach to follow-up care.

1.4.9 Summary

There is no perfect model of follow-up for patients with IBD, taking into account the fluctuating nature of the disease, its spectrum of severity and chronicity. There are also clear differences in patient's preferences and expectations. The above studies demonstrate that the traditional model of care is unable to meet the needs of a significant number of patients. Despite this, only limited evidence is available to demonstrate the effectiveness of changes to the model of IBD care. It is clear from both reviewing the literature and the recommendations of the IBD Standards, use of information technology will play a key role in delivering improved care across the IBD population. The next section examines the potential role of IT in chronic disease management, focusing upon the few studies published in the IBD literature.

1.5 Information technologies in health

1.5.1 Background

As previously highlighted healthcare services face significant pressures with the increasing prevalence of LTCs and rising patient expectations. There is a considerable need to find new ways of improving the quality and safety of care, whilst achieving efficiencies. In parallel to this rising healthcare demand, there has been an explosion of innovation in IT. There is now enormous potential to apply web-based technologies often termed 'e-health' to support the delivery of care in chronic illness. Most health policymakers see e-health as one of the key factors to improve health outcomes in the 21st century. [80]

1.5.2 E-health

As e-health is an emerging and rapidly evolving field, many of the concepts and terms are in a state of flux. Indeed, there is still no consensus definition of e-health. Some authors define the term broadly, using it to encompass the vast range of IT systems used in all healthcare; including computer hardware, software, medical devices, telemedicine and tele-health. Other authors use a more narrow definition, describing technologies that specifically use the Internet to support patient care. [81] Eysenbach's definition is often quoted, describing e-health as:

'an emerging field intersecting medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies'. [82]

Using IT to support the delivery of care provides near limitless possibilities. Currently, most systems designed cover three overlapping domains; the storage and management of data, supporting decision-making and the remote delivery of care.

Many benefits are postulated and evidence is emerging of the positive effects of using e-health in supporting chronic disease management. There are significant difficulties in evaluating the literature in this field, given the wide range of terminology used, the heterogeneity of interventions developed and the complex interplay between the technical,

human and organisational factors required to set up such services. [83] Numerous studies report difficulties with implementation. [84] This section outlines the opportunities provided by using web-based technologies, potential concerns and the current evidence-base of e-health applications to support the management of LTCs. Lastly, the limited number of IBD studies published using such technologies will be reviewed.

1.5.2.1 Health and the Internet

The Internet provides a powerful tool to engage patients given its accessibility, convenience and capacity to provide information and services. Throughout society, the development of the Internet has reshaped the way people communicate; through the use of email, online networks, instant messaging and as a platform for multi-media. [85] Its influence and use in healthcare is rapidly increasing due to its ability to provide information, social support, health promotion and potential to deliver services. [86]

Internet use has dramatically increased over the last decade. Latest surveys show 80% of UK households have broadband access compared to 57% in 2006. [87] Further coverage is provided through portable devices. In 2009 over 97% of the UK adult population owned a mobile phone and with technological advances, 49% of people have online access via this platform. [87] Concerns are raised about the 'digital divide' as factors including older age, lower levels of education and income are associated with reduced levels of access. [88] In the UK this divide appears to be shrinking. The majority of people without access choose not to use the Internet as a lifestyle choice because 'they did not need it' (54%). Other barriers reported include a lack of computer skills (22%), costs of equipment (15%) and access costs (14%). [89] As its use has grown, more people are going online to review health information. 71% of Internet users search for health-related information and this figure has doubled in the last 5 years, representing the second most popular search for information. [87]. Its use is also potentially changing health behaviours, as increasingly patients have reported health websites have influenced their decisions about treatment and when to consult with a healthcare professional. [90] This demand for health information, it has been argued, is due to a lack of information provision from 'traditional' sources. [91]

As its use and influence has grown, anxieties are often expressed about the quality and accuracy of much of the information provided. Studies have estimated that between 20-60% of resources available online are incorrect. [92] In an attempt to address these concerns, guidelines are being developed to quality assure information. In the UK a new Information Standard has been supported by the Department of Health, certifying credible sources. Significant funds have been used to develop NHS Choices, a Department of Health sponsored website for health information.

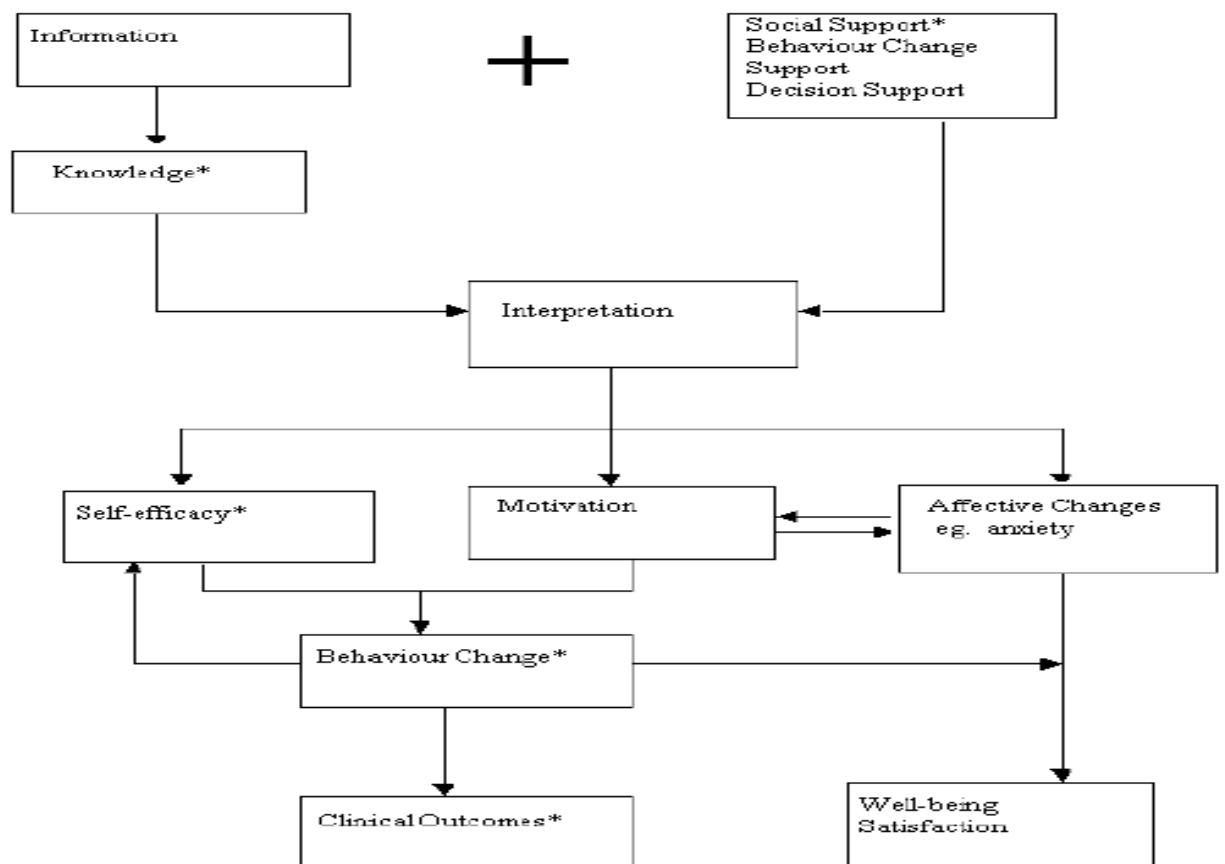
1.5.2.2 The potential benefits of e-health in chronic disease management

E-health applications provide real potential to encourage people with chronic conditions to be more active about their health needs. [93] Web-based systems can store high volumes of data that can be processed; delivering highly personal and tailored information to suit the needs of a patient. Combined with interactivity using multi-media, these technologies offer unique opportunities to provide high-quality information and support tools to manage chronic disease. After the initial design phase, further benefits can be realised due to the scalability and relative low maintenance costs. Web-based systems therefore have the potential to be highly cost-effective when used by a large number of people. [94] There are a variety of potential functions that e-health applications could use to enhance self-management and improve care. These include:

- Providing infrastructure and the support to share part or all of a patient's electronic medical record through a secure platform.
- The use of high-quality information sources and ability to tailor this information to the user both in content and delivery.
- The use of evidence-based educational applications to adopt and maintain health behaviours.
- Enabling patients to record patient reported outcomes measures (PROMS), treatment goals and action plans.
- The development of disease monitoring tools to keep a diary of symptoms and provide automated computer-assisted decision support and feedback.
- Enhancing the channels of communication with use of secure two way messaging.

Systems designed with these elements have the potential to improve patient satisfaction, communication and adherence to therapies. To provide a theoretical structure to the potential of e-health applications, Murray et al. conceptualised a pathway of action, incorporating the health psychology and self-management literature, as well as specific health information technology actions. The authors postulated that e-health applications used to manage LTCs act by combining information with additional functions such as decision support, peer support (e.g. social networks) or behavioural change support. This combination allows users to internalise and interpret the information presented, leading to changes in knowledge, increased self-efficacy and health behaviour change. They further proposed that these factors interact with one another and the combination of enhanced self-efficacy, knowledge and motivation leads to behavioural change and an improvement in clinical outcomes over time. (See Figure 5)

Figure 5. Postulated pathway of action of e-health applications



1.5.2.3 Concerns and potential harms

Although studies to date have not reported any significant harm from the use of web-based systems, a number of potential concerns have been discussed. Using web-based technologies has the potential to exacerbate health inequalities for those without access. Even if the application is accessed, potential benefits can be constrained by both health and computer literacy. Studies have shown those with chronic illness and disabilities already have reduced levels of Internet access. [87] Despite this decreased use amongst people in disadvantaged groups, those that do have access have been shown to have higher rates of searching for health-related information. [95, 96]

Using e-health applications also has the potential to negatively affect communication with patients. Without face-to-face contact the tone and meaning of conversation can be lost. Patients lacking a technical background may interpret information incorrectly and start inappropriate treatments. The additional delivery of information may confront HCPs with greater workloads to clarify content. It could also lead to information overload and confusion for users. Patients with greater access to information may question or challenge the care provided. This may lead to frustration and diminishing trust. [97] Some HCPs may see this loss of power as a threat. [91]

1.5.2.4 The evidence-base for e-health

E-health applications have been tested in a vast number of clinical areas. The majority of studies have assessed their effects in the settings of health promotion and mental health. A range of health behaviours have been specifically targeted and shown benefits following introduction of the interventions. Systematic reviews have shown improvements in knowledge, self-efficacy and health behaviour. [98] Varied topics have included smoking [99], exercise [100], and alcohol consumption. [101] Furthermore, there is particularly strong evidence to support web-based cognitive behavioural therapy (CBT) in a diverse set of clinical settings. [102]

In the setting of chronic disease management, the field of research is still in its relative infancy and thus evolving. Nevertheless, there is a growing body of evidence supporting its potential. [103, 104] Reviewing the literature is complicated by the heterogeneity, both in the design, content, functions and target population. The interventions themselves are complex and coupled to this, a variety of outcome parameters measured. These have ranged from the more 'subjective' outcomes of patient satisfaction, knowledge, anxiety and empowerment, to 'harder' outcomes such as clinical outcomes, adherence, quality of life and healthcare resource use. [105]

A Cochrane review in 2005 synthesised the available data published at the time, in a wide variety of LTCs. The primary focus of the applications included were health behavioural changes, both in children and adults. The meta-analysis examined the effects of these 'web-based interventions' on a range of parameters including; knowledge, social support, self-efficacy, emotional outcomes, behavioural outcomes, clinical outcomes and health-resource utilisation. The meta-analysis pooled data across a wide spectrum of conditions and studies using a variety of intervention designs. In total 24 RCTs were identified involving 3739 participants. Effect sizes were calculated using the standardised mean difference (SMD), with positive effects towards the intervention classified above 0 and negative when in favour of the control. The results were further classified using the Lipsey categories where values between 0-0.32 equates to a small, >0.32 medium and >0.55 a large effect size.

The analysis suggested that the e-health applications included had a medium positive effect on knowledge (SMD 0.46, 95% CI 0.22-0.69) and perceived social support (SMD 0.35, 95% CI 0.18-0.52) and a small positive effect on behavioural outcomes (SMD 0.20 95% CI 0.01-0.4) and clinical outcomes (SMD 0.18, 95% CI 0.01-0.35). The review was unable to determine the effect on emotional or health resource utilisation due to the lack of available data. The spread of effect sizes showed considerable heterogeneity and methodological limitations were noted due to the diverse diseases, age groups, intensity of exposure and differing countries the studies reported. Furthermore, many of the RCTs were underpowered and variable outcome measures were used for the specific categories postulated. The

review did provide preliminary evidence that e-health applications in LTCs have a potential positive effect on users.

1.5.2.5 Patient accessible electronic records

Another specific area of interest within e-health is the patient accessible electronic health record. In North America and more gradually in the UK, Electronic Health Record (EHR) systems are increasingly being adopted by both primary and secondary care organisations. This switch from paper-based records is being driven in part due to centralised incentives, as well as emerging evidence of their influence in improving the quality, safety and efficiencies of care. With health records increasingly stored electronically, there is the potential to enable patients secure access, via the Internet. Those with LTCs are logically the most likely to benefit from this change, supporting their involvement in managing their disease.

Various models are described, dependent upon the control and responsibility of the source of the information. Personal Health Records (PHRs) are primarily the responsibility of patients, to collate and maintain multiple sources of health-related information from different healthcare providers. Examples include Microsoft Vault and the now discontinued Google Health.

Patient Web Portals (PWPs) are usually administered by healthcare organisations and offer patients secure online access to their generic health record. These systems can be further separated into tethered-systems, provided by the patients' healthcare provider or by stand-alone applications. [105]

The boundaries between definitions are merging, along with an ever expanding list of possible functions to support self-management, enabling patients to be more actively involved in managing their health and disease.

These additional functions can include personalised summaries, immunisations, medication lists, test results, health reminders, tailored educational material, patient reported outcome measures, disease monitoring tools and personal care plans. The ability to provide two way secure messaging and book appointments has the potential to improve communication.

Despite this potential and increasing use in North America, there are limited studies in the literature evaluating the effects of PWP in specific chronic diseases. Many PWPs are designed for generic use for all users, without being personalised to their primary LTC. Numerous studies in self-management programmes have shown disease-specific interventions have increased uptake and the potential for greater impact. [30, 106]

The objectives of this project were to develop an IBD-specific Portal incorporating self-management functions. The literature reviewed was therefore limited to disease-specific systems designed with similar core elements that the author aimed to implement within the IBD-specific web-based Portal. These central functions included patient access to medical records, personalised health information, self-monitoring tools and enabling secure messaging with HCPs.

A variety of LTCs have been evaluated. The majority of these studies were performed in North America and have focused upon diabetes and asthma management. There is limited evidence of their use in IBD worldwide. Below is a review of the literature to date.

1.5.2.6 Congestive cardiac failure (CCF)

The first reported randomised controlled study was performed in 2004, at the University of Colorado. Ross et al. evaluated the effects of web-based system in the management of congestive heart failure. They randomised 83 patients to receive usual care or were given access to a secure web-based system ("SPPARO") and usual care. This system provided access to an online educational guide, a messaging system and their medical record (clinic notes, bloods and imaging). Participants received questionnaires at baseline, 6 months and 12 months. The primary end-point measured was a change in self-efficacy. The study found

no statistical differences between the groups, although there was a trend towards improvement in the intervention group.

A number of other secondary end-points were measured but the trial was not powered to measure these parameters. Patients felt more satisfied with understanding their problems and explanations of their condition. This study was one of the few to evaluate adherence. They found that general adherence to medical advice was improved in the intervention group with no statistically significant improvement in medication adherence but a trend towards. [107]

Attrition rates were high with only 24% of enrolled patients using the system in a given month. Secure messaging was found to supplement telephone messages, with higher total contact in the intervention group. Post study interviews showed staff did not feel the web-based system increased workload. The authors concluded that patients' access to records and information could improve certain aspects of care but was unlikely to improve health status. They highlighted the need to integrate behavioural strategies within the system to empower patients to care for themselves. [108]

1.5.2.7 Diabetes

The majority of studies reported using e-health applications have targeted diabetes. [103] The current evidence-base is evolving and reported outcomes have been mixed. Due to the heterogeneity of the trials, systematic reviews have deemed meta-analysis not to be applicable. [109]

The relevant studies, which contain the same core elements as the authors proposed system, are described below. Ralston et al. from the University of Washington reported a trial where 83 patients with Type 2 diabetes were randomised to usual care versus care augmented with a web-based management system for 12 months. The intervention provided access to test results, clinical summaries of diabetes care, secure messaging, online reminders, educational materials and the ability to upload glucose readings. Participants

were encouraged to send weekly glucose readings and send secure messages as needed. The intervention was based on Wagner's CCM as described in section 1.2. [9]

The primary endpoint measured was a change in glycosylated haemoglobin (HbA1c). The levels decreased significantly in the intervention arm ($p=0.01$). Secondary end-points included BP recordings, lipid levels and healthcare utilisation. No significant differences were reported in these measurements or in hospital admissions or number of consultations. Usage of the system included 76% accessing their electronic record, 69% used the secure email, 43% uploaded their glucose recordings and 33% entered medication and nutrition data. [110]

The same group repeated the system in Type 1 diabetic patients. 77 patients were randomised into each arm. This time the HbA1c decrease did not reach statistical significance. The authors commented that the trial was underpowered. The secondary endpoint of self-efficacy measured using the Diabetes empowerment scale improved. Attrition rates were high with only 20% using the resources regularly throughout the period. Unfortunately no qualitative analysis was performed to analyse barriers to its use. [111]

A further US group from the Veterans Affairs institution in Boston, evaluated a web-based care management system for poorly controlled diabetics in 2005. 104 patients in total were randomised to either usual care, versus the web-based care management. The intervention group received a notebook computer, a blood pressure monitor, a glucometer, free internet use and access to a diabetes care management website. Unlike this project, patients did not have access to their personal health record. However, they were able to send and receive secure messages to and from their care team. They also had access to educational links and web-based diabetes resources. Whilst HbA1c levels decreased over time in both groups, the intervention group demonstrated a greater decline over time (decrease of 1.6% versus 1.2% in usual care group). Blood pressure declines were also greater in the intervention patients with hypertension (-10 versus -7 mm Hg) while there were no

differences in lipid levels. Attrition rates were better than other reported studies but still high with 52% of subjects using the system for the full 12 months. [112]

A further sub-analysis report from the same group evaluated the systems effect on diabetes distress. They found those in the intervention group with the most sustained and regular use, had the greatest improvements in diabetes distress. The paper indicated that those with lower levels of distress from the outset tended to be the same people that used the web-based system. They concluded that only certain patient characteristics may be suited to gain from using a web-based approach to care. [113]

Lastly, a third but separate group from Boston, Massachusetts, USA evaluated the effects of a secure online personal health record named 'Patient Gateway' in Type 2 diabetic patients. A regional care group covering 20 primary care practices uses this e-health system. It allows patients limited access to their health record, the ability to securely email care providers and a health information library. The system was modified with a diabetes-specific interface, providing patient's current clinical data, education material, secure messaging and enabling patients to author a "Diabetes Care Plan'. [114] This system was tested in a cluster RCT over a year. 244 patients were enrolled. Primary end-points were improvements in the clinical outcomes of hyperglycaemia, hypertension and hyperlipidaemia. They also hypothesised that the 'digital-divide' would lead to reduced use amongst poor and older patients.

Patients enrolling in the system were significantly younger, Caucasian and had lower HbA1c levels at baseline compared to non-participants. In both arms of the study HbA1c levels decreased and in the intervention arm HbA1c levels were lower but the change was not significant. In sub-analysis those in the intervention arm with the highest levels of HbA1c did have a significant improvement. Those using the care plan module prior to clinic had greater changes to their medication regimen and they concluded that the system might reduce barriers to change at clinic appointments. Adherence was not measured. This would have added further strength to this argument. This study underscored the findings from other

reports of difficulties in engaging patients to use such systems and those patient's with the most need to change their health behaviours are the least likely to enrol. [115]

Following this paper the group reported a sub-study examining the effects of the system on medication accuracy and safety. They found the intervention decreased discordance between the EHR and patient-reported medications and reduce discrepancies for potential severe harm from adverse drug events. [116] Further large studies are currently recruiting to evaluate the effects of more comprehensive web-based systems in diabetes both here in the UK and abroad. [117, 118]

1.5.2.8 Asthma

A number of web-based interventions have been evaluated in the management of asthma. The majority, have been applications for recording symptoms in an electronic diary and electronically monitoring peak-flow rates. These systems create automated action plans based on the readings and are monitored remotely by HCPs. These decision-support tools have been shown to improve symptoms, quality of life and lung function. [119, 120]. Patients with the poorly controlled asthma appear to have the greatest improvements. Again, these studies all report high attrition rates with enrolled participants. [121, 122].

Ahmed et al. have described the development of a web-based intervention with similar core elements that the author proposes. Their designed PWP provided tailored asthma education, online access to their personal health data, secure messaging to HCPs and self-monitoring. The system is currently under evaluation in a RCT in Toronto, Canada. [123] Preliminary results were reported again showing significant attrition rates. The monitoring and feedback function were the most visited on the PWP. The trial is currently on-going. [124]

1.5.2.9 IBD

Very few published studies have evaluated e-health technologies specifically in the IBD population. This is despite the conditions suitability compared to other chronic diseases given half of all patients are diagnosed under 30 years of age. [125] Two groups have reported results.

Finkelstein et al. designed and evaluated a home tele-management system for managing ulcerative colitis. They hypothesised their system would lead to an improvement in disease activity and quality of life compared to best available care through improved monitoring, medical adherence and participant knowledge. [126] The intervention comprised a web-enabled laptop and weighing scale connected to the care providers through a secure server. Participants were requested to answer questions through the web interface on symptoms, side effects, adherence and received online education material. These data were securely transmitted to an automated programme, set up to for customised clinical alerts and action plans. Participants were requested to answer the 15 questions on a weekly basis. Secure messaging to the nurse co-ordinator was provided. A feasibility and acceptability trial was published in 2007 using 25 participants. The system was shown to be acceptable and improved IBD quality of life and symptom scores over a 6-month period. [127]

The group went on to perform a RCT. They calculated 84 participants were needed for sufficient power to detect differences in their primary and secondary outcomes. Only 47 were recruited, worsened by attrition once the trial commenced. Despite randomisation, there were significant differences between the two arms at baseline with higher disease activity and immunosuppressant use, as well as worse quality of life reported in the intervention group. Overall the studies headline findings were considerably limited due to these factors. The web-based system designed was also unlikely to be useful in the long-term due to the intensive and repetitive requirements of the service and need for home installation. However, the study does help highlight barriers to the design and implementation of an IBD web-based system for routine practice. [128, 129]

A Danish group designed the only other web-based intervention published for IBD. Munkholm et al. designed a web-based package called 'Constant-Care'. The system was originally designed to optimise aminosalicylate therapy for patients with ulcerative colitis. The service has been further developed for Crohn's disease and other G.I. disorders. [130] The authors hypothesised the service would improve quality of life, self-adherence and reduce dependency on doctors. In the original UC study, the web programme automated responses from the six questions of the simple clinical colitis activity index (SCCAI) and combined these answers with a sub-set of four questions from the short inflammatory bowel questionnaire (s-IBDQ). [131] [132] This integrated scoring system has not been validated. Responses to these questions resulted in a traffic light system of action plans. Self-initiated treatment changes were recommended if they scored in the red or amber zone, with options to increase 5-ASA oral therapy, add topical therapy and/or steroids. This response was set according to the patient's own experience. As well as this disease monitoring function, educational material on UC and results were presented to users on the web interface. This included an e-learning centre to test user's knowledge. Secure messaging was provided and an administrator page to remotely monitor participant's symptoms. Patients IBD health records were not available. In addition to the web-package, an educational 3-hour course was provided to the users of the web programme at the start of the study. This comprised 1.5 hours of IBD-specific education and 1.5 hours of training on using the web application. [133]

The intervention was tested in a RCT across two countries (Denmark and Ireland) in patients with mild to moderate ulcerative colitis. Participants in the intervention arm were asked to log-on once a month when stable. If a relapse occurred they were requested to enter data weekly, until remission was achieved for a total of 4 weeks. The control arm continued 'usual' care but were asked to fill in paper records of their IBDQ and SCCAI scores in case of relapse. Data were collected at baseline, 6 and 12 months. Multiple outcome parameters were measured. These included IBD knowledge (CCKNOW), satisfaction, compliance, disease symptoms, quality of life, changes in depression and anxiety, as well as costs. In Denmark they randomised 233 participants and in Ireland 100 participants. Attrition rates

were not formally reported but were relatively low (23.1%) compared to other web-based interventions. [134] The reported completion of paper-based data from the control group (82.3%) was even higher, despite previous reported difficulties in obtaining patient diaries in similar studies. [54, 135]

The trial headline findings reported that the system increased “*patients’ compliance, quality of life, and empowerment to self-initiated treatment, and it reduces healthcare costs*”. This summary of the significance of the findings is somewhat misleading. Despite the multi-centred approach the data across the two sites were reported entirely separately. Most significant differences were found only in Denmark. Compliance was measured with the authors own scale despite a number of validated scales available. [136] Prescription refill data showed no differences and the only difference in adherence was to 4 weeks of higher dose 5-ASA treatment. Costs did not include attending the 3-hour educational session. Outpatient visits did statistically decrease in both countries.

The authors have gone on to further develop the system and have reported a preliminary study investigating the use of the system in Crohn's disease patients. The objectives were to see if use of the system could help personalise medication delivery of Infliximab from the usual scheduled care of 8-weekly injections. Again their pilot data suggest their web-based service can be used to interact and enable a select cohort of patients to support the management of their IBD. It is positive the service continues to be adapted and developed.

1.5.3 Summary

This research field is in its relative infancy but there are a growing number of studies using e-health portals that aim to actively involve patients in managing their health. The literature is evolving and newly developed systems are becoming more sophisticated. With the growing use of the Internet and its potential capabilities, coupled with changes to governmental policies, use of PWP in supporting the delivery of care is likely to significantly increase. However due to the heterogeneity and settings of the published studies, it is difficult to draw conclusions on their overall impact to clinical care.

The evaluation processes described are highly variable. It is unclear what aspects of the many potential components provide the most benefit and what demographic and clinical factors influence success. Further problems are highlighted with their implementation and high attrition rates are reported in most studies.

The review showed most studies were conducted in the outpatient setting and Diabetes was the most prominent condition evaluated. The majority of interventions involved factors beyond simply providing access to personal information and included patient-entry functions and messaging systems. The literature also showed a wide range of measured outcomes. There is a variety of postulated effects from introducing such systems, within the complex field of healthcare. To provide a structure to the evaluation process, the following domains could be used to categorise the impact of such systems.

Usage	Frequency, timing and attrition rates
Patient Experience	Satisfaction, ease of use, effects on communication and support
Health Outcomes	(i) Behavioural outcomes e.g. self-efficacy, adherence, engagement (ii) Clinical outcomes e.g. HbA1c, disease activity, calprotectin
Health resources	Outpatient appointments, hospital admissions, contacts with HCPs

Using these domains, the literature shows that many of the systems developed have low adherence to use and increasing attrition throughout the length of studies. Attitudes towards such systems from both the patient and HCP perspective need to be assessed early in the design and may help address this effect. There are significant potential barriers to adoption and certain patient characteristics may impact use. Although data are conflicting, a number of studies have reported higher use amongst patients of higher social-economic status, Caucasian and younger age groups. If there are highly selected users, the potential benefits will only be realised by a sub-set of the target population. [137] This may lead to a further widening in health inequality. Against this, one could argue that if specific healthcare interventions decrease the overall costs or utility of the service, more resources would be available for those most in need of care. This would provide a net benefit to all, even if the more active participants gain the most.

In general, the reported outcomes from the studies reviewed show the potential of PWPs to advance the current models of care. The strongest evidence of their effect is on improving the patient experience, with most studies demonstrating improved patient satisfaction and communication. Some individual studies show actual improvements in clinical outcomes, although there is limited evidence supporting this effect, especially when considering the influence of publication bias. A number of studies show behavioural improvement with enhanced disease-specific self-efficacy. If this effect was to be maintained after completion of the study, it may lead to positive effects on clinical outcomes over a longer period of time. In terms of resource use, the evidence is conflicting but the likelihood is a minimal effect on health utilisation.

Overall, more studies are needed to provide a greater understanding of the impact of PWPs and in different target populations, given the variations reported. Few studies report any harm from their introduction but concerns need to be addressed in creating a two-tiered service with widening inequality for those unable to access and use the latest technologies. On account of the issues raised in this review, the author has designed a bespoke web-based system for patients with IBD. The hope is that this will address many of the

challenges in developing and evaluating web-based interventions. The aim is to expand the evidence in this exciting field of health research, with direct relevance to how IBD is managed in the NHS. The next chapter describes the design and implementation process of the IBD web-based service 'My IBD Portal'.

2.0 Methodology

2.1 Development of 'My IBD Portal'

2.1.1 Background on the design and implementation of e-health

As highlighted within the introduction, health policy-makers have become increasingly enthusiastic about utilising e-health systems in an attempt to improve quality, broaden access and increase efficiencies. [5, 96, 138] Despite this, most web-based systems are not successful in realising these postulated benefits. The literature suggests one of the main reasons is too great a focus placed on technical aspects of the development phase, with a lack of emphasis on contextual factors. Often, the designed technologies provide little practical benefit for users and fail to fit into routine clinical practice. Unforeseen organisational factors can also cause adoption difficulties, leading to sub-optimal outcomes. It is clear from the literature and from the authors' involvement in this project, that the processes involved in developing web-based technologies in the NHS setting are very challenging. Support is required on multiple levels and efforts made almost always prove to be more complex and time-consuming than anticipated [139]

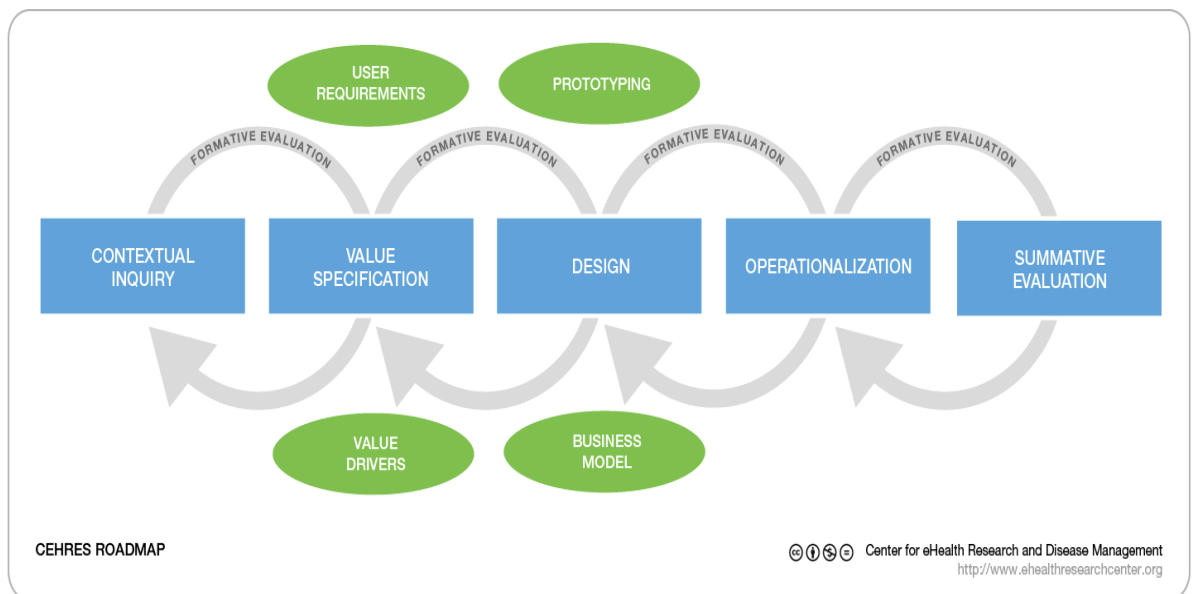
As the use of e-health steadily grows, an increasing number of studies have described various methods used to design and implement e-health technologies. Most reports are based on unique systems, detailing the 'barriers' and 'facilitators' that influenced their development. This makes the literature fragmented and spread across a wide range of specialties.

There are a small number of theoretical frameworks published, providing a roadmap to the development and implementation process. It has been widely recognised that the introduction of IT systems, even at a local level, is complex and fraught with difficulties. It requires leadership, coordination, project management and communication, often with numerous stakeholders.

For this project, a 'holistic' e-health framework was used as a guide for development. This roadmap was first described in 2011 and followed a comprehensive review of the previous literature. The authors, who are leaders in the e-health field, examined a variety of original theories supporting the development of e-health technologies.

Their review examined a broad range of concepts from user-designed principles and behavioural models based on health psychology, to innovation diffusion frameworks; emphasising implementation and organisational aspects. The authors appraised the data in an attempt to identify the key constituent elements. Most previous frameworks described a theoretical approach. Following their review, they described a framework offering a practical guide (See figure 6). The framework emphasises a 'holistic' approach and the need to consider the social, technical and human factors, which are inter-dependent of each other. Following the award of funding, its guidance helped in the coordination, planning and execution of this project.

Figure 6. A practical roadmap for the development of e-health technologies



The 'holistic' framework contains six working principles. These are that e-health development:

1. Is a participatory process
2. Involves continuous evaluation cycles
3. Is intertwined with implementation
4. Changes the organisation of care
5. Should involve persuasive design techniques
6. Needs advanced methods to assess impact

The guide highlighted the need to identify the key stakeholders at an early stage and the multi-disciplinary approach required to manage the project. The design process required multiple evaluations at different levels of methodological rigour over a number of stages. Implementation issues were appraised from the beginning of the project. This includes the resources available, organisational factors and, rather crucially, the IT Departments willingness to provide significant support. The framework emphasised the need for the system to fit within routine clinical practice to significantly aid adoption. The designed system also needed to be inter-operable within the NHS setting and be affordable to maintain. Finally, the methodological challenges of assessing the systems impact were highlighted. With all these inter-dependent factors in mind, below is a description of how the web-based package was designed and implemented.

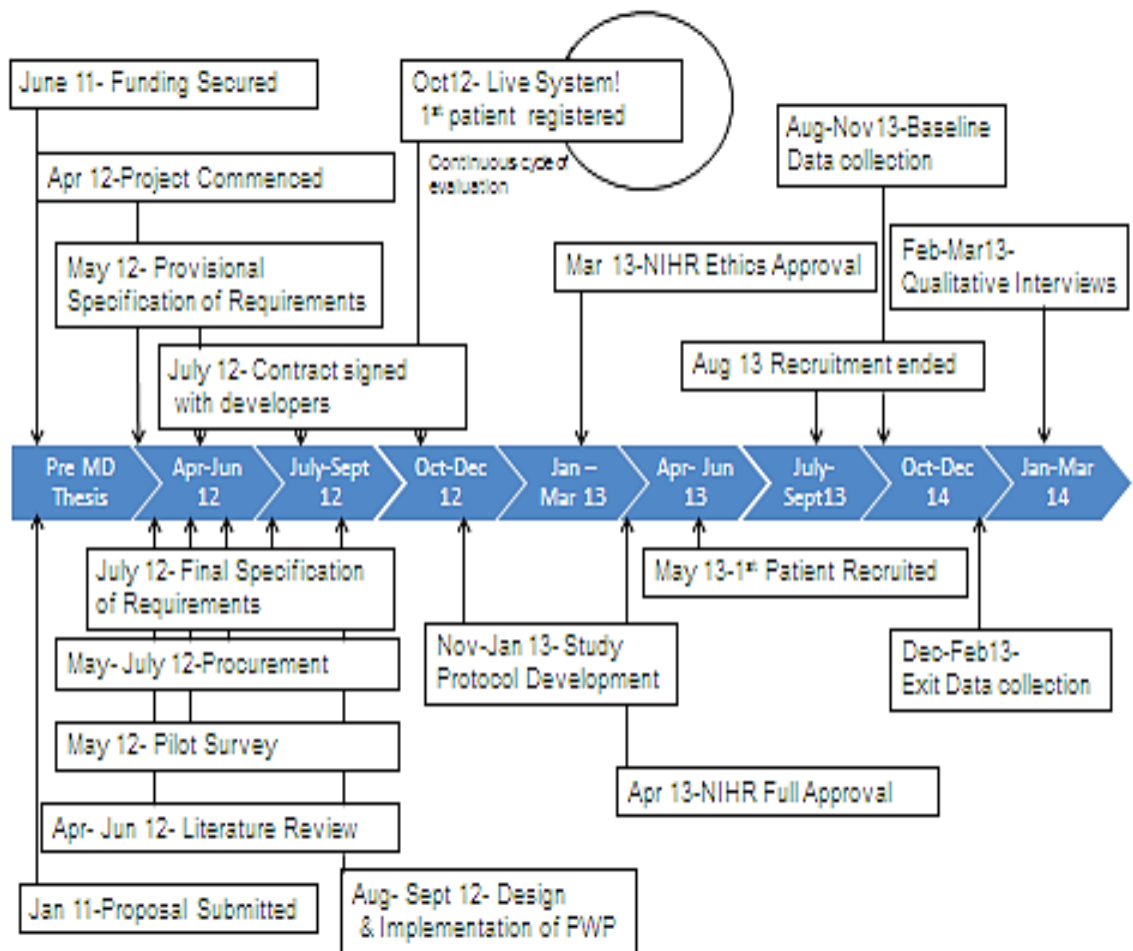
2.1.2 From concept to funding

The primary motivation of this project was the authors' drive to provide patients the opportunity to be more involved and have greater confidence in managing their care. The plan was to use an evidence-based approach for development. The long-term aim was to create a system that in the future could be easily adopted across multiple NHS Trusts. This project offered the opportunity to develop new skills, an in-depth understanding of service design and to analyse the potential and challenges of developing web-based technologies in healthcare.

An extensive review of e-health systems used in the NHS was undertaken and an initial grant proposal outlining the projects objectives was written in January 2011. This initial work ensured that the processes required to develop the concept were feasible.

To move forward a pilot NHS Trust was needed where the support of the key stakeholders were aligned. This Trust needed to share the vision of the proposal, have the necessary technical skills and IT infrastructure, enthusiastic HCPs and research governance. Salford Royal Foundation NHS Trust (SRFT) proved the ideal site. The Trust had an advanced EHR system, coupled with strong support from the IBD clinicians and a large cohort of patients. To ensure the projects feasibility, the IT and Information Governance teams were approached and were keen to engage. Following further guidance from the R&D Department, a final grant application to the charity, Crohn's and Colitis, UK, was successful in June 2011, providing funds. This funding commenced in April 2012 and enabled the author to design, implement and evaluate a proof of concept web-based IBD care package at the single centre.

Figure 7. Timeline of project



2.1.3 Start of project to implementation

The first stage of the process in development involved a review of the literature on e-health design, implementation and evaluation. Based on this review a provisional specification of requirements was written. External software developers with experience in working with NHS organisations were approached and assessed on their costs and ability to deliver these requirements in the limited timescale available. This process proved complex and took longer than expected.

At the same time as procurement commenced, further work was undertaken to ensure the initial requirements planned would closely meet the needs and expectations of patients. A pilot survey of IBD patients (May 2012) and a patient focus group (PFG) were convened for this purpose (June 2012). After minor modifications, a final specification of requirements was drawn up. Significant negotiations then took place with the potential developers and finally the contract for development was awarded in July 2012.

The author then worked through each aspect of the design from the colour scheme and layout of the interface, to the added functionality embedded that aimed to support self-management. As the software developers were unfamiliar with the condition and its complex terminology, an online project management site was set-up for daily communication (Basecamp[®]). Twice-weekly conference calls were scheduled. After many changes to the design, a satisfactory prototype was developed by October 2012.

The main set back during this phase were problems with the Trust's data collection. No clinical information system within the EHR was present to register IBD patients and record a summary of their condition. This required the design and implementation of further functionality within the EHR to collect these relevant datasets. This 'IBD flowsheet' had the further benefit of creating a simple way to identify consented users by providing a 'flag' in the EHR. After this function was incorporated, the data transfer process from the Trust to the developers secure server was set up with prototype patients. The system was then repeatedly tested to remove any errors present. Finally in October 2012, the first test patient

was enrolled onto the system. 22 further patients consented to test and evaluate the site. After further minor changes, the author was confident that a fully working system was in place in December 2012.

A study protocol to assess the impact and acceptability of this service was then proposed and revised to fit in with the reduced time available. After multiple drafts, a final version was submitted to the National Research Ethics Service (NRES) and ethical approval for the study was granted in February 2013. Final R&D approval from the NIHR was received in April 2013 and recruitment started in May 2013. Recruitment ended in August 2013, with baseline and follow-up data collected and analysed (see next chapter).

Below is a summary of the key stakeholders involved in this design and implementation phase. A significant number of people have enabled the project's development. This included many departments within the Trust; the HCPs, the charity, the chosen software developers and most importantly the patients for whom the proposed service was designed.

2.1.4 Patients

A key priority throughout the design process was to directly involve patients. If the proposed web-based care package fails to meet their needs and expectations, it will clearly not achieve the potential benefits envisaged. Repeated studies have shown end-user engagement is a vital component to the success of e-health projects. [140] A top-down approach, with development guided only by the software developers and HCP beliefs about patient-users, has often resulted in sub-optimal systems that fail to meet the challenges faced by patients.

Fortunately, significant work had already been completed investigating patients needs of an online IBD record. As part of a larger scoping study, the 'Do Once and Share' project commissioned by the Department of Health, explored patient attitudes to providing patient access to their IBD record online and desirable functions for such a system. The authors of

this project used qualitative methods to seek patient views. This work helped in drawing up the provisional specification of requirements at the start of this project. [141]

To assess the potential use and acceptability of the system in the local IBD population, a pilot survey was conducted over a 4-week period in May 2013. All IBD patients attending outpatients were asked to complete the questionnaire. The survey aimed to assess Internet use, perceived information needs, support and engagement in managing IBD.

108 patients completed the survey. The mean age of respondents was 41 years with 49% male and 51% female. 64% had Crohn's disease, 33% ulcerative colitis and 3% were yet to be classified. 87% had access to the Internet with 83% using it at least weekly. 53% accessed using a mobile phone and 29% tablet devices. Of the patients responding 59% had searched specifically for information about IBD. There was significant variation in opinion on whether this information was reliable and trustworthy. An appetite to learn more about the proposed system was expressed, with 71% of patients interested to use the planned new service.

To further explore patient preferences for the proposed system, a focus group meeting was convened in June 2012. A purposive sample of patients attending clinic were invited by letter. 8 patients and the members of the IBD clinical team directly involved in the project attended the meeting. Open-ended questions were used to explore attitudes, preferences, concerns and useful content in providing patients online access to their IBD record. At the end of the meeting, a demonstration of a potential layout of the site was discussed to gain further insight. The meeting was recorded, summary notes taken with the data analysed and categorised. The following three distinct but inter-dependent themes emerged.

1. Information needs- Patients requested access to trusted information, personalised to illness type. Preferences included a timeline of their condition, blood results, letters and medication profile. Assistance in the interpretation of data was a set requirement.

2. Improved communication and emotional support- Email communication with HCPs and the availability of online peer-led support, via a forum, blog or 'buddy' system were valued as a platform to share information and provide emotional support. Concerns were raised about moderation of content and misuse.
3. Organisational issues – Security risks were highlighted as a concern. The ability to book appointments on request, as well as notification alerts when new information or results became available were deemed to be helpful functions.

In summary, the group attitudes were positive to the projects vision. Perceptions were of a comprehensive system, delivering information, emotional and organisational support, providing timely access to services. Most of the patient needs were incorporated in the provisional design, however a number of potential functions were not able to be embedded, as they were currently not feasible or affordable within the current budget. This included the use of social media and the ability to review and book appointments. These expectations could be met in the future and may improve the benefits of the service. After this work, the final specification of requirements were confirmed and used to commission the design of the system. (See appendix 1).

2.1.5 Healthcare professionals (HCPs)

An area consistently highlighted in the e-health literature as a major barrier to implementation, is professional resistance to new technologies. HCPs are often reported to show little enthusiasm, especially if new technologies adopted potentially increase workload or provide little benefit to patients. [142] This barrier appears obvious and it was clear that to successfully implement this new service, the HCPs directly involved in the provision of care needed to be persuaded of the benefits in adopting the new service.

The IBD team at the Trust played a crucial role in the design and development. Without their enthusiastic support and innovative vision, the development would not have gone past the conceptual phase. Each member of the team contributed. This included the outpatient nurses, helping collect pilot questionnaires and the senior clinicians supporting the application process and providing expert supervision. The IBD specialist nurses shared the

projects' vision and played an integral role in advising on the design, verifying content, helping organise the focus group meeting and adapting their delivery of service.

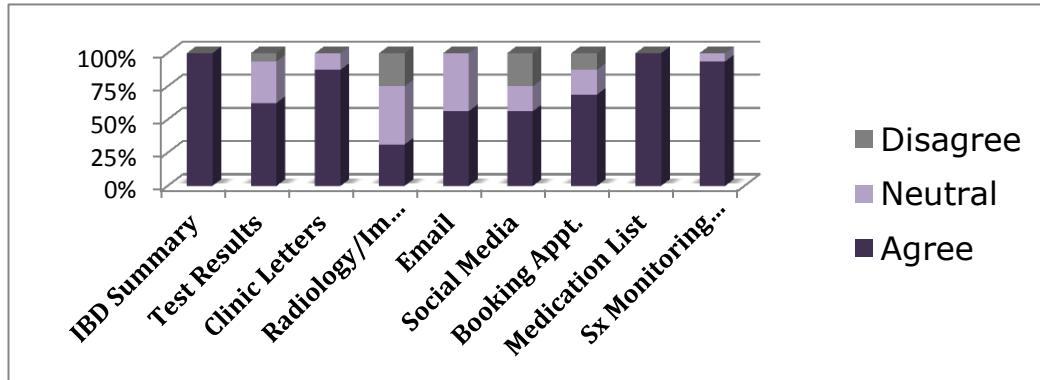
Despite this strong local support, it is clear that to adopt a web-based package on a wider level, significant resistance from HCPs may be encountered. To evaluate clinician's attitudes and preferences an open-ended questionnaire was adapted from a previous study, assessing perceived advantages, disadvantages and pre-conditions of providing patients online access to their IBD record. [143] Preferences of the proposed components were elicited using a 5-point Likert scale and open-ended questions. This questionnaire was handed out during a regional North-West GI meeting. Significant limitations to the findings of the survey included assessing only GI physician's attitudes, as well as the poor response of 16 completed questionnaires out of the potential 42 attendees. These data were coded into categories and the following themes emerged.

Table 1. Categories of perceptions and pre-conditions to an IBD portal

Perceived	1. Increased patient involvement
Advantages	2. Improved knowledge and understanding
	3. Enhanced patient-provider communication
	4. Improved safety
Perceived	1. Misinterpretation of the data
Disadvantages	2. Extra workload
	3. Inequalities of service
Pre-Conditions	1. Informed consent
to service	2. Opt-in only
	3. Automation of data transfer, security and restriction of selected data

Views on the specific content of the web-based package were also assessed by quantifying the scores for each proposed component and calculating the percentages of clinicians who agreed, were neutral or disagreed.

Figure 8. Stacked graph showing clinicians views on the proposed content of an IBD portal



This is a small survey, but clearly revealed that clinicians' opinions varied considerably. Greatest concerns identified were in providing imaging and endoscopy reports. A majority of respondents felt these reports would be misinterpreted and cause anxiety. Furthermore, the enhanced communication that web-based systems could offer, with online email support and social forums divided opinion with worries over moderation, use and content. The opinions were taken into consideration within the design. Imaging and radiology reports were excluded. In contrast to the clinicians concerns however, many patients in the pilot survey highlighted a desire to view all their health record.

2.1.6 The IT department

A main finding throughout the design and implementation phase has been the central role of the IT Department in development process. Without the strong support of a number of key members of the department, the project would not have gone past than the conceptual phase.

Involving senior members from the very start of the project enabled many of the implementation issues to be resolved in a timely manner. To aid this process two members of the IT Department provided significant support to the author. Their expertise in understanding the technical aspects of transferring data from the EHR and project management skills were invaluable.

2.1.7 Software developers

The choice of software developers to design the web-based package, within the constraints of the budget and timescale, was seen as one of the most important factors in the whole project, and vital to successful initiation and conduct. This procurement process took longer than originally anticipated, but as the whole project was dependent on this platform the research team considered it vital to make sure that the correct longer term decisions were made. Based on the literature review, the provisional specification of the requirements unique to this project was composed. Following a review of UK-based patient information systems, three external companies (the unsuccessful tenders are not identified herein) were approached. The advantages and disadvantages of each were carefully assessed.

The first company offered to develop the proposed system at minimal cost. They were already developing a separate PWP for intestinal failure patients at the Salford Royal Trust. Using their software may have offered an advantage, as their system could link with others in the GI department. Furthermore, the process to approve the information governance surrounding data transfer would have been streamlined. This requirement had real potential in causing considerable delay to implementation.

Despite these factors, significant disadvantages were highlighted. The platform for patients was to be based on a generic interface with increasing links required to access relevant IBD-related information sources. Previous studies have shown that both condition-specific and personalised information increase the uptake and outcomes of web-based systems. [144] The companies experience within the NHS was also limited. At the time less than 100 patients were enrolled in their service. They were also unable to meet the full specification of requirements and were unwilling to design the proposed self-management tools proposed within the requirements.

The second company evaluated had recently succeeded in tendering for the development of a clinical management system for a national IBD Registry. It would make sense for a PWP

system to link with a Registry, as it would have the potential to improve the accuracy of data held and provide further support for patient recruitment in research. The company was willing to design the system to the required specification but they were unable to meet the tight timescales set out. Also, the company objectives were entirely commercial and it was unclear following the design where the rights of ownership would lie with regard to the content developed.

After careful consideration, the third company reviewed (Solid State Group) were chosen as the software developers. These developers had a proven track record in designing and maintaining a patient information system used widely in the NHS.

This team had designed, rolled out and developed 'Renal Patient View'. This patient information system has been in use for over 10 years and had been adopted across 50 NHS Trusts. The designed system provided renal patients' online access to blood tests and clinic letters through a secure username and password. At the time of procurement over 19,000 NHS patients were registered with the system and this included over a 1000 patients at the pilot Trust in Salford.

Basing the IBD project on a tried and tested system used by a large number of patients both within the pilot site and nationally, provided many clear benefits. The IT infrastructure, security system and governance issues were already in place, as well as a huge amount of experience from their own development processes. As the technology was already linked with the Trust's EHR, it has made the process of data transfer and approval by the Information Governance committee relatively straightforward. A further benefit of basing the design on this system was that the computer code to write the software was open source and therefore not commercially driven. As a result if this pilot project proved successful, future development costs could be reduced, enabling wider adoption.

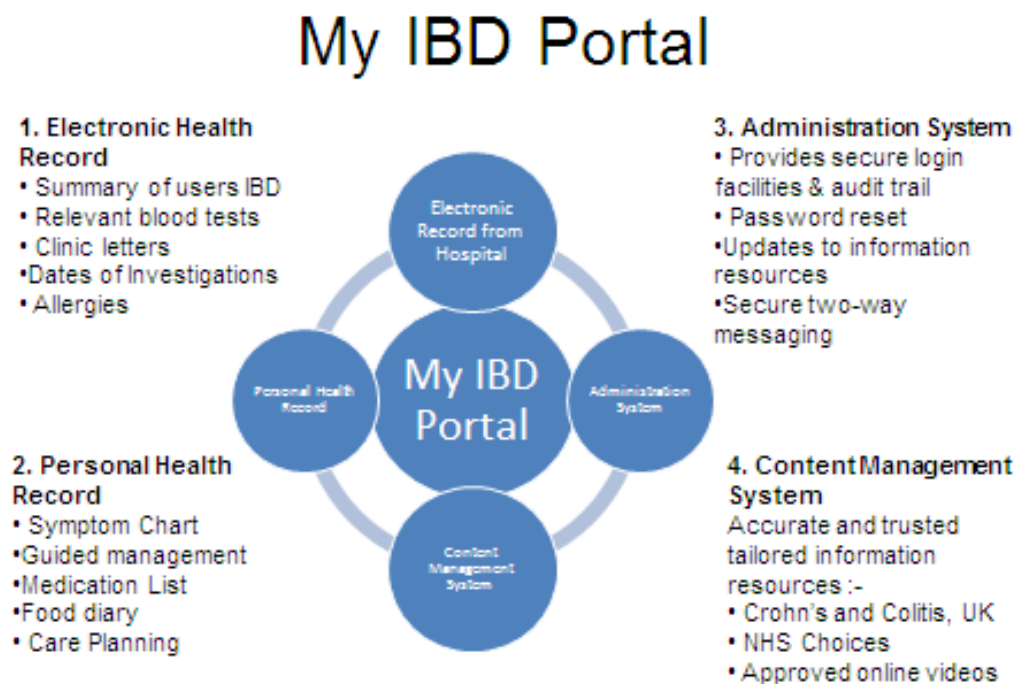
2.1.8 The web-based care package

The web-based system developed was named 'My IBD Portal'. The domains' www.myibdportal.com and www.myibdportal.org were licensed to the author and the IT infrastructure and interface of 'Renal Patient View' was extensively adapted and modified to meet the requirements of the project within the constraints of the budget. Below is a detailed description of the incorporated infrastructure, content and functions of 'My IBD Portal'. The developed web-based package aimed to meet the concepts vision; to engage IBD patients and facilitate them in managing this lifelong condition.

2.1.8.1 System infrastructure

'My IBD Portal' combines four separate systems linked together: (see figure 9 below)

Figure 9. The four elements of 'My IBD Portal'



2.8.1.1.1 The electronic health record (EHR)

Selected data fields from the NHS Trusts EHR are securely exported to the PWP. The EHR contains a comprehensive record of patient clinical encounters at the Trust. After the literature review and qualitative work described earlier, the following datasets were selected to provide users with a comprehensive record of their IBD. These datasets are securely transferred to 'My IBD Portal' by setting up a secure information exchange process. Following informed consent, a flag developed in the EHR identifies the PWP users. The selected data of consented patients are tabulated by the Trust on a secure server. These datasets are then encrypted twice and sent by a secure ftp file to the software developers named server. These files are then decrypted and used to populate the care package. To match the data with the patient login details, the patients NHS number is used as the unique identifier. For more details on security and information governance see appendix 2. The following datasets were made available to view by the patient.

Demographics details

- Name
- NHS Number
- Contact Details
- Date of Birth
- Address
- GP Details

Summary of condition

- Coded diagnosis
- Date of diagnosis
- Allergies
- Weight
- Previous Operations
- Named Nurses
- Extent of disease
- Complications
- Extra-intestinal manifestations
- IBD related family history
- Hospital admissions
- Named Consultant

Investigations

- Blood Tests (Full Blood Count, Urea & Electrolytes, CRP, Liver Function Tests)
- Stool sample tests (Faecal calprotectin)
- Date and type of imaging scan (Full reports were not provided after assessing the HCPs attitudes)
- Date and type of endoscopy procedure

Clinic letters

Letters specific to:

- Gastroenterology
- GI surgery
- Dietetics

2.8.1.1.2 Personal health record (PHR)

A PHR initiated and maintained by the user, inputted directly via the secure login was developed. The following interactive tools were designed to facilitate self-management.

Users could input their data on:

- Current and previous medications
- Personalised IBD Care Plans with goal setting and action planning
- Symptom charts for both Crohn's disease and ulcerative colitis were designed. Automated support is offered dependent on the individual users symptoms.
- Nutrition support- weight and food diary entry

2.8.1.1.3 Information management system

A separate website (www.myibdportal.org) with cloud-based content management facilities was set-up to provide updated and reliable information links to the system (Heroku[®]). Permission from the charity, CCUK was granted to adapt their information booklets to web format (html). These resources are certified by the Information Standards certificate but were only available in pdf versions (Adobe[®]). This meant several clicks would have been needed for users to access relevant information. Converting the booklets to this html format enabled

bite-sized hyperlinks to be created in an effort to personalise information for users. This process was not factored into the project originally but took considerable time. Other nationally approved resources were used and, where small gaps were found in the material available, educational material was written and approved locally.

2.8.1.1.4 Administration system

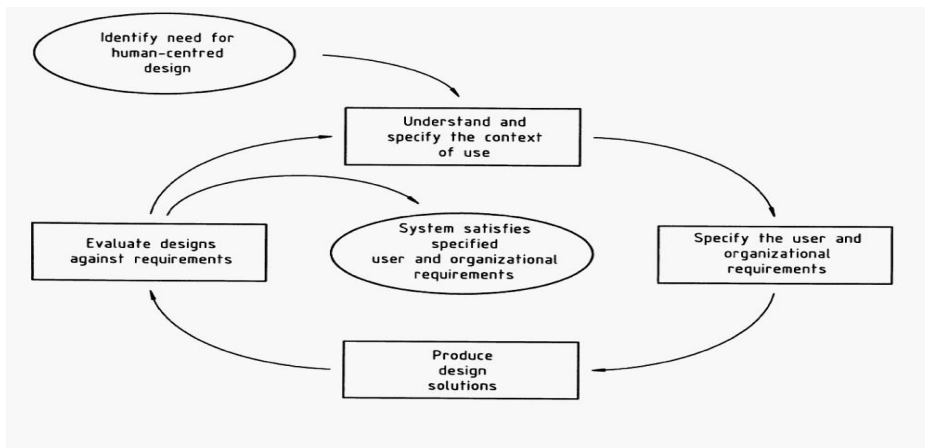
The administration system creates the username and password for the users to login. The system also extracts the relevant datasets of consented users from the Trusts EHR and populates the relevant fields within the web pages of the system. To anonymise the data sent, and to comply with the Information Governance, the fields are double encrypted and the data are hosted on a single secure named server. This process meets the expectations required for the Data Protection Act, 1998 and security standards for the NHS. To enable the data transfer, the software developers used the current infrastructure of the 'Renal Patient View' system. Adjustments were needed to the layout of this system to enable the hyperlinks created to be personalised to the patients' disease type. The login system, data security and server were exactly the same as those used by 'Renal Patient View'.

Allowing the data transfer for this project required the approval of the Caldicott Guardian, and of the local information governance committee at the pilot Trust.

2.1.9 Interface design

The interface was designed using the principles of human-centred design. (See figure 10) The key tenet of this process is ensuring the system meets the needs of users. The aim was to create a web interface that was clean, adaptable and efficient to navigate. Information was organised in a way to make the system intuitive to use and visually appealing. The colour scheme was chosen to comply with NHS guidance for websites. A number of iterations were made from the original prototype following feedback from selected patients, the software developers and HCPs directly involved with the project.

Figure 10. ISO standard for user-centred design processes for interactive systems



To demonstrate the PWP a 'dummy' username and password were created. The site can be viewed at the website address: www.myibdportal.com. To login as a Crohn's patient the username is **p** and password **crohns**. To view as an ulcerative colitis patient, the username is **q** and password **colitis**.

Below are the details of the content and functionality of the twelve sections designed. The tabs that were created are listed and described in more detail below:

Table 2. The sections designed for 'My IBD Portal'

1. Home Page	7. Nutrition
2. My Details	8. Diagnostics
3. My IBD	9. Results
4. Enter Symptoms	10. Letters
5. Medicines	11. Contact
6. Care Plan	12. Information

2.1.9.1 Home page

Registered patients used the home page to login to 'My IBD Portal' using their designated username and password. The page highlighted the background to the project and the most important information resources. Hyperlinks to a help page, the SRFT website and the charity were incorporated. To roll out the service in the future, the contents of this page could easily be adapted at minimal cost.

NHS Providing up-to-date medical information for patients and healthcare professionals

Username Password Login

Home

My IBD Portal

- Manage your condition and medications
- Monitor your symptoms and tests
- Make contact with your Unit

About My IBD Portal

My IBD Portal is a project sponsored by Crohns & Colitis UK and is being trialled at **Salford Royal NHS Foundation Trust**. The portal provides secure access to an online record of your condition. It provides access to blood tests, clinic letters and your current management plan. You can keep an up-to-date list of current and previous medications. We have provided reliable and trusted information links, so you can learn more about the condition, what it is like living with the illness and treatments. The portal also provides the opportunity to monitor and chart your symptoms.

To learn more about the project [click here](#).

About Crohns & Colitis UK

The charity Crohns and Colitis UK aims to improve life for everyone affected by Inflammatory Bowel Disease (IBD). It provides support and advice for all people diagnosed with IBD, their families and health professionals involved in managing the condition. It offers a comprehensive information service and an advice helpline, to talk with someone who has personal experience of living with IBD. The charity welcomes support from anyone who would like to help.

Further Information

- » **Outpatient Information**
Useful information about your visit to SRFT.
- » **Useful Information about SRFT**
This link provides a link to maps, contact numbers, parking and visiting times.
- » **NHS Choices- Ulcerative Colitis**
- » **NHS Choices- Crohn's Disease**
- » **Information Prescription Service**
- » **My IBD Portal Information Site**

2.1.9.2 My Details

'My details' provided patients access to their demographic information held on the Trusts EHR. The page included the patients' contact and GP details. The data was automatically uploaded from the EHR. Previous studies have shown over 30% of information held in EHRs is inaccurate. [116] Allowing patients to check and verify their data may improve communication and safety.

My Details

• My details contains basic information from your hospital records. Please check that your details are correct. If there are any errors please contact us by [clicking here](#).

• To complete a full summary - please enter any other health conditions and your email address in the box below. This is for your own personal record and does not become part of the hospital record.

• If your details are correct please click on the tabs above to navigate to areas of interest to you.

Patient Details for James Smith

Last Name	Smith
First Name	James
Date of Birth (dd-mm-yyyy)	06-09-1961
NHS Number	9876543210
Hospital Number	1111111
Address	2 John Street Wolston Manchester
Postcode	M40 4PB
Telephone	0161 9999 8888
Mobile	0777 123 456
Diagnosis	
GP name	Dr D Nobby
GP telephone	020 1111 1111
GP address	St Paul's Square Mappery Manchester M41 1OX
Other Conditions	<input type="text"/>
Email Address	<input type="text"/>

[Update](#)

2.1.9.3 My IBD

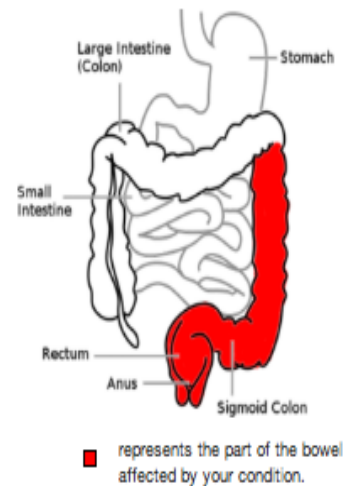
This page was designed to provide a clear summary of the patients' disease. The datasets were automatically transferred from an IBD-specific flowsheet set up in the hospital's EHR. These datasets were carefully chosen to enable a prospective database to be kept at the Trust and to be used as a flag to show a patient had consented to use the system. The information links provided were personalised as to whether the user has Crohn's disease or ulcerative colitis. The hyperlinks for each sub-section offered bite-sized resources, tailored to the specific topic area.

A graphical representation of their disease extent automatically uploaded to help with understanding. Their personal record of medications was also populated from this separate section in order to provide a full profile of their condition.

My IBD

- My IBD helps you keep a track of your inflammatory bowel disease. The information is provided from the records held at the hospital. If there are any obvious errors, please contact us by [clicking here](#).
- The hospital is not able to keep an accurate list of your IBD medications. To complete your own personal up-to-date record, please enter your current medicines by clicking on the [Add New Medicine](#) icon in the [Medicines](#) section.

Primary Diagnosis:	Ulcerative colitis ⓘ
Disease Extent:	Left Sided colitis ⓘ
Year of Diagnosis:	2005
Complications:	Osteopaenia ⓘ
Other parts of the body affected:	None ⓘ
Weight:	97.4
IBD Related Family History:	Family history of bowel cancer ⓘ
Surgical History:	None ⓘ
Smoking History:	Previous smoker ⓘ
Vaccination Record:	Previous history of chicken pox, Previous TB (BCG) vaccination
Year for Surveillance Colonoscopy:	2015 ⓘ
Nurses:	Cath Stansfield
Named Consultant:	Dr P Practice
Current Medications:	No current medicines



2.1.9.4 Enter Symptoms section

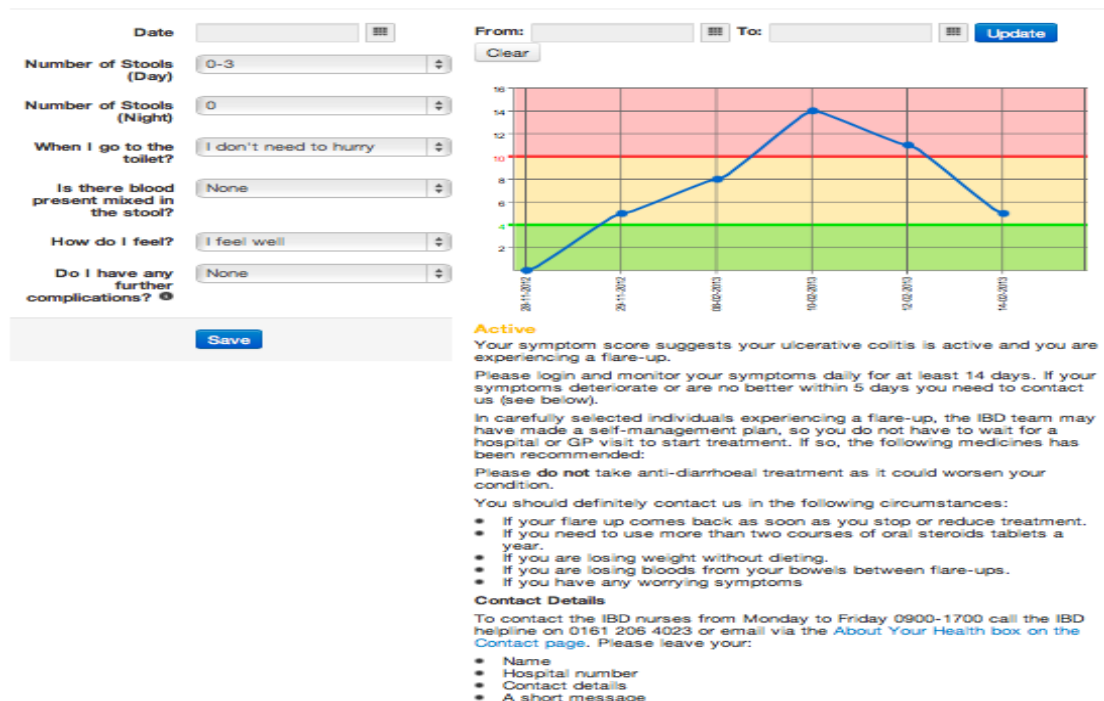
The unpredictable nature of flare-ups may be a significant barrier for patients to monitor their condition. Research on trend perceptions has shown it can be difficult for patients to recognise changes in disease control when information is presented in a partitioned manner. [145] If IBD patients view their symptoms as acute episodes rather than a natural part of the relapsing/remitting nature of the condition, this may prevent monitoring changes in their disease. Providing patients with the ability to keep a personal track of their symptoms over time, using graphical charts, may improve disease control.

In addition, an automated decisional-support system was designed. This function provided medical guidance dependent on their symptom score, enabling patients to learn and develop skills to self-manage more effectively. The trigger alerts provided information in a traffic light system, based on whether they had very active (severe), active (moderate) or inactive (remission) disease. A modified version of the Harvey Bradshaw Index was used for Crohn's

disease and the simplified clinical colitis activity index for UC. [131] The settings can be individually adjusted for each patient. (See appendix 1 for more details). Helpful information on how to manage flare-ups and useful tips to deal with these acute episodes were written specifically for this section. In providing these functions, the author aimed to enhance patients' ability to recognise flare-ups and periods of remission. This may also help patients adopt more problem-focused coping strategies that are perceived to be an adaptive mechanism for coping.

Colitis

- The symptom checker can be used to keep a personal record of your colitis symptoms over time.
- The scores generated from the questions are based on previous validated research studies.
- If you have 3 days of worsening symptoms from your bowels, record your symptoms every day on the chart for 2 weeks.
- Please note the symptom checker is not reviewed by healthcare professionals and is for your personal use only.
- Guidance generated by the chart is advice only. If you have any concerns about your condition, please do not hesitate to [Contact us by about your health](#) or via the IBD helpline on 0161 20 60423.
- For more information about flare-ups [click here](#).



2.1.9.5 Medicines

For the vast majority of IBD patients, medications are essential to prevent recurrence of disease and as chemoprophylaxis. These need to be taken regularly and in the correct manner to maximise their effectiveness. This is particularly true with topical therapies. Patients often do not know the role of their medications to manage flare-ups and maintain remission and medication adherence is a significant problem in IBD. [46]

For logistical reasons, particularly due to the lack of accurate data held within the Trusts EHR, and coupled with the fact that in primary care patients are often prescribed treatments

without informing the hospital team, a patient health record of medication use was chosen as the best mechanism to record these data. To develop this page a spreadsheet of the common drugs with dosage and frequencies was tabulated by the author. To enhance the efficiency of recording the drugs, automated drop down boxes were designed by the software developers.

Medicines

- This section is for your own personal use, to help you keep a track of your current and previous IBD medications.
- The hospital is not able to keep an accurate list of your IBD medications. In order to complete your own personal up-to-date record, please enter your current medicines by clicking on the icon.
- If for any reason you discontinue or complete a course of treatment, you can record this by clicking the icon.
- If you take a medication not present in the drop down boxes, you can enter the drug using the dropdown box labelled- Other to complete your medicines record.
- For more information about common medicines used click on the links below.

Links for IBD Medicines:

- [Introduction to drugs used in IBD](#)
- [Guide to using suppositories / enemas](#)
- [Aminosalicylates](#)
- [Steroids](#)
- [Immunomodulators](#)
- [Biologics / Anti- TNFs](#)
- [Other drugs used in IBD](#)
- [Research Trials in IBD](#)

Current Medicines

Date Started	Type	Medication	Dose	Frequency	Actions
01-12-2012	Aminosalicylates (Mesalazine / 5 ASAs)	Salofalk 3 G granules	3G	Once a day	<input type="button" value="Stop"/>

Stopped Medicines

Date Started	Date Stopped	Type	Medication	Dose	Frequency	Reason for stopping
03-01-2013	25-02-2013	Oral Steroids (Prednisolone / Budesonide)	Prednisolone	30mg reducing by 5mg per week	Once a day	Finished course

2.1.9.6 Care Plan

Personalised care plans are not a new concept but are more commonly performed in primary care to support the management of LTCs. The creation of a care plan is perceived to help engage patients and motivate changes in behaviour. [146] Health policy is currently advocating that every patient with a LTC should be offered a personalised care plan in primary care. [138] To develop a plan, a patient should discuss areas where they need further support, assess the impact that their condition is having on their life and think what they could do to be more confident in managing their illness. Realistic future goals are discussed, and an action plan to achieve these goals is clearly set out, with a review date. The aim is to provide a more holistic approach to care, improving overall health and well-

being. Systematically using this structure has been shown to better meet an individuals' full range of needs and improve patient satisfaction. [147]

During and after your appointment

My goals to improve my health

What goals would you like to change or improve about your health in the next year?

My goals for changing/improving my IBD are:

Stop smoking
Do more exercise
Take my medicine regularly

Think about these goals, what one goal would you like to achieve?

Take my medicines more regularly

How important is achieving this goal to you?

Important

Action plan

In this section a specific plan on how to achieve the goal will be made.

What am I going to do to achieve this goal?

(How, what, when, where, how often)

Set an alarm on my phone to remind me

What are the barriers that could get in the way?

I am too busy

What can I do about this?

Relax

How confident do I feel?

Confident

Date set to review my Care Plan

04-01-2013

Save

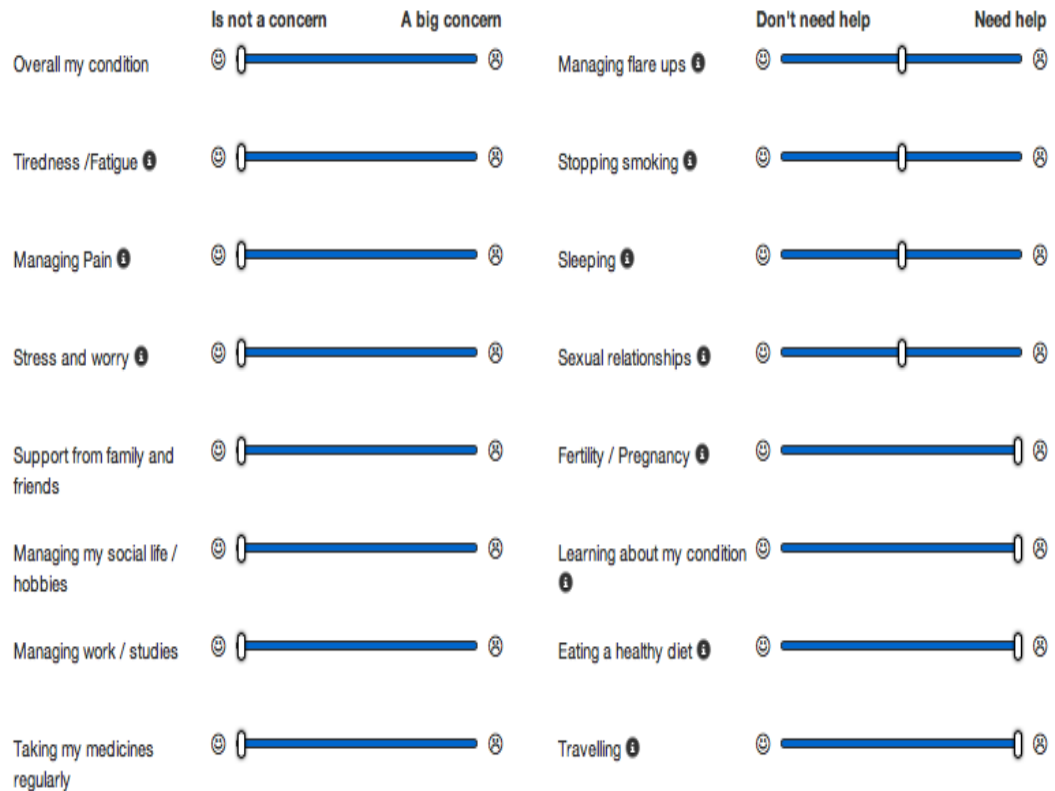
Personal Care Plans are not currently used routinely in the management of IBD in the UK. To facilitate this process of creating a plan, an online patient reported outcome measure (PROM) was adapted from a paper version and tailored to meet the requirements of IBD. [148] The tracker aimed to help patients highlight areas of concern or where they felt they needed more help, outside of questions asked routinely in clinic. The aim was to prompt discussion and encourage participation in consultations. This review is best performed prior to clinic appointments to encourage reflection. The information can then be used to provide

support and generate discussion to formulate goals and the action plan previously described.

Care Plan

Before your appointment

- Whether you are newly diagnosed or have been living with IBD for a number of years, the challenges of managing a chronic condition can change quickly.
- Use this section to help think about how well you are currently managing your condition and to highlight areas where you need more support.
- My IBD Tracker© shows the common topics that can cause difficulties in living with IBD. Move the tracker to show how much each area is a concern and where you may need more help at your next appointment. For further resources click on the ⓘ links.



Use the box below to add further topic areas that you would like to explore.

- If you would like, you could create a personal care plan. To learn more about care plans and for further tips on getting more from your appointments [click here](#).

2.1.9.7 Nutrition

This section contained an electronic food diary and reliable information resources about diet.

Nutrition and diet has repeatedly been shown to be a significant concern for patients.[149]

Nutrition Discover up-to date information about food and IBD

- When you have IBD it is important to have a well-balanced, healthy diet. Although there is no research to date suggesting diet causes IBD, some people have found that certain foods can play a role in worsening their symptoms.
- Below is a list of helpful resources about food and IBD, as well as a food diary. You can use this to keep a note of certain foods that you feel may be making your symptoms worse.
- Please click on the information links to learn more:
 - [Food and IBD- Crohn's and Colitis, UK](#)
 - [Diet and Nutrition- Crohn's and Colitis Foundation of America](#)
 - [Healthy Eating](#)
 - [Malnutrition](#)
 - [BMI Calculator](#)

Food diary

- This section is for you to keep a record of any foods that you think may upset your condition.
- Make a list of the foods that you have eaten and what symptoms it may have caused (e.g. abdominal pain or diarrhoea).
- Stop eating this particular food for a few weeks and then try it again.

Date	Foods that disagree with me	Enter a comment on the food
02/01/13	Onions	Caused bloating

2.1.9.8 Diagnostics

This page listed all the dates of patients' imaging and endoscopy procedures. As highlighted earlier in the chapter, there are significant differences of opinions towards the provision of these data. If at a future date full reports were felt to be beneficial, these data could be transferred for patients to view with little difficulty.

Diagnostics

- The Diagnostics section lists your previous imaging and endoscopy tests direct from the hospital record.
- Please note only the date and type of test is recorded. The full report is not available.
- If you have any further questions about your tests please contact us by [clicking here](#).
- To learn more about the investigations used commonly in IBD click on the following links:

Links about Diagnostics

- [Endoscopy \(Colonoscopy / Sigmoidoscopy/ Gastroscopy\)](#)
- [X-Rays- Plain and Barium tests](#)
- [CT scans and MRI scans](#)

Imaging

Exam Date	Exam
27/01/12	Xray Chest
18/04/12	MRI Small Bowel Study

Endoscopy

Procedure Date	Procedure
29/06/12	Endoscopy Examination

2.1.9.9 Results

This page was automatically populated from the EHR. Relevant test results for IBD patients were uploaded. To help patients interpret the results, hyperlinks were designed to describe each of the tests, their relevance to inflammatory bowel disease and their normal ranges. Most of this educational material was needed to be produced and was verified by the clinical team at the Trust. Further links were made available to Labtests online, a non-profit information site developed collaboratively from the professional laboratory societies. This site provides accredited resources specifically designed for patients.

Results

- This section helps you monitor your latest blood and stool tests, direct from the hospital system.
- Most routine test results are updated within 48 hours from when the sample was taken.
- Certain results take longer to be processed and may not register for over 2 weeks.
- To learn more about what the results mean, click on the links.

Links about blood tests

- [What are the common tests performed in IBD](#)
- [Labtests Online](#)

Note- You may see test results before the IBD team have had chance to review them. If you have any concerns about the tests, [please contact us here](#) or via the IBD helpline on 0161 20 6423.

Result panels

First	Prev	1	2	Next	Last
-------	------	---	---	------	------

Test results for Q Q												
Date and time	Label	Hb	WBC	Platelets	CRP	Albumin	Bilirubin	ALT	ALP	faecal calprotectin	Weight (KG)	Source
20/03/12 14:00		8.60	6.00	113								A
20/03/12 13:55											94.2	A
17/03/12 14:55											95.6	A
15/03/12 15:20											93.2	A
13/03/12		8.90	4.10	115		40	4	10	47			A
08/03/12 14:00		9.30	4.50	118	6	38	4	7	45			A
06/03/12 14:00		8.90	4.20	114								A
03/03/12 13:55											92	A
28/02/12 13:55											94.7	A
28/02/12		9.80	9.00	111	25							A
23/02/12 14:00											92.4	A

2.1.9.10 Letters

This page linked to the clinic letters that were automatically uploaded from the EHR and presented in a format similar to the original layout created. Only letters specifically related to IBD were included. The letters included gastroenterology, dietetics and gastrointestinal surgery.

Letters

- Letters are only shown where they can be retrieved from your unit's computer system.
- It is important to note that letters may be shown here before they have been finally approved and had mistakes corrected. This mainly applies if you are reading letters soon (e.g. within a week) after they have been typed.
- If you have any concerns you should discuss it at your next clinic appointment, or contact the author of the letter.

Links about Letters

- [Glossary of terms used in IBD](#)

Letters for Q Q

Date	Letter Type	
24/01/12 11:24	Sample Letter	read letter...
18/01/12 10:38	Another Letter	read letter...

2.1.9.11 Contact

To encourage self-management and optimise care, patients need to be able to contact their health team and receive feedback between appointments. This helps create a partnership and improves future decision-making. To facilitate communication the contact page was designed to enable users to contact the IBD unit with ease. This function was provided through a secure email messaging service to the IBD team. Two separate contacts were created. 'My IBD Health' for direct health concerns and 'My IBD Portal' for administrative issues. When a user sent a message, the system automatically attached their name and NHS number and asked for a preferred contact email or telephone number.

Contact Details

Questions about your health

- If you have any questions about your condition you can contact us by email below. Alternatively you can leave a message through the IBD helpline on 0161 20 64023.
- We aim to review and respond to messages by the end of the next working day. In case of emergencies and you haven't received a response, please contact your GP or attend your local A & E department in cases of emergency.
- **Note:** Your name and NHS number will be sent with this message.
- Please enter your message here with your preferred contact email or phone number.

Message

Preferred contact email or phone number

Questions about your details, the site, feedback, any other questions

- For Frequently Asked Questions please visit the Help section. For any queries about login problems, incorrect details on the site, content issues, results not appearing or being wrong, or any concerns or feedback, email us here.
- **Note:** Your name and NHS number will be sent with this message.
- Please enter your message here with your preferred contact email or phone number.

Message

Preferred contact email or phone number

2.1.9.12 Information

As the delivery of medical care continues to move away from paternalistic care towards a more patient-centred service, it is clear information from the Internet will affect management and practice. [149] The Internet has the ability to present information promptly and in a variety of formats and sizes. Most website information available to patients' can be characterised as variable in quality or inaccurate and can provide little interactivity. [96] There is also variation in the reading ability required to understand the information. This factor needs to be considered given the low literacy levels in a subset of the population.

These difficulties may be abetted by providing patients with accessible and verified health information, produced to set quality standards. Furthermore, tailoring this information to each individual, in a manner that is more easily understood, could improve education. [71] With these objectives in mind, the My IBD system was designed to maximize opportunities for patients to source accurate information.

To achieve this aim, accredited resources were collated. Permission to use the charity's (CCUK) educational material was granted and the educational booklets converted to web (html) format. To enable bite-sized parts of the material to be available, hyperlinks to each section were produced in a cloud-based content management system. These resources were published on a new website. www.myibdportal.org

After reviewing the CCUK booklets, gaps were found in the provision of information. Further accredited websites were assessed and linked to the relevant sections of the system providing a detailed, reliable and personalised resource. Despite the large amount of information on the Internet, further material was needed to be written and verified by the clinical team. This included information on managing flare-ups and interpretation of results. To enable the resources to be updated easily, the administration system was set up to provide links to any publically available website.

Selected pages from the following websites are currently linked to the system:

- Crohn's and Colitis, UK (www.nacc.org.uk)
- Crohn's and Colitis Foundation of America (www.cdfa.org)
- NHS Choices (www.nhs.uk)
- myibdportal.org (www.myibdportal.org)
- Salford Royal Foundation NHS Trust (www.srft.nhs.uk)
- Latest clinical trials in the field (www.clinicaltrials.gov)

Information

Having reliable and accurate information helps provide a platform to take control of your illness and improve your quality of life. Below is a list of helpful websites for trusted information.

Links for IBD

- My IBD Portal Information
- Crohn's and Colitis, UK
- Crohn's and Colitis Foundation of America
- Life and IBD, European Federation of Crohn's and Ulcerative Colitis Federation Associations (EFCCA)
- NHS Choices - Crohn's Disease
- IBD and Me is for young people aged 16 - 29 living with IBD
- Clinical Trials for Crohn's Disease
- NHS Choices - Ulcerative Colitis
- Clinical Trials for Ulcerative Colitis

www.myibdportal.org

This site provided the majority of the tailored information links and was published using a cloud content management system (Heroku). This enabled the material to be updated without difficulty.

Crohn's Disease

This article has been adapted with permission from an information booklet produced by Crohn's and Colitis, UK

Introduction

If you have recently been diagnosed with Crohn's Disease or even if you have had Crohn's for some time, you may have many questions about the condition. Knowing more about your condition can help you to lead a full and active life and to take an active part in decisions about your treatment. We hope this booklet will give you more understanding about Crohn's and how it is treated.

What is Crohn's Disease?

Crohn's Disease is a condition that causes inflammation of the digestive system, also known as the gastrointestinal tract or gut. Inflammation is the body's reaction to injury or irritation and can cause redness, swelling and pain. Crohn's Disease was first described by a Scottish surgeon, Dalziel, in 1913. However, it gets its name from a New York doctor, Burrill Crohn. He and two colleagues reported a number of cases in 1932, when it became more widely known. Crohn's Disease is also known as Inflammatory Bowel Disease (IBD). IBD is the name of a group of illnesses, of which Crohn's and a similar condition, called Ulcerative Colitis, are the two main ones.

Crohn's is sometimes described as a chronic condition. This means that it is ongoing and usually lifelong, but there may be long periods of good health, alternating with times when symptoms are more active. At present there is no cure for the illness, but drugs and sometimes surgery can give you long periods of relief from symptoms. Crohn's is not infectious.

What causes Crohn's disease?

Although there has been much research, the cause of Crohn's Disease is not yet known. However, over the past few years major advances have been made, particularly in genetics. Researchers now believe that Crohn's is caused by a complex interaction of factors: the genes a person has inherited and an abnormal reaction of the immune system (the body's protection system) to certain bacteria in the intestines, triggered by something in the environment. Viruses, bacteria, diet, smoking and stress have all been suggested as environmental triggers, but there is no definite evidence that any one of these is the cause of Crohn's. However, research shows that stopping smoking reduces the severity of Crohn's, particularly after surgery.

Researchers are beginning to understand how differences in a person's genetic makeup might lead to a tendency to develop Crohn's and why certain parts of the intestine or body are affected in some but not others. This would mean that treatment could be appropriately targeted from the beginning and eventually it may be possible to predict the risk of complications, the response to medication and the need for future surgery.

How common is Crohn's Disease?

Crohn's Disease affects about one in every 1,000 people in the UK. For reasons that are not yet fully understood, it is more common in urban rather than rural areas and in northern developed countries, though the numbers are beginning to increase in developing nations. The condition is also more common in white people of European descent, especially those descended from Ashkenazi Jews (those who lived in Eastern Europe and Russia).

Recent surveys in the UK and elsewhere suggest that new cases of Crohn's are being diagnosed more often, particularly among teenagers and children. The reason for this is not clear. There are more girls than boys among young children with Crohn's, but over the past decade more men than women have developed Crohn's. The disease is more common among smokers than non-smokers. Crohn's can start at any age, but usually appears for the first time between the ages of 10 and 40.

Which part of the gut does Crohn's affect?

You will see from the diagram, that the gut is like a long tube that starts at the mouth and ends at the anus. Crohn's can affect any part of the gut, though the most common part is the end of the ileum, known as the small intestine or small bowel, and/or the colon, known as the large intestine or large bowel.

The areas of inflammation are often patchy with sections of normal gut in between. A patch of inflammation may be small, only a few centimetres, or extend quite a distance along part of the gut. As well as affecting the lining of the bowel, Crohn's may also go deeper into the bowel wall.

What happens in the gut?

The gut breaks down the food we eat so that our body can absorb its nutrients to give us good health and energy. The first stage of breaking down food is chewing. As food is swallowed it goes down the oesophagus into the stomach, where digestive juices break it down further over two-four hours.

The stomach then empties the food into the small intestine, which has three parts – the duodenum, jejunum and ileum. Here the food is split into tiny parts (proteins and sugars) and nutrients are absorbed through the intestinal walls into the blood stream to reach all parts of the body. The waste products from this process, which include liquid and undigested parts of food, are then pushed into the colon.

Finally, the colon absorbs the liquid and the leftover waste becomes solid faeces (stools), which pass out of the body in a bowel movement through the anus (back passage).

How does Crohn's affect the gut?

Inflammation in the gut affects your body's ability to digest food, absorb nutrients and eliminate waste in a healthy way. As a result you may have varying symptoms, which may depend on where in your gut you have Crohn's.

What are the symptoms?

Symptoms may range from mild to severe and vary from person to person and may change over time. Because Crohn's is an ongoing condition, you may have times of good health, called remission, when there are few or no symptoms, alternating with times when your symptoms are more active, called relapses or flare-ups. It is a very individual condition with some people remaining well for a long time, even for many years, while others have frequent flare-ups. The most common symptoms during a flare-up are abdominal pain and diarrhoea. Sometimes mucus, pus or blood is mixed with diarrhoea. People with active Crohn's often feel extremely tired and lethargic. This can be due to the illness itself, as well as a number of other things such as a lack of sleep because of pain and getting up at night with diarrhoea. Some people have a fever. You may feel generally unwell and lose your appetite, so you may lose weight. Weight loss can also be due to the body not absorbing nutrients from the food you eat because of inflammation in the gut. Mouth ulcers are also common and may be treated with an antibiotic mouthwash or a steroid spray. You may have anaemia (a reduced number of red blood cells) if you lose a lot of blood, are not eating much, or your body is not absorbing nutrients. Anaemia can also make you feel very tired.



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- What are the main types of Crohn's?
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- How does Crohn's affect other parts of the body?
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- Do I need to change my diet?
- What about pregnancy and Crohn's?
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- Can Crohn's lead to cancer?
- What about complementary and alternative approaches?
- How will Crohn's affect my life?

2.1.10 Summary

From the original concept to full implementation, a significant number of stages of development and testing were required. Numerous stakeholders were involved, each providing their own set of skills to support the process. To reach the stage of a 'live' fully functioning system required careful coordination and planning, particularly with the limited funds available. Despite best efforts to keep to schedule, the timeframe was in hindsight too short. After the research team were confident that a fully working system was in place, methods to evaluate its impact at implementation were considered. The next chapter describes the pilot approach used.

2.2 Methods used to assess the impact of ‘My IBD Portal’

2.2.1 Background to evaluation

E-health interventions are complex in nature, with several interacting components and have the potential to affect a number of outcome parameters. Their evaluations are often performed in randomised controlled trials. However these ‘gold standard’ studies are often not suitable for identifying what works in ‘real-life’ practice and in measuring the impact of organisational innovations that influence sustainability and effectiveness. In an attempt to capture these data many authors express the need for a mixed–methods approach to evaluate the impact of new technologies. [150, 151]

Other researchers with an interest in e-health have proposed using the Medical Research Council (MRC) framework for designing, evaluating and implementing complex interventions as a guide to developing applications.[152] First published in 2000 and revised in 2008, the framework suggests a phased approach, with the early stages of the work dedicated to analysing the literature and underpinning theories. Following this stage, qualitative methods can be used to determine acceptability and feasibility of the proposed intervention. This phase aims to improve both the intervention and study parameters. These stages of assessment occur in tandem with development of the platform until the intervention has been optimised and its mechanism of action ideally defined. Only then should a Phase 3 randomised controlled trial be performed to establish effectiveness. [27]

At present, there are no UK studies in the literature that have evaluated a web-based IBD e-health application. As shown by the literature review, there is considerable potential for the system to impact a number of parameters. These include patient experience, healthcare outcomes and health resource utilisation. Further contextual data on usage and factors influencing engagement will enhance understanding of the proposed intervention.

Therefore at the current phase of development, a proof of concept study was needed. The aim of this study was to not only to assess the impact of the proposed intervention but also test the methods used, the validity of the outcome parameters and estimate rates of

recruitment. If the pilot study results were promising, the data would help inform a future more definitive and larger scale study.

A number of possible experimental designs were considered for this proof of concept study after full implementation of the system in October 2012. The primary choice was between a randomised controlled trial (RCT) or a prospective observational pre-post designed study.

Advantages of a pre-post design study were that a greater number of potential participants could be recruited. Data would be collected prospectively and comparisons made between the baseline and exit questionnaire results. The primary outcome of patient experience would be from a greater sample size without the need to recruit controls. This design method allows collection of the necessary data to meet the objectives of evaluating the patient experience, moderating factors and potential for future development. The recruited population would also be suitable for the qualitative data to be collected at the end of the study.

A major disadvantage of the observational design method is the absence of a control group. This limits the interpretation of the causal effect of the system on the postulated outcome measures. Changes observed during the study period can be attributed to the intervention but there is no way of knowing whether these changes would have happened anyway.

To minimise temporal factors and increase the validity of the findings would require a RCT. Randomisation of participants would minimise the potential for confounding factors and potential recruitment bias. However, using this experimental method would halve the number of recruits. At this early stage of development the primary aim of the proof of concept study was to maximise the evaluation process and to gain insight into future development. Furthermore, the constraints of time and funding needed to be factored into the methods and due to the complexity of construction and implementation, developing a 'live' system took longer than anticipated.

After significant consideration, an observational study design was decided as the best method of evaluating the impact of the platform at this stage of development. An application to approve the study protocol was made to the National Research Ethics Service. Ethical approval for the study procedures was granted in February 2013 and final authorisation to commence the NIHR portfolio study was received on the 10th April 2013. The study started enrolment on the 10th May 2013. Below is a detailed description of the study protocol.

2.2.2 An observational pre-post designed study to assess the impact of 'My IBD Portal'.

The study used a mixed-methods approach to assess the impact of the intervention over a 6-month period. This was consistent with previous methodological approaches to evaluate such technologies.[118] The quantitative aspect of the study provided data on usage, patient satisfaction and perceived usability. The potential impact of the intervention on a number of postulated healthcare outcomes were also measured. These data was augmented with qualitative data. The aim of this approach was to enable an increased and enriched understanding of the patient experience in using the intervention.

2.2.2.1 Objectives

The primary objective of the study was to evaluate the impact of 'My IBD Portal' on:

A: Patient Experience- To assess usage, usability and patient satisfaction

The secondary objectives were to explore:

B: Predictors of use- To investigate factors that moderated engagement

C: Healthcare outcomes- To examine the interventions associated effect on disease-related knowledge, patient engagement, medication adherence and health resource use

The following section describes these objectives in greater detail.

Objective A: Patient experience

Usage

To evaluate usage, data from the administration system and Google web analytics were extracted at completion of the study. The number of logins, pages viewed and sections visited were analysed. Usage data on the information links were also obtained to help identify the information needs of participants.

Usability

An assessment of the perceived ease of use and usefulness of the system were measured using the validated Systems Usability Scale. [154]

Satisfaction

The end of study questionnaire examined participants acceptability of the intervention. Both quantitative and qualitative data were collected at the end of the trial period.

Objective B: Predictors of use

The level of engagement with the system was expected to be variable. This objective aimed to identify factors associated with use. Demographic, disease and IT-related characteristics of the participants were collected. Disease activity was measured using the surrogate marker of the need for an increase in either medical or surgical therapy. Perceived confidence in using the Internet, information needs and illness beliefs were identified as potential moderating factors influencing engagement. After completion of the study, barriers and facilitators were further explored using qualitative methods, to gain a deeper understanding of the factors predicting use.

Objective C: Effect on health outcomes

The intervention, by offering patients' electronic access to their IBD record, reliable health information, disease-monitoring tools with decision support and a personalised care plan, aimed to support patients to be more active participants in their care. The author postulated that use would have the potential to improve disease knowledge, patient engagement and medication adherence. These outcomes were measured using the IBD-knowledge score (CCKNOW), the Patient Activation Measure scale (PAM-13), the Long-Term-6 questionnaire (LTC-6) and the Morisky Medication Adherence Scale (MMAS-8). These data were collected at baseline and follow-up after 6-months. [153] The author postulated use of the system would potentially increase users understanding, confidence and skills to self-manage, leading to an increase in disease knowledge, patient engagement and medication adherence scores.

2.2.2 Hypotheses

The study aimed to address the following hypotheses:

2.2.2.1 A: Primary hypothesis:

The web-based system:

1. Is an acceptable method of information delivery and perceived to be easy to use.

2.2.2.2 B: Predictors of use

Use of the intervention will be potentially predicted by a number of factors. These can be categorised into:

- Patient Characteristics- Age, gender, education, engagement (PAM-13)
- Disease-related Characteristics- Disease type, activity, duration, medication adherence (MMAS-8) and knowledge (CCKNOW)
- IT-related Characteristics- Internet use, number of devices used for access and perceived confidence
- Illness beliefs- Measured using the Brief Illness Perceptions Questionnaire (BIPQ-9)

2.2.2.3 C: Secondary hypotheses

Use of the web-based system:

1. Improves disease-related knowledge measured using the Crohn's and Colitis Knowledge score (CCKNOW).
2. Enhances patient engagement, measured as an increase in the Patient Activation Measure (PAM-13) and perceived support questionnaire (LTC-6)
3. Improves self-reported medication adherence measured using the Morisky-8 scale (MMAS-8).
4. Healthcare utilisation (including visits to hospital, in-patient spells) will not be increased.

2.2.3 Inclusion/Exclusion criteria

The study was designed to allow the maximum number of patients receiving outpatient IBD follow-up care at the pilot NHS Trust to participate. The basic requirements for inclusion were:

2.2.3.1 Inclusion criteria

- A diagnosis of IBD based on clinical history, endoscopic and histological findings
- Any patient older than 16 years old
- Willing and able to give informed consent

2.2.3.2 Exclusion criteria

- Patients unable to give informed consent
- Other significant clinical factors that would significantly interfere with participation in the study. Examples included concurrent illness sufficient to prevent study participation. This was based on senior IBD physicians clinical judgment.

A screening log was kept detailing anonymised information about those approached to take part in the study, including age, gender and wherever possible a reason for non-inclusion.

2.2.4 Recruitment

The study took place at the Salford Royal Foundation Trust, a large tertiary centre acute NHS Trust, managing over 2000 patients with IBD. Sixty new patients are diagnosed each year with 160 inpatient-recorded episodes with IBD per annum. There are 7 dedicated IBD clinics per week. Information about the study was submitted and included on the Salford Citizen Scientist website which provides a sign-posting service for studies. (Please see <http://www.citizenscientist.org.uk/>)

2.2.5 Enrolment procedure

Potential recruits meeting the inclusion criteria received an invitation letter (Appendix 3) and information sheet (Appendix 4) describing the study in a 2-week period preceding a scheduled IBD outpatient appointment. This information informed them of the nature and purpose of the study, its requirements, possible hazards, and their rights to withdraw at any time, without prejudice and without jeopardy to any future medical care at the NHS pilot Trust.

If they wished to seek further information prior to their clinic attendance, a contact telephone number and email address of the author was given. Participants interested in enrolling were asked to attend clinic 30 minutes earlier than scheduled, to ask any possible questions and complete the consent process. Each participant gave informed written consent to the investigator or a qualified research nurse for participation. They were asked to sign three consent forms, one for the research folder, one for the hospital record and the other for himself/herself. Signed consent forms remained in the study file and are available for verification by monitors at any time. The author was named the chief investigator and either he or a qualified research nurse undertook the consent process.

After consent, participants were asked to complete the baseline questionnaire (Appendix 5). They were then given secure access and a brief demonstration of the system. An information sheet of the functions of 'My IBD Portal' was also provided (Appendix 6). A check was made of patients' disease history and severity, ensuring the information recorded

was accurate. Participants were asked to use one of the designed interactive features at least once during the 6-month trial period. If any further help was needed, access to the research team was provided through a secure email and a contact telephone number. Follow-up questionnaires were asked to be completed at 6-months. (Appendix 7)

2.2.6 Baseline and follow-up assessments

All recruited participants were asked to complete the following assessments. The questionnaires collected the following data.

2.2.6.1 Baseline questionnaire (see appendix 5)

Participant and clinical characteristics

Demographic data included age, gender, education, medications, smoking status, disease type, severity and duration. Further data on participants use of the Internet, information needs, confidence in using the Internet and perceived knowledge were measured using a self-reported 1-10 response scale.

Predictors of use

A number of factors were identified as potentially influencing use of the system. The identified *a priori* predictors were recorded from the medical records or collected through the baseline questionnaire. Information needs and confidence were assessed using a 1-10 response scale. Illness beliefs were measured using the Brief Illness Perceptions Questionnaire. (BIPQ-9) [154] This validated questionnaire measures both the cognitive and emotional representations of illness.

Healthcare outcomes

Knowledge

Knowledge was assessed using the Crohn's and colitis knowledge score (CCKNOW). This validated 24-item questionnaire measures patient disease-related knowledge across four specific domains. Areas include general understanding of disease, diet, treatment and

complications. [155] The index has been used in a number of studies and has been reported as having high internal consistency and reliability.

Patient Activation Measure (PAM-13)

The patient activation measure is designed to elicit responses from a person about their attitudes towards knowledge, skills and confidence in self-managing their health. [156] The scale is based on the Guttman technique with items ordered by their level of difficulty. A 4-point Likert scale is used to measure the levels of agreement with 13 statements. Responses result in a raw score from 13-52. This is converted to a linear scale of activation scores from 0 (lowest activation) to 100 (highest activation). The scale has been validated in a number of health populations and has been shown to be a predictor of health processes, outcomes and future resource use [4]

The Long-term conditions 6-questionnaire (LTC-6)

The LTC-6 is a 6-item questionnaire designed by the NHS quality, innovation, improvement and production programme (QIPP). Each question is drawn from previous validated questionnaires. [157] The questionnaire measures understanding and experiences of care received. The scale indicates knowledge, beliefs and perceptions of care that are necessary to sustain change over time.

Medication adherence

Medication adherence was measured using the Morisky Medication Adherence scale (MMAS-8). [158] This 8-item self-reported scale has been used to measure adherence in a number of different health populations. It is simple and practical to use and a recent study has validated the scale in an IBD-specific population setting.[159]

2.2.6.2 End of study questionnaire (see appendix 7)

Patient experience

To assess patient experience of the platform, separate questionnaires were developed for users and non-users. This method allowed more detailed information to be collected from these sub-set populations.

A mixed-methods approach assessing the impact of the service was thought to provide a more comprehensive evaluation. The purpose of the qualitative aspect of the research was to explore in greater depth individuals' experience of the system and to gain a greater understanding of the utility of the newly designed components. Originally, semi-structured interviews were planned to be undertaken from a purposive sample. However due to time constraints this process was not feasible. To enable qualitative data to be collected, a pragmatic approach was adopted by adapting the exit questionnaire. Open-ended comments were devised, covering the major topics previously identified for this aspect of work. Thematic analysis was used to analyse these qualitative data. Responses were collected, reviewed and coded to analyse patterns.

Users

To assess satisfaction amongst users a 12- item questionnaire was developed. Questions were a mix of open-ended and closed items. Topics included overall satisfaction, clarity of content, use prior to appointments, perceived support, concerns, perceived help with decision-making, usefulness of features and predicted future use and developments. (See appendix 7a)

Non-Users

To identify potential factors inhibiting use, a 4-item questionnaire was developed for non-users. Open-ended questions on the reasons for non-use were elicited, as well as overall satisfaction, perceived support and predicted future use. (See appendix 7b)

Usability- System usability scale (SUS)

The SUS was used to assess usability. This 10-item Likert questionnaire was originally developed to test the usability of generic IT systems.[160] The scale has been used across a number of different industries, including the evaluation of healthcare technologies. Numerous studies have shown it to be reliable and a valid measurement of perceived usability of IT-based applications. [161] The questionnaire provides a measure of perceived ease of use and is converted to a scale from 0-100. The mean average score of IT systems is 68 and the score of the intervention can be measured against other systems by a process of normalisation. Using this scale meant the system could be compared to other developed web-based health interventions in the future and to quantify the effect of future improvements.

Repeat validated scales from the baseline questionnaire

The following measures described previously were repeated after completion of the 6-month study period. Participant characteristics, PAM-13, LTC-6, CCKNOW, illness BIPQ-9 and the MMAS-8.

Health resource utilisation

To capture accurate data about health resource use, a combination of self-reported data from the follow-up questionnaire and a review of the hospital medical records were examined. If data conflicted between these sources, data from the hospital records was used. Details included:

- The number of IBD and IBD-related outpatient visits over the course of the study and preceding 6-months.
- Records of medical treatment and investigations during the study
- Records for surgery for IBD and length of stay as an inpatient
- Details of drugs prescribed
- Time off work or education

2.2.7 Statistical analysis

To describe results, means and standard deviations were provided for normally distributed continuous variables; median and ranges for skewed continuous variables; number and percentages for discrete and categorical variables.

2.2.7.1 Objective A: Patient experience

Descriptive analyses on the following outcomes were conducted: The number of logins during the study period; total time spent using the intervention; pages visited and usability. The quantitative and qualitative data from the exit questionnaires were triangulated to describe the acceptability, feasibility and impact of the intervention.

2.2.7.2 Objective B: Predictors of use

To examine possible associations predicting use, logistic regression analysis was performed. For the response variable, users were defined as participants that had logged on at least twice after the day of registration. Non-users were those participants that had never visited the site or logged on only once during the study period following registration. The predictive variables included demographics, disease-related, IT-related and outcome-related variables (knowledge, engagement and adherence) recorded at baseline. All predictors were entered at once into the regression model.

2.2.7.3 Objective C: Healthcare outcomes

Change in health outcomes: Initially, univariate analyses were used to compare knowledge scores (CCKNOW), activation scores (PAM-13), perceived support (LTC-6 questionnaire) and adherence scores (MMAS-8) at baseline and 6-months. Multiple linear regression analyses were then conducted to explore the changes in knowledge scores (CCKNOW), activation scores (PAM-13), perceived support (LTC-6 questionnaire) and adherence (MMAS-8) scores whilst controlling for co-variable factors. To model the effect of use of the intervention on the healthcare outcomes, the post-outcome measure was used as the response variable and the pre-outcome measure, usage, disease activity, age, gender and disease duration as predictor variables.

2.2.7.4 Sample size

It was planned to recruit up to unselected 150 patients for this study. This convenience sample size was based on what the team believed to be feasible in the time available for the study and previously reported attrition rates.

2.2.8 Ethics

The study was conducted in accordance with the relevant regulations and guidance including the research governance framework for Health and Social Care (version 2). The study was submitted for approval to the National Research Ethics Service (NRES Ethics Approval:13/LO/0454) and to the relevant Research and Development Departments to gain NHS approval and adoption to the NIHR portfolio prior to study commencement (Study ID: 122852).

2.2.9 Quality assurance, data handling, publication policy and finance

The Research and Development department at the pilot Trust took responsibility for overseeing the study in accordance with local policies on sponsorship.

The information and data gathered during the study were managed and kept in accordance with the data protection act and the NHS code of confidentiality. After completion, the study data and records were archived with the Sponsor and will be retained for 5 years.

3.0 Results

3.1 Recruitment

Recruitment of participants started at Salford Royal NHS Foundation Trust on the 10th May 2013 and was completed by the 12th August 2013. Potential participants were identified by reviewing the Electronic Health Record of patients due to attend the gastroenterology clinic within two weeks. Patients identified as fulfilling the inclusion criteria were posted an invitation letter (Appendix 3) and patient information sheet (Appendix 4). In total 336 patients were identified as potential study participants during the recruitment period.

A variety of factors limited recruitment within this population. Table 3 below details the recruitment process from the sample population. Many potential participants were unable to be seen during their attendance, due to time pressures in the clinic. Scheduled appointments were occasionally changed during the two-week period and a small number of patients failed to attend. Of those able to be seen, 45 had no Internet access (13.4%) and 18 were not interested in participating (5.3%). Two patients were excluded, one due to a wrong diagnosis and the other due to mental health reasons. A small number of patients expressed an interest in participating but lacked the time to complete the full registration process at the time of their appointment. To support their participation, a decision was taken to allow these patients to post the entrance questionnaire at their earliest convenience. 5 patients failed to return the baseline questionnaire and were not included in the final analysis.

Taken as a whole, this meant approximately 75% of patients approached were able and interested in participating in the project.

The original target for recruitment was for up to 150 patients. Recruitment proceeded more quickly than anticipated, averaging over 13 patients per week. It was therefore agreed with the study sponsor to continue recruitment beyond this target until the time window passed, the objective to improve the quantity of data and validity of the study findings.

Table 3. Recruitment from the sample population

Eligible for Study	Number	Total Number	Proportion of potential recruits remaining (%)
Invitations letters sent out	336	336	100
Did not see in clinic	57	279	83.0
Re-scheduled / did not attend	26	253	75.2
No Internet access	45	208	61.9
Not interested / would not use	18	190	56.5
Excluded	2	188	55.9
Recruited for study	188	188	55.9
Baseline questionnaire not returned	5	183	54.5

3.2 Demographic characteristics of participants

The following section describes the demographic characteristics of the recruited participants.

The mean age was 40.6 years and median 37 years. Figure 11 shows the age ranges after categorisation.

Figure 11. Age of participants

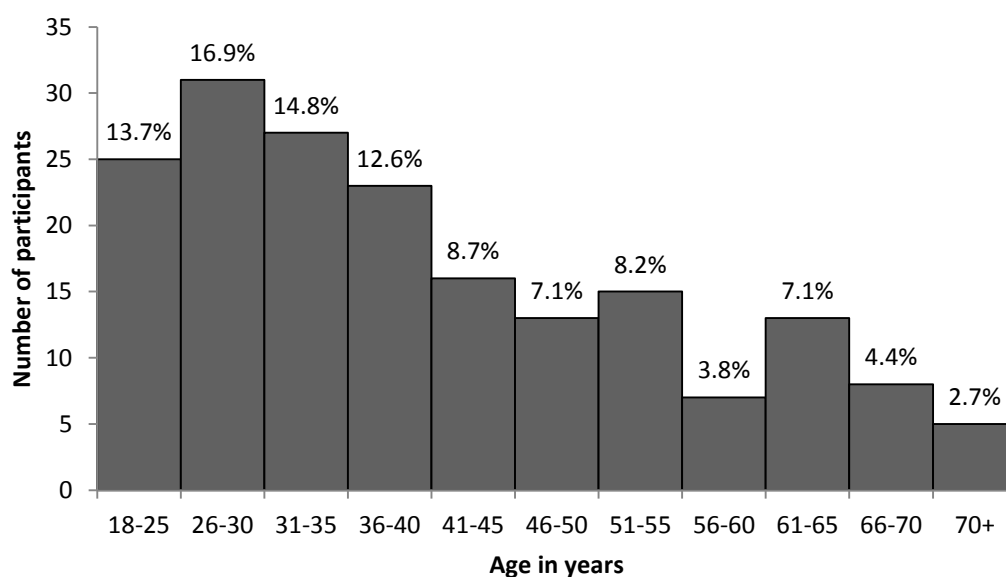


Table 4 describes in detail further patient demographics. Gender was effectively equal with 50.8% females compared to 49.2% males. Most patients were in work (58.6%) or retired (14.4%). Half had continued education after 18 years old (50.3%). A significant proportion had obtained a degree or professional qualification (37.9%) and a quarter were members of the charity Crohn's and Colitis UK.

Table 4. Patient Demographics

Demographic characteristics at baseline	Total (n=183)
Age (Years)	
Mean (SD)	40.6 (14.6)
Median (Range)	37 (17-76)
Gender n (%)	
Female	93 (50.8%)
Male	90 (49.2%)
Work n (%)	
Paid Work	106 (58.6%)
Seeking Work	8 (4.4%)
Retired	26 (14.4%)
DLA	24 (13.3%)
Family Home	8 (4.4%)
Full-time Education	8 (4.4%)
Other	1 (0.5%)
Missing	2
Education (%)	
Continued school after 18	92 (50.3%)
Degree or professional qualification	67 (37.9%)
CCUK Membership (%)	
Members	45 (25.1%)

3.3 Disease characteristics

Details about the participants IBD are outlined in Table 5. There were more patients with Crohn's disease (58.9%) than ulcerative colitis (34.4%). This does not reflect the pattern in the general population. Given the disease prevalence in the community, you would expect approximately one third of patients to have Crohn's disease compared to ulcerative colitis. [35] This pattern is likely to reflect the fact that Salford Royal NHS Foundation Trust is a specialist centre, dealing with more complex patients. This factor is supported by analysing the disease distribution. 37.4% of ulcerative colitis patients had extensive disease beyond the splenic flexure compared to an estimated 20% in the general IBD population.

Table 5. Disease characteristics of participants

Disease characteristics of participants	Total Number (%)
Type	
Crohn's disease	108 (59.0%)
Ulcerative colitis	63 (34.4%)
IBD-Unclassified	12 (6.6%)
Ulcerative Colitis/ IBD-Unclassified	
Proctitis	16 (21.3%)
Left-sided colitis	29 (38.7%)
Extensive colitis	28 (37.3%)
IPAA	2 (2.7%)
Previous operation(s)	4 (5.3%)
Peri-anal involvement	1 (1.3%)
Crohn's Disease	
Ileal	29 (26.9%)
Ileo-colonic	34 (31.4%)
Crohn's colitis	43 (39.8%)
Isolated upper GI tract	2 (1.9%)
Previous operation(s)	55 (50.9%)
Peri-anal involvement	26 (24.1%)
Duration of illness	
Mean (SD)	10.7 (9.4)
Median (Range)	8 (0-51)
0-2 years (%)	29 (15.9%)
3-10 years (%)	78 (42.6%)
+10 years (%)	76 (41.5%)
Smoking status	
Current smoker	21 (11.6%)
Previous smoker	70 (38.7%)
Never smoked	90 (49.7%)
Medications at baseline	
Oral 5-aminosalicylates	76 (41.5%)
Suppositories	13 (7.1%)
Enemas	21 (11.5%)
Oral steroids	29 (15.3%)
Immuno-modulators	72 (39.3%)
Biological therapies	38 (20.8%)
Disease Activity (6 months prior to enrolment)	
Active Disease (EHR)	91 (49.7%)
Step-up in Treatment	75 (41.0%)

The length of time since diagnosis ranged from 2 months to 51 years, with a mean duration of 10.7 years. 15.9% of the participants were diagnosed within 2 years from the start of the study. Around 50% of the population had never smoked with only 11.6% reporting being current smokers. At baseline 15% of participants were on oral steroid treatment, nearly 40% were prescribed immunomodulators and around 20% biological therapies. Based on the hospital records, 49.7% had active disease in the 6 months preceding recruitment and 41.0% requiring an increase in surgical or medical therapy (e.g. dose escalation or surgery).

3.4 Baseline health resource use

Health resource use was measured using a combination of the hospital records and self-report questions. For hospital resource use, the EHR was used as the primary source of information. GP data was calculated using self-report questions. Each participant's hospital record was explored in detail over the preceding 6-months from recruitment and during the 6-month study period. The appointment at the time of recruitment was excluded. Data collected included outpatient visits, emergency and elective hospital admissions, use of the IBD helpline, number of inpatient nights and investigations. Table 6 summarises health resource use for the 6-months prior to enrolment. The resource data were calculated using the mean number of visits per patient per year.

Table 6. Health resource use in the 6 months prior to recruitment

Outpatient Appointments	Total in 6 months	Mean visits per patient per year
IBD Nurse	157	1.72
IBD Dr	105	1.15
Surgical Nurse	32	0.34
Surgical Dr	17	0.19
Total	311	3.40
GP	151	1.65
Helpline		
Telephone	76	0.84
Email	1	0.01
Hospital Admissions		
	Total in 6 months	Mean visits per patient per year
Emergency inpatient admissions	17	0.19
Elective inpatient admissions	9	0.10
Number of nights	209	2.28
MIU admissions	118	1.28
Investigations		
	Total in 6 months	Mean visits per patient per year
Colonoscopy	28	0.31
Sigmoidoscopy	16	0.17
MRI Scan	26	0.28
CT Scan	11	0.12
Fluoroscopy	6	0.07
Bone Density DEXA Scan	10	0.11

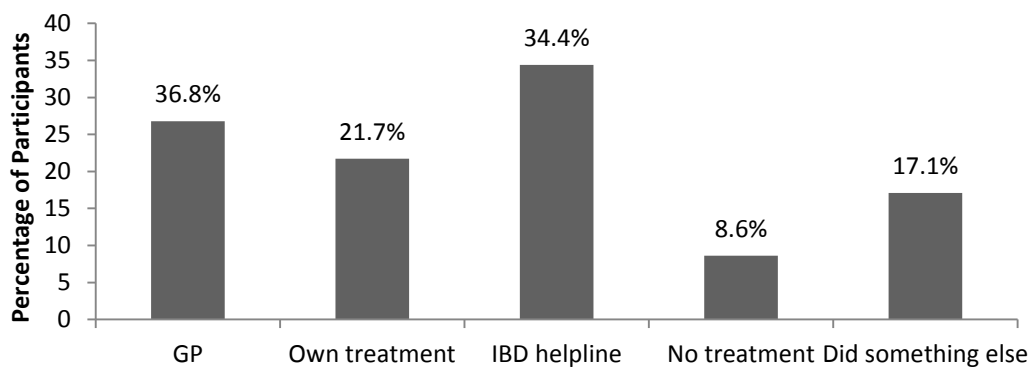
The results showed that participants attended a total of 311 medical or surgical outpatient appointments related to their IBD in the 6-months prior to recruitment. This equated to a total of 3.40 IBD outpatient visits per year, across both medical and surgical specialties. The majority of appointments held were with the IBD nurses (1.72 visits/year), followed by the medical Doctors (1.15 visits/year).

26.1% of participants used the telephone IBD helpline, a total of 76 times (range 0-5). This equated to a mean of 0.84 telephone calls to the IBD helpline per patient per year. Only one patient contacted via email. 28 patients (15.3%) required inpatient hospital admission, either for emergency (17 patients) or elective reasons (9 patients). 13 patients underwent a surgical operation. There were a total of 118 day-case admissions to the elective unit (range 0-5), equating to a mean average of 1.28 day-case admissions per patient per year. A total of 44 endoscopic procedures were performed and 53 radiological tests.

3.5 GP visits and flare-up management

48.4% of participants reported visiting the GP about their IBD in the previous year, averaging 1.64 visits per patient per year. 59.7% stated they had at least one flare-up, with over a third (36.8%) initially contacting primary care to manage this episode. This compared to 34.4% that phoned the IBD helpline, 21.7% providing their own treatment and 17.1% reported doing something else. See figure 12 below.

Figure 12. Management of last flare-up



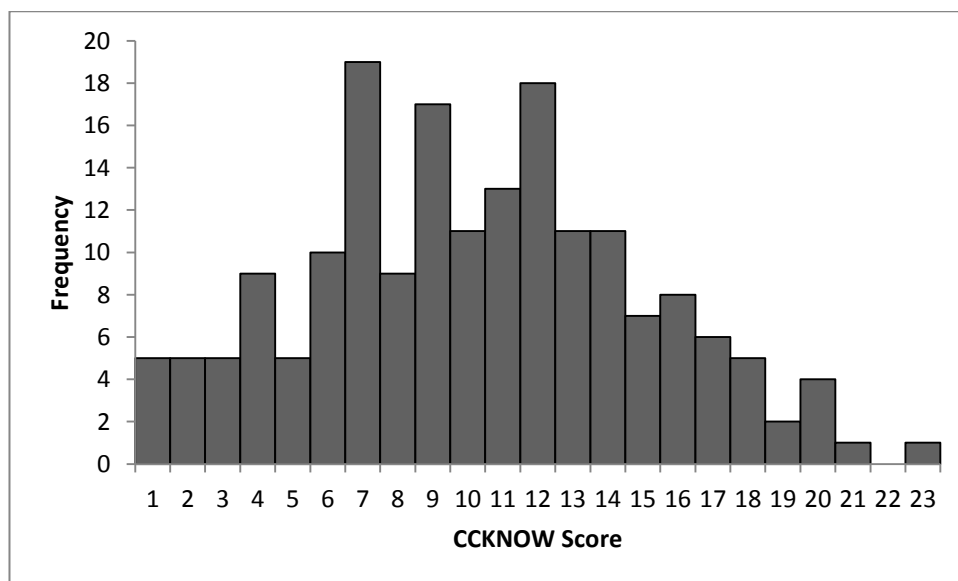
3.6 Baseline healthcare outcome data

3.6.1 Disease-related knowledge

At baseline participants disease-related knowledge was assessed using the 24-question CCKNOW questionnaire. First reported in the early 1990s, the questionnaire has been validated and subsequently used in a number of studies to measure patients' knowledge. Recently, there have been criticisms of the scale, as many of the terms are outdated or too specific for each sub-classification of disease. [162] The questionnaire also takes considerable time to complete and if used in future studies, could possibly lead to a decreased response rate.

Figure 13 demonstrates the CCKNOW scores of participants after completing the entrance questionnaire. The mean score was 10.2 (SD 4.7) and median 10 (IQR 7-13). These baseline scores are consistent with previously reported cohorts.

Figure 13. Participants' baseline CCKNOW scores



3.6.2 Patient engagement

An objective of the developed web-based service was to support patients in managing their health. Whilst certain patients are very proactive about their health needs, many are passive recipients. Patient engagement was measured using the Patient Activation Measure (PAM) and the LTC-6 QIPP questionnaire.

3.6.2.1 Patient Activation Measure

The Patient Activation Measure (PAM) was originally developed in the USA in 2004 by Professor Hibbard and colleagues and has been validated across diverse health populations, including UK patients. The questionnaire requires a licence to administer and is designed to assess an individual's knowledge, skill and confidence in managing their health. [163] A number of studies have shown that patients with higher activation scores are significantly more likely to engage in health information-seeking behaviours and obtain preventive care, including recognising reliable websites for health information, reading medical resource books and subscribing to health newsletters. [4, 164]

The PAM has previously been used as an evaluative measure in studies to assess the impact of self-management and the scale has been promoted to stratify patients for tailored support, by customising education to the individual patients' level of activation. [165] The PAM asks participants about their beliefs, knowledge and confidence for engaging in a range of health behaviours. Based on responses, an "activation score" from 0-100 is assigned. (See appendix 5). Alternatively the scores can be classified into 4 stages. Table 7 provides a description of these stages.

Table 7. The four stages of patient activation

Stage 1	Individuals tend to be passive and feel overwhelmed by managing their own health. They may not understand their role in the care process.
Stage 2	Individuals may lack the knowledge and confidence to manage their health
Stage 3	Individuals appear to be taking action but may still lack the confidence and skill to support their behaviours
Stage 4	Individuals have adopted many of the behaviours needed to support their health but may not be able to maintain them in the face of life stressors.

To assess activation in this study, the shortened 13-item version of the PAM was used [29]. The PAM is considered a generic scale and was developed using qualitative and psychometric methods. The resulting measure is a uni-dimensional, interval-level, Guttman-like scale. The individual raw scores of participants were converted based on the nominal scale provided by the copyright licence. [153] The PAM data was normally distributed with a mean score of 60.9 (SD 12.6). Table 8 below shows the activation stages in the study population at baseline and compares the data to previous large cross-sectional surveys in other LTCs.

Table 8: Activation stage study population versus UK and USA Survey

Stage of Activation	IBD Participants (n=183)	UK Survey [166] (n=2879)	USA Survey [167] (n=1469)
Stage 1 (least activated)	12.1%	7.9%	11.8%
Stage 2	20.3%	32.5%	29.3%
Stage 3	37.9%	38.7%	36.5%
Stage 4 (highly activated)	29.7%	20.9%	22.3%

Compared to these reported cohorts, participants showed similar levels of activation, with the exception of a larger proportion at the highest level (Stage 4). The mean score was also

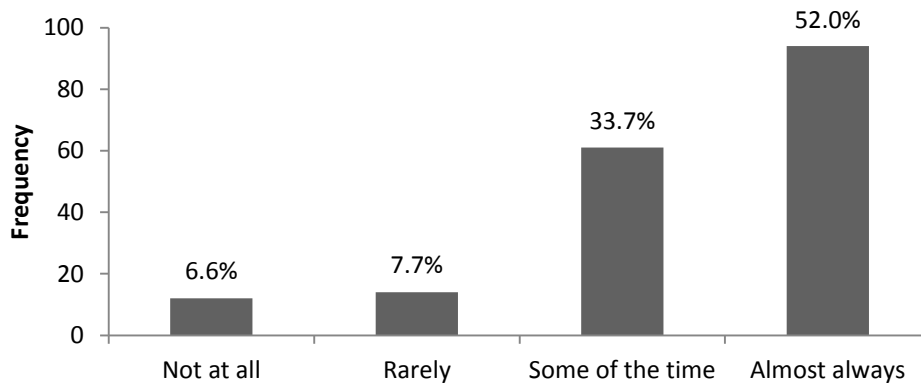
very similar to the large cross-sectional populations of 59.4 and 59.8, conducted in the UK and USA. [167]

3.6.2.2 Long-term conditions questionnaire (LTC-6)

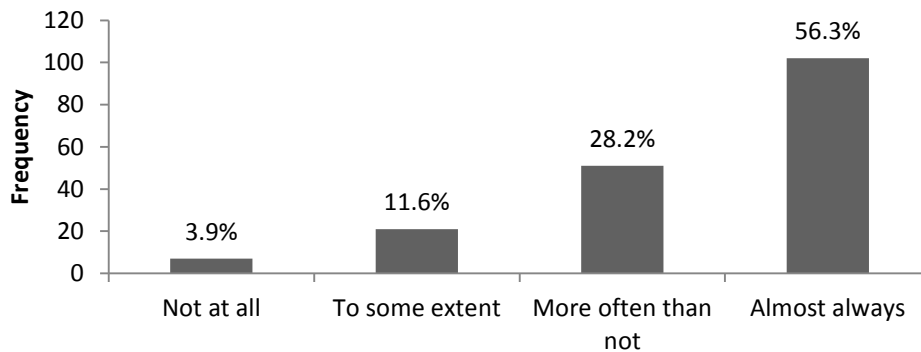
The long-term conditions questionnaire (LTC-6) was designed in the UK by the NHS Quality Improvement Productivity and Prevention (QIPP) programme to measure patient experience in care provision. The 6-item questionnaire was constructed from previous individual validated questions and was free to use. It aims to measure patient perceptions of person-centred care; shared decision-making; information provision, self-management support and integrated care. The questionnaire has not been previously reported in an IBD population. Each question has four responses that are converted in a scale from 0-3, providing a total range score of 0-18. Patients scoring highly perceive their care is well supported and coordinated. The baseline median score was 15 (IQR 12-15). The histograms below show in detail the responses to each individual question.

Figure 14. Baseline responses to the LTC-6 questionnaire

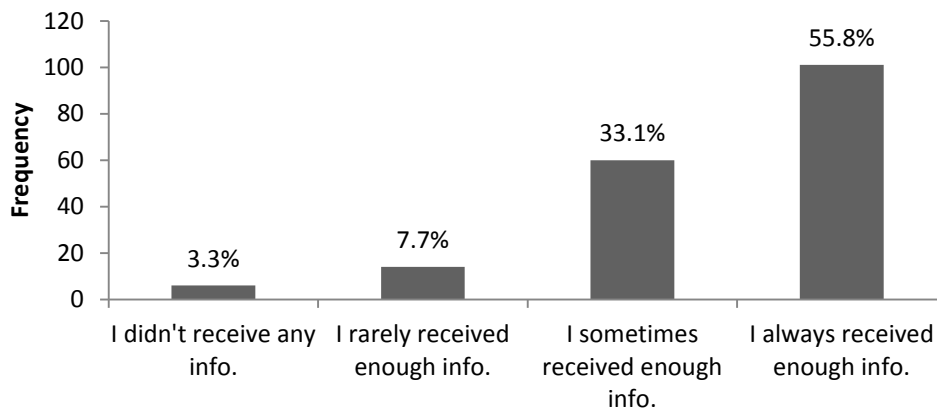
Qn 1. Did you discuss what is most important for you in managing your own health?



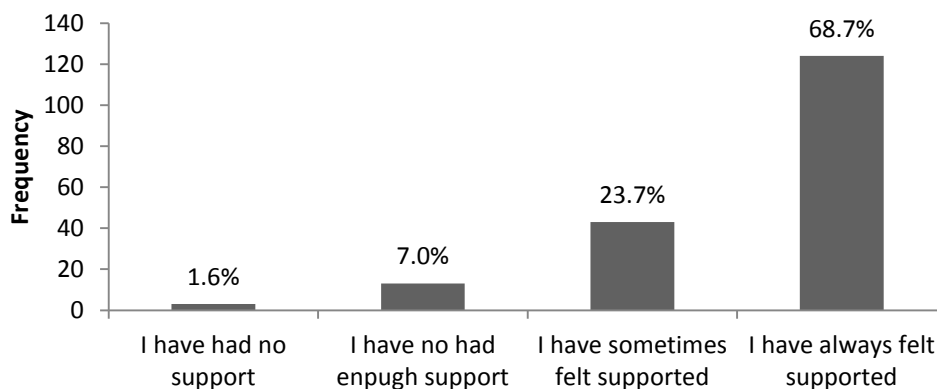
Qn 2. Were you involved as much as you wanted to be in the decisions about your care or treatment?



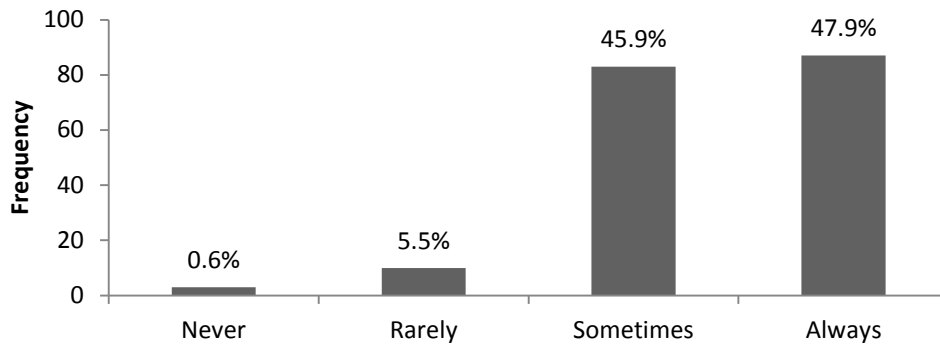
Qn 3. How would you describe the amount of information you received to help you manage your health?



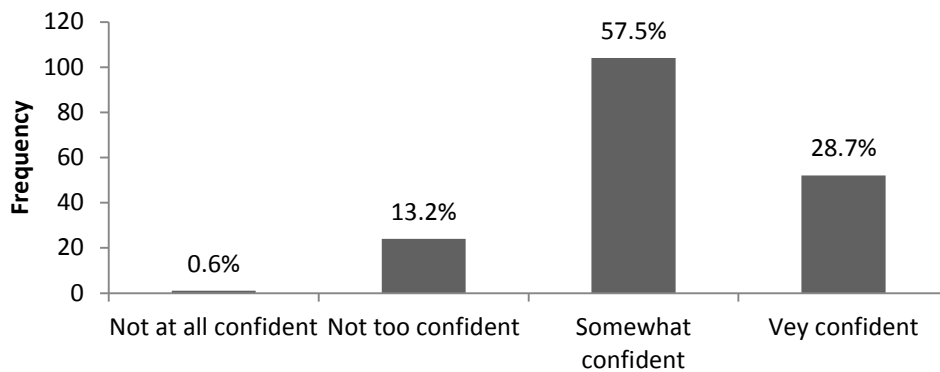
Qn. 4. Have you had enough support from the hospital and your GP to help you to manage your health?



Qn. 5 Do you think the support and care you get is joined up and working for you?



Qn. 6 How confident are you that you can manage your own health?



The results show approximately half of all the participants (48.0%) at baseline perceived they did not discuss what is most important to them. 43.7% felt they were not fully involved in the decision-making process, and 44.2% had not always received enough information. 47.9% perceived their care was joined up over the last 12 months. Around two-thirds of participants had felt fully supported (68.7%) and only around a quarter of participants were very confident in managing their health (28.7%). The results show that there is significant room for improvement in supporting patients' perceptions in managing their health needs.

3.6.3 Medication adherence

Adherence to medications is an essential component in the management of IBD. Various studies have estimated low adherence rates to therapies, ranging from 40-72%. Low adherence to treatment is associated with worse clinical outcomes and higher healthcare costs. [46] A variety of methods have been described to screen for medication adherence. These include patient interview, self-report adherence surveys, reviewing pharmacy refill data, metabolite monitoring and pill counting. Patient interview has been shown to be the

least valid method with very low sensitivity. [168] Whilst metabolite monitoring, pill counting and collecting pharmacy refill data are the most accurate methods, they are time consuming and expensive. Adherence questionnaires are cheap to administer, quick and easy to use. Once low adherence is reported and the cause identified, a number of interventions can be used to improve rates. Examples include providing greater information and support, tailoring treatment, improving the patient-HCP relationship, exploring patient beliefs and providing memory aids. [169]

Adherence to medications was measured using the self-report 8-item Morisky medication adherence scale (MMAS-8). [158] The objective was to see if medication adherence was associated with use of the intervention and secondly if use, by providing greater information and support, improved medication adherence.

At baseline, the median adherence score was 7 (range 0.25–8). 61 patients (34.3%) scored less than 6 (low adherer), 62 (34.8%) had a score from 6 to less than 8 (medium adherer) and 55 (30.9%) scored 8 (high adherer). As previous studies have described, due to a lack of clinical discrimination amongst scores from 6 to 8, the medium and high adherers were grouped together. The results show that approximately one-third of patients were defined as low adherers. This finding was consistent and within range of the previous reported literature. [159, 170]

3.6.4 Internet-related data

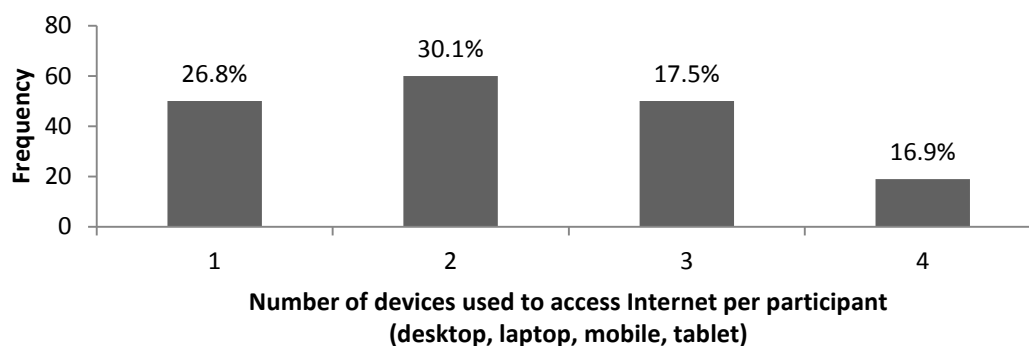
The 183 participants were asked a number of questions about their Internet habits. This included average use, number and type of devices used for access, perceived confidence in using the Internet and trust in health websites visited. Participants mean average time spent on the Internet was 15.7 hours (median 14, IQR 7-21) per week. Many participants used more than one device to access the Internet. The type of device used by each participant is highlighted in table 9. Desktops, either at work or home, were still the most common hardware used (70.7%), followed by smart mobile phones (59.1%), laptops (53.6%) and tablet devices (37.0%).

Table 9. Type of device used to access the Internet

Type of Device	Frequency	Percentage
Desktop	128	70.7%
Laptop	97	53.6%
Mobile	107	59.1%
Tablet	67	37.0%
Other	2	1.1%

Many participants were multi-device users. Previous studies have shown individuals accessing the Internet using several devices, are more likely to engage in email, social networking and creating online content. [171] The number of devices used by each participant were aggregated. Over two-thirds of participants used greater than one device with over 10% using four or more devices (see figure 15).

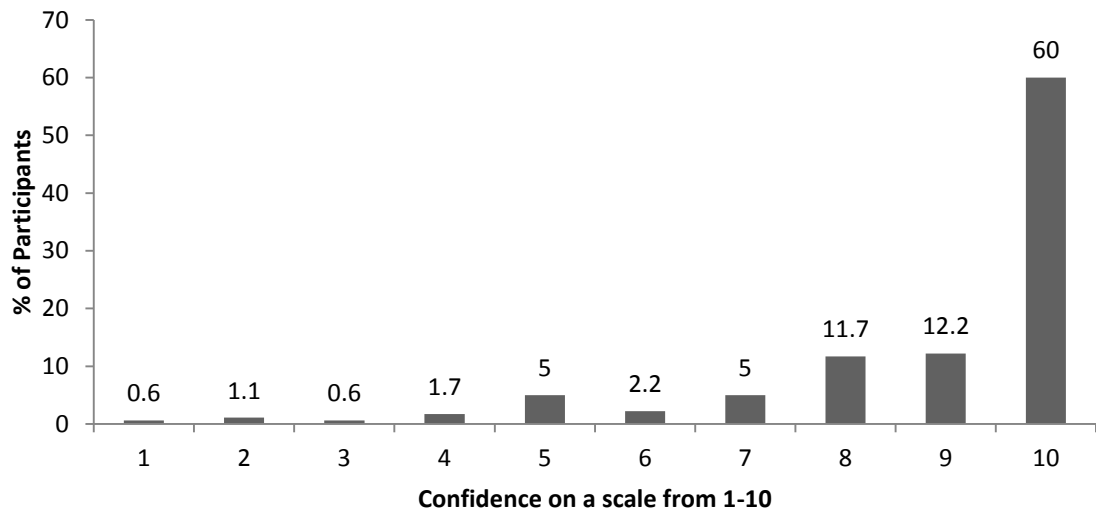
Figure 15. Number of devices used to access the Internet



Health information searching, confidence in use and trust

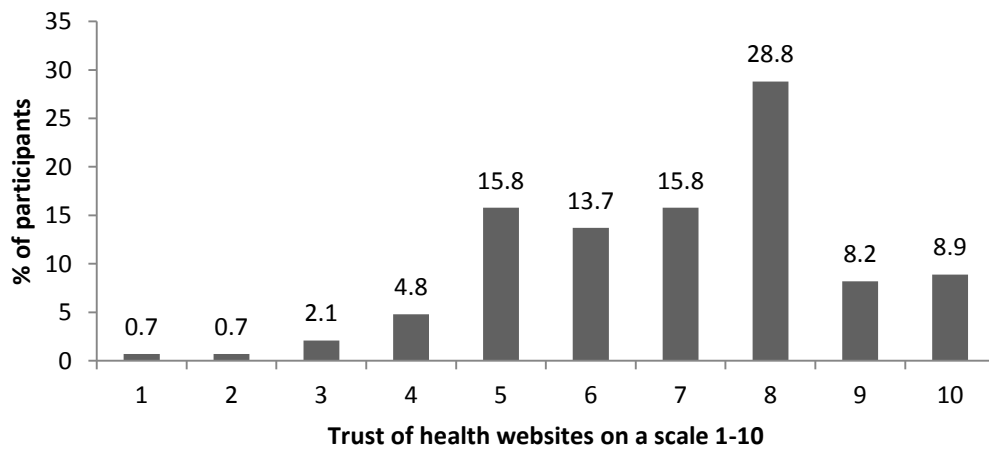
81% of participants had used the Internet to search for information about IBD. Confidence in using the Internet and trust in health websites visited was also measured using a scale from 1 to 10. The vast majority of participants were extremely confident in using the Internet as shown in figure 16 . (Mean 8.9, median 10, IQR 8-10)

Figure 16. Perceived confidence in using the Internet.



Perceived trust in health websites visited was lower, with nearly a quarter of participants measuring 5 or less. (Mean 6.9, median 7, IQR 6-8). See figure 17 below:

Figure 17. Patient's trust of health websites visited.

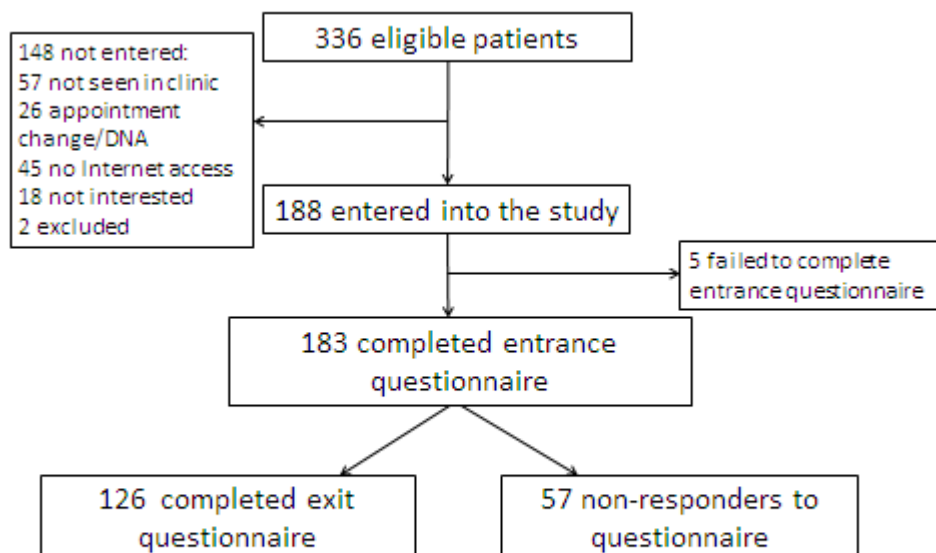


3.7 Patient follow-up rates

All participants who had returned the entrance questionnaire were sent the 6-month exit questionnaire. The follow-up strategy started by sending all participants by post the exit questionnaire booklet (appendix 7) with a covering letter and stamped addressed envelope. If there was no response after 4 weeks, a phone reminder to complete the questionnaire was used. At this point, participants were offered an alternative to complete the questionnaire using a secure online questionnaire service (Smart Survey[®]). If there was still no response or an inability to contact by phone, the questionnaire was sent to the email address of the participant provided at registration. The medical records were also reviewed. If participants were attending clinic in the month following completion of the study period, they were asked to complete the exit questionnaire at the time of their appointment.

Figure 18 shows the profile of the 6-month study. Of the 183 that completed the entrance questionnaire, 128 completed the exit questionnaire. Two responses had been returned with the majority of data missing and were excluded from the analysis. The 126 completed exit questionnaires led to an overall response rate of 68.9%.

Figure 18. Trial Profile



To analyse the representativeness of the responders to the exit questionnaire, the differences between the responder and non-responder groups were compared. Where data was normally distributed, the unpaired t-test was used and for non-parametric data, the Mann-Whitney U test was applied.

This comparison revealed a trend in younger people being less likely to respond but there were no statistical differences between the groups based on age (responders mean age 41.6 years versus non-responders mean age 38.5 years, $p=0.15$). There were no differences in the groups based on school leaving age, professional qualifications, disease type, disease duration or activity in the preceding 6 months. Nor were there differences between the two groups at baseline in patient activation, disease-related knowledge or adherence to medicines. Patients who perceived their support was greater, measured using the LTC-6 questionnaire, were significantly more likely to respond ($P=0.02$). The data showed male participants were significantly less likely to respond than females. ($P=0.002$). See table 10 below.

Table 10. Sex distribution of response categories for exit questionnaire

Gender	Responders	Non-responders	Total
Female	74 (58.7%)	19 (33.3%)	93 (50.8%)
Male	52 (41.3%)	38 (66.7%)	90 (49.2%)
Total (%)	126 (68.9%)	57 (31.1%)	183 (100%)

Many other researchers have documented that male participants are less reliable in responding to questionnaires than females, particularly younger males and this is likely to explain this finding. [172]

Response rates to the exit questionnaire were also significantly different when comparing users of the service ($p=0.005$). Table 11 on the following page shows the response rate based upon use. Of the 126 participants that responded to the exit questionnaire, 83 were classified as users (Use \geq 2 after registration) compared to the 43 responders classified as non-users (Use \leq 1 after registration)

Table 11. Response rate to exit questionnaire based on user categorisation

Use	Responders	Non-responders	Total
User	83 (76.9%)	25 (23.1%)	108 (59.0%)
Non-user	43 (57.3%)	32 (42.7%)	75 (41.0%)
Total	126 (68.9%)	57 (31.1%)	183 (100%)

3.8 Summary of baseline data

183 patients were recruited between 10th May 2013 and the 12th August 2013. The sample was representative of the Trusts IBD population but differed compared to the epidemiology of the general IBD population within the UK. Approximately two-thirds of patients eligible for the study were recruited. Only a small proportion declined to participate, the commonest reason was due to a lack of Internet access. Baseline questionnaire data were available for the 183 participants, as well as full access to the hospital records. The response rate to the exit questionnaire was 68.9%. Of the participants that were recruited, non-users, male patients are those that felt less supported were less likely to respond.

At baseline, patients' knowledge measured by the CCKNOW was the same as other UK reported studies. [162] Patient activation and medication adherence levels were also very similar to other reported cohorts. Participants used the Internet an average of 15.7 hours week and three-quarters of participants accessed the Internet using more than one device (59% mobile device and 37% Tablets). National weekly use is reported to be 16.9 hours per week, with similar proportions using mobiles (58%) and tablets (30%).

Participants attended clinic a mean average of 3.4 times per patient year and most frequently were reviewed by the IBD nurses. 49.7% had active disease in the preceding 6-months and 41.0% required an escalation of treatment. The results of the intervention are described in the next section, starting with the primary outcome of patient experience.

3.9 Objective A: Patient Experience

To describe the experience of patients that participated in the study, a number of inter-related factors were recorded. These categories included data on usage, usability and patient satisfaction. The quantitative results from the study are presented followed by the qualitative data.

3.9.1 Usage

Usage was recorded for each individual participant in the administration section of the system, logging individual use and timing. Further analysis was possible by embedding Google[®] Analytics software within the websites (www.myibdportal.com and www.myibdportal.org). Data provided included counts on individual visits to the service, the number and content of pages viewed, duration of visits and type of device used for access. The Google[®] analytics data, included additional visits from the small number of patients (22) registered prior to the study commencing. This small group of patients tested the feasibility of the system before recruitment into the observational study.

Figure 19 on the next page shows the usage data for each individual participant. This graph shows that there were no changes in the levels of use as recruitment progressed. The number of logins excluded use on the day of registration.

In total during the 6-month study period, 2080 separate logins to the service were recorded. The mean number of logins over the 6-month period per participant was 11.4 (SD, 21.5) and median 3 (IQR, 1-12). The data was skewed by a number of heavy users, with a range of logins per participant over the 6-month study period from 0-136.

Figure 19. Logins per individual participant

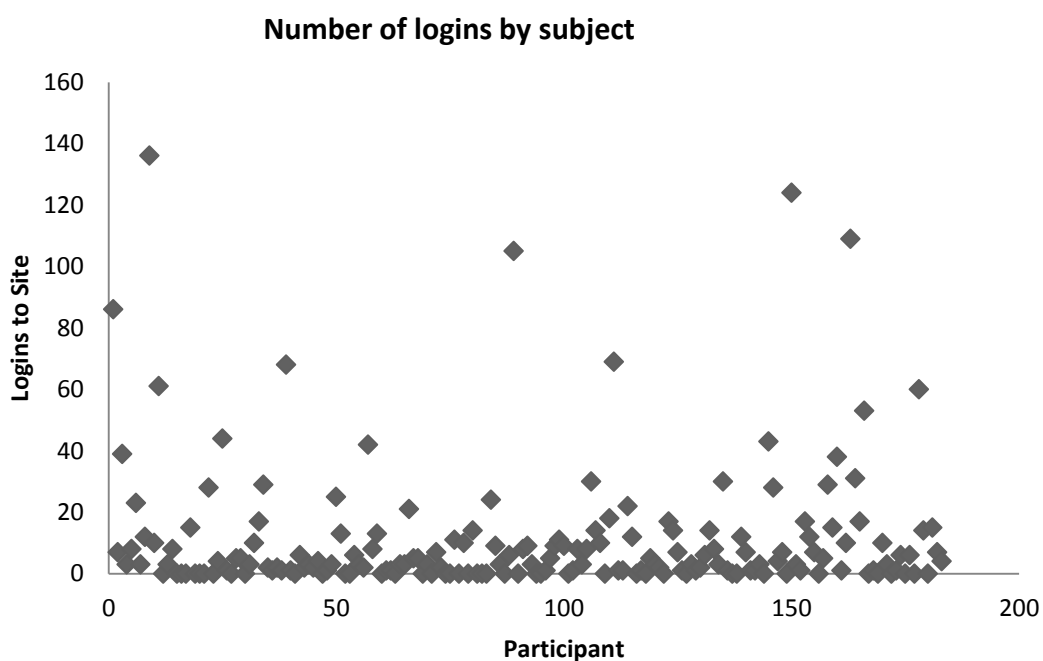


Table 12 categorises these data . A quarter of participants did not use the site following the day of registration (25.1%). Of the 74.9% of participants that used the site, 21 participants logged in only once after the day of registration (11.5%). Approximately two-thirds of participants were classified as users (63.4%), having returned to the site at least twice after the date of registration. Of these, 38 participants used the site between 2-5 times (20.8%) 31 participants between 6-10 times (16.4%) and 21 participants between 11-20 times (11.5%). 27 participants logged in over 20 times during the study (14.5%).

Table 12. Number of logins during 6-month study period

Logs / 6 months	Frequency	Percentage
0	46	25.1%
1	21	11.5%
2-5	38	20.8%
6-10	31	16.4%
11-20	21	11.5%
+20	27	14.5%

Table 13 shows overall use of the site during each month of the study. The table demonstrates attrition in use over time from registration. The mean number of logs decreased from 4.16 (SD, 8.0) in the first month to 0.71 (SD, 2.0) in the last month of the study.

Table 13. Total number of logins per month

Month	Total Logins	Mean (SD)	Median (IQR)	Range
1st Month	763	4.16 (8.03)	2 (0-5)	0-58
2nd Month	417	2.28 (6.43)	0 (0-2)	0-42
3rd Month	358	1.96 (4.66)	0 (0-2)	0-32
4th Month	236	1.29 (4.21)	0 (0-2)	0-30
5th Month	176	0.96 (2.08)	0 (0-1)	0-18
6th Month	130	0.71 (1.97)	0 (0-0)	0-14
Total	2080	11.36 (21.50)	3 (0-12)	0-136

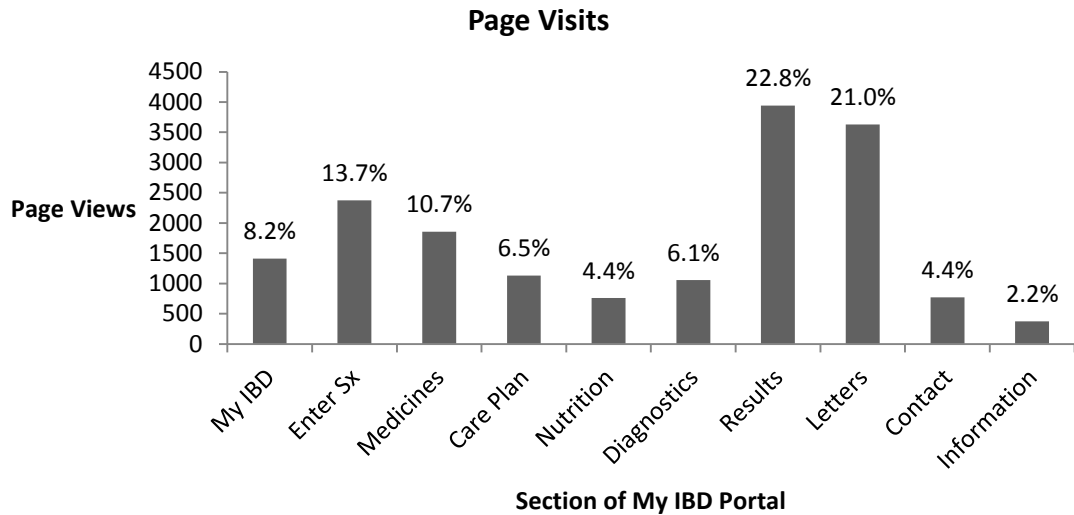
3.9.2 Pages visited

Embedding Google Analytics[®] software within the two intervention websites enabled data to be collected on the number of individual visits to the sites, duration of visits, pages viewed and resources used for access. Data were extracted and analysed from the start of the study on the 10th May 2013, to completion on the 12th February 2014. This data included 22 users from the initial site testing but reflected the pages visited by users.

In total there were 2271 visits to www.myibdportal.com. A mean average of 9.8 pages were viewed per visit, with the mean duration of each visit lasting 5 minutes 33 seconds. The site was mostly accessed via a desktop computer (52.8%), compared to a tablet device (24.6%) or mobile device (22.6%). Figure 20 shows the pages viewed per section as a percentage of total pages viewed. This data excluded the patient details section, as this page automatically

loaded as the first page viewed when accessing the service. User interest in the remaining sections was calculated by aggregating the pages viewed in each individual section.

Figure 20. Individual sections viewed within 'My IBD Portal'



The most frequently visited section of the site was the results section (22.8%), followed by the letters (21.0%) section.

This finding was confirmed by reviewing the pages viewed on the information site www.myibdportal.org, where over half of all visits were for the explanatory pages of the results section.

3.9.3 Use of interactive features

A number of interactive features were developed within the web-based service to enable patients to enter their own data. These features included the enter symptoms section, a disease-specific monitoring chart designed with decisional support. A medicines section, designed for patients' to keep a personal list of current and previous medications. A care plan section, this aimed to support users in planning their clinic appointment around their individual needs and preferences. Finally, there was a nutrition diary, enabling patients to enter foods that disagreed with them. (Please see section 2.1.9 for details of their design). At the start of the study, participants were asked to use any of the interactive features at least once, to measure adherence to patient entry of data.

Table 14 shows the use of the patient entry features during the 6-month period. In total 95 participants used at least one of these features (51.9%). Many of the participants that entered their own data used multiple features. The most widely used was the disease-monitoring chart. 83 participants had entered data about their symptoms at least once. The frequency of symptom data charted per individual user were spread across a wide range (0-92). The data were again skewed with a small number of high frequency users. The mean frequency of use was 3.9 times (median 0 and IQR 0-4). 74 participants self-entered medication data at least once during the study (40.4%). 25 participants used the nutrition diary (13.6%) and 24 used the care plan section (13.1%).

Table 14. Use of patient entry features of 'My IBD Portal'

Feature	Frequency of individual patients N (%)
Enter Symptoms	83 (45.4%)
Medications	74 (40.4%)
Nutrition Diary	25 (13.6%)
Care Plan	24 (13.1%)

3.9.4 Usability

Another element of the patient experience is the systems ease of use, commonly known as 'usability' in health informatics terminology. The term refers to the quality of users experience when interacting with an IT interface. Usability is about the systems effectiveness, efficiency and overall user satisfaction. Usability of the system was measured using the Systems Usability Scale (SUS) This scale was described over twenty years ago, is non-proprietary and is flexible in its use. The scale has been psychometrically validated and reported in over 200 studies across a wide range of interface technologies including web applications. [173]

79 users completed the scale from the exit questionnaire (73% of users). Respondents rated the systems usability with a mean score of 85.3 (SD 14.3). This rating compares favourably with other e-health systems that have been measured and places the perceived usability in the top decile. Previous reported studies have shown that interfaces with scores above 80.3 are more likely to be recommended to other users, with the mean average score reported for web interfaces of 68.1 (SD 21.6). [161]

The individual usability score for the system can be used as a benchmark to measure improvements in the future development of the service. With successive iterations, a quantitative measure of the effectiveness of changes can be undertaken. The score will also allow for comparison between competing systems and new interfaces on different platforms (e.g. mobile applications).

3.9.5 Satisfaction

To quantitatively assess satisfaction amongst users, a 7-item questionnaire was developed. Items included overall satisfaction, clarity of content, use prior to appointments, perceived support, concerns, help with decision-making and future use. In total 81 out of the 108 users (75%) responded to this questionnaire.

Table 15 on the following page presents the data. The results demonstrate that satisfaction amongst respondents was high. Overall, 98% felt either satisfied or very satisfied with the service. All respondents (100%) rated the display of information to be clear or very clear.

90% perceived the service supported them in managing their IBD, with a third (32%) reporting the service helped them make decisions about their treatment. With regards to use, 24% recorded using the service before GP visits and 71% before hospital appointments.

29% of respondents allowed another person to access their record. The vast majority were partners or family members. This proportion was much higher than anticipated.

8% of users completing the questionnaire expressed a concern with the service. Only one respondent stated they planned to stop using the website following completion of the study.

Table 15: User Satisfaction and use

Qn. 1	Overall, how satisfied were you with 'My IBD Portal'?			
	Very Satisfied	Satisfied	Dissatisfied	Very Dissatisfied
	58%	40%	2%	0%
Qn. 2	How would you rate the content of the information on the site?			
	Very Clear	Clear	Unclear	Very unclear
	65%	35%	0%	0%
Qn. 3	Do you think using 'My IBD Portal' helps support you to manage your IBD?			
	Yes		No	
	90%		10%	
Qn. 4	Did you use My IBD Portal prior to any:			
	GP Visits		Hospital Visits	
	Yes	No	Yes	No
	24%	76%	71%	29%
Qn. 5	Did you allow anyone else to use the Portal?			
	Yes		No	
	29%		71%	
Qn. 6	Do you have any concerns about the site?			
	Yes		No	
	8%		92%	
Qn. 7	Has using the Portal helped you make any decisions about your treatment?			
	Yes		No	
	32%		68%	
Qn. 8	Do you want to continue to use 'My IBD Portal' in the future?			
	Yes		No	
	99%		1%	

3.10 Qualitative Data

To explore patients' experience of the intervention in greater depth, open comments were collected from the exit questionnaire. Separate questions on specific topics were developed for non-users and users (see appendix 7). The aim was to gain a contextual understanding of use of the service and its impact. Of the total 183 participants, 119 offered comments (65%). The responses were transcribed, coded and categorised. Thematic analysis was used to look for patterns in the data.

3.10.1 Non-Users

Patients who had not used the intervention will be covered first. 22 non-users (30.6%) made comments at the exit questionnaire. Reasons given for not using the IBD portal were grouped into four main themes; disease inactivity, access issues, poor IT skills and perceived lack of time.

3.10.1.1 Disease Inactivity

Several patients commented that because they were well during the time of the study, they had no need to login to the web-based care package. Patient 12 said 'another reason for not using it, is that I have not been suffering this year. My condition is under control with maintenance therapy at the moment.' This was echoed by Patient 23, stating that 'I did not have a flare-up when having hospital appointments, so not useful to use.' Patient 27 commented 'I have been well over recent months' and Patient 81 that 'my illness is controlled at this time and I have not felt the need to use it'.

3.10.1.2 Access issues

A number of patients cited issues remembering their login details as reasons not to use the intervention. Patient 71 said 'by the time I was home I had forgotten what I was supposed to do and how to access online (an age thing! Not you!!)' and Patient 116 confessed that 'I forgot about it, I did not know where I put the documents you gave me'.

One patient suggested an iPhone or equivalent app may have helped them or reminders to be sent out – Patient 21 'I did not even log in. An iPhone app would help improve accessibility and would make it more likely for me to use. Text alerts or email reminders would also prompt memory to use and allocate time outside of business to enter information.'

A final access issue cited was no computer access; Patient 175 said 'I don't have constant access to the Internet and Patient 180 commented that 'I have got rid of my computer'.

3.10.1.3 Poor IT skills

Patients also reported a lack of IT skills as a reason for not accessing the Portal. For example, Patient 71 'As stated above not very computer literate, forgot how to access the site.' Furthermore Patient 82 commented 'I am not very good with my laptop but I do think it is a good idea and I'm sure people who are better than me with the Internet will make great use of it.'

3.10.1.4 Perceived lack of time

Lastly, a number of patients listed work/life balance, as well as time issues as their reasons for not accessing the portal. Their comments included; Patient 27 was 'overloaded with work and family commitments, I just did not have the time' and Patient 69 remarked 'not a lot of time, busy lifestyle'.

3.10.2 Users

Many more comments were made by users of the IBD portal. 97 of the 108 patients (89.8%) offered comments. Following thematic analysis, three broad inter-related themes were identified; greater access, support for self-management and communication.

3.10.2.1 Access

The ability of patients to access their blood results and clinic letters was seen by many participants as a positive step in their management. This was considered the most useful feature. This can be demonstrated by the following comments; patient 155 'as I live far away from the hospital and don't always have access to my IBD team, I found the ability to access results online very useful'. Patient 94 stated 'viewing my results history is very helpful to me.' Providing access allowed patients to monitor their results accordingly - Patient 139 said 'I could monitor my weekly blood results for 'iron' and medication taking'. The service helped inform patients – Patient 165 noted 'I can keep an eye on my blood results and now understand what the different terms mean.'

With regard to letters; the system allowed patients unprecedented access to their medical information and many patients enjoyed this facility. For example; Patient 24 found that 'for the first time ever I can access my medical information at any time. Like online banking for your health management.' Furthermore, Patient 54 indicated that 'I think the IBD portal is a fantastic idea and a great way of allowing patients access to their information and what was discussed at my appointments.'

Another area of improved access were for family members of participants. A large proportion of patients shared access with partners. Patient 2 stated 'The portal has allowed me to show my wife what effects my condition has on me and give her a better understanding of the condition.'

Improvements

Patients enjoyed access to blood results and letters and many would have preferred even greater access to information. Patient 3 said 'I'd like to see implemented access to imaging exams (colonoscopies, etc.) and their respective reports'. Furthermore, Patient 34 suggested 'I would like a summary of things such as MRI scans and colonoscopy reports' A further area to potentially improve upon would be providing access to primary care. Patient 170 commented, 'Link to GP so they can see too' and Patient 107 offered that 'possibly allowing GPs access to the system or the system to sync with GPs systems so blood results get to them quicker'.

3.10.2.2 Self-management

Users comments regarding self-management were sub-divided into three categories:

1. Knowledge and understanding
2. Ability to track symptoms
3. Confidence and support in decision-making

Knowledge and Understanding

Patients commented about improving their understanding of the condition. For example, Patient 153 noted 'It has helped me understand more about my disease and also to keep me up to date with medication.' Patient 49 commented 'answers any queries I may have in a clear easy to understand way' and Patient 181 'A great way to learn and understand about IBD.' In addition, Patient 2 noted 'Explained the condition I have very clearly. When I have used it I've found it a great help in understanding more about the problems I have. The 'My IBD Portal' is a fab idea.' Patient 34 found this to be 'an excellent resource.'

Tracking symptoms

Many comments were specific to tracking symptoms or perceived triggers of disease. A number reported benefits from self-monitoring. Patient 51 commented 'was very reassuring to be able to chart my symptoms.' Patients felt the chart acted as a historic record. Patient 155 noted 'has helped me record symptoms and things I wanted to discuss with consultant

IBD nurse' and Patient 146 offered that 'It helps me keep track of flares, symptoms and to see what causes them.' The theme of using the tracker tool to identify food triggers was further commented on; Patient 10, 'I think the Portal is a brilliant tool for people who have issues on a regular basis with IBD to track what they have eaten and link bad episodes with what they should stay clear of' and Patient 66: 'helped me monitor and avoid trigger foods.'

Decision-making

A number of comments highlighted how participants using the service, were supported in making decisions about their care. Patient 72 stated, 'I have been very impressed with the entire site, it has been invaluable to me, I have used it often to help resolve minor flare-ups which I would normally have had to go to the GP for medical advice. This site has given me confidence in being able to deal with minor problems and being able to access all my test results at a glance. It has often allayed any worries I may have had.'

Other respondents commented that the system helped them understand the therapeutic options available. Patient 32 said 'It made me look more in depth into treatment/surgery options' and Patient 85 'helped with med decisions and decision to go the route of surgery'. Other comments highlighted prompting the use of therapies. Patient 72 found 'It was very helpful in helping me diagnose minor problems and implementing speedy treatment'. Patient 18 reflected that 'It prompts me to take the medication I need when I flare.' Thirdly, Patient 24 noted 'It helped me anticipate the need for an iron infusion before I was told.'

Improvements

The majority of comments to improve self-management focused on the monitoring chart. Despite many respondents positive comments, improvement in the scoring systems were identified as the main changes that would be of benefit. The scores generated were based on validated non-invasive scales for the two sub-groups of diseases (Harvey-Bradshaw Index for CD and the Simplified Clinical Colitis Activity Index for UC). A number of patients felt that the scores generated to estimate disease activity were limited and did not reflect their symptoms. This is exemplified by the below comments; Patient 123 remarked that 'the

drop down menu 'other symptoms' is limited and restricting' and patient 165 commented 'when I put in my symptoms it always told me I was having a flare-up'.

Others stated a wish to enter even greater detail. Patient 28 stated 'the ability for the patients to enter their own weight on the 'My Symptoms' page' and 'for the patients to add written notes about general health at the time (for instance - 'recovering from a cold', or 'ate bacon') which might help to explain fluctuations in health.' Patient 100 wanted to 'include a category for notes so I can include any other symptoms, concerns etc. not included in the set questions'. Finally, Patient 183 commented they 'would like a facility to record more general symptoms from a patient orientated view'.

3.10.2.3 Communication

Many patients noted the benefit of being able to contact the IBD nurses via email. Examples of comments included Patient 76: 'I needed some advice off the nurse and she responded within 24 hours'. Patient 7 commented 'I recently had a query on some medication that I was due to take and used the system to contact the hospital and received a very prompt answer.' Patient 121 felt reassured, 'although I remained well I found it comforting just knowing it was there with info and contact details.' Patient 54 noted 'It's a very convenient way of getting access to the outcome of appointments.' Another positive aspect was greater continuity; Patient 76 felt benefits from 'being able to contact directly the person who is dealing with your treatment.'

Improvements

Further improvement to the Portal in relation to communication included patients' desire for a patient forum. With extensive use of social media, a number of patients commented that this is an area that could be incorporated within the service. Examples include - 'Maybe a forum link where you could post a question or comment and it would show up on the homepage or other users to share experiences or advice.' Patient 2, 'User forum e.g. dietary anecdotes etc.' and Patient 37: 'Maybe a chat facility for a limited time period'.

3.10.3 Summary

The overwhelming majority of user comments expressed a positive experience from using the web-based care package. Examples included Patient 5, 'Just to say I think it is great idea that makes living with my condition all that bit easier! Thank you!'. Patient 6, 'very useful addition to managing health' and Patient 37 'is a great idea and makes people want to know more about the disease and how it can be treated.'

The most useful feature was the ability to review blood tests and letters online. A number of patients felt the symptom tracker did not reflect their disease status and missed a variety of symptoms people associated with flare-ups.

There were limited concerns raised by responders, with only 11 patients making comments. Most were technical issues; Patient 178 'was not able to update certain screens i.e. my details of my GP, phone number etc.' and Patient 92 wanted 'more options when describing the symptoms and a few times I was caught out between definitions of pain'. A small number of concerns were raised on human factors in relation to the service. Patient 147 'Left an email regarding a concern I had with my IBD. The Portal promised a response within 24 hours. Didn't get one'. Patient 5 commented on the importance of 'Getting the support of the consultants & clinic staff to actively check patients updates in prep of follow up appointments. This in turn could assist in monitoring patients well-being as well as allow doctors etc. to make more informed decisions.'

Finally many expressed a wish to continue using the service. Patient 114 commented, 'It is a great system and fellow IBD sufferers (brother) who did not have access to it, felt there care was missing something' and Patient 62 'I think that it is a great idea - and I hope it is transferable between hospitals soon'.

3.11 Objective B: Predictors of Use

To explore possible associations that predicted use of the intervention, logistic regression analysis was performed using the dichotomised variable of users versus non-users. Users were defined as participants that had returned to the site more than once after the day of registration.

The analysis included all the *a priori* predictors that were postulated to influence use prior to recruitment. These factors included patient and disease-related characteristics, IT factors, patient knowledge, engagement, medication adherence and illness beliefs.

Table 16 on the following page shows the results from putting all the proposed variables into the regression model. The model showed that participants with active disease in the 6-months preceding recruitment were significantly more likely to use the intervention ($P < 0.02$). Other factors associated with use included male gender, a diagnosis within 2 years, being prescribed an immunosuppressant or biologic, patient knowledge of the condition and patient activation ($p < 0.25$). None of the illness belief responses appeared to predict use within the studies sample size. Due to the high number of *a priori* predictors compared to the population size, the accuracy and reliability of the model was weakened. (Response to predictor ratio of 8.3, Goodness of Fit deviance = 0.03). To improve the fit of the model, backward elimination analysis was performed at the statistical level of $P < 0.25$. Table 17 shows the results of this model. (Response to predictor ratio of 36.6, Goodness of fit deviance = $P = 0.002$).

Table 16. Logistic regression analysis of all postulated factors predicting use

Predictor	Variable	Users	Non-Users	Odds Ratio	95% C.I.	P-Value
Age	Years	40.9 (14.5)	40.2 (14.8)	1.03	0.99 - 1.08	0.11
Gender	Female	49	44	1		
	Male	59	31	2.66	0.98 – 7.24	0.06
Education	School leaving age					
	<18 years	47	37	1		
	+18 years	56	36	1.03	0.36 – 2.91	0.95
Disease	Type					
	Ulcerative Colitis/IBD-U	42	33	1		
	Crohn's Disease	66	42	1.11	0.32 – 2.50	0.84
Disease Duration	Time from diagnosis					
	<2 Years	22	7	1		
	+ 2 Years	86	68	0.32	0.08 – 1.35	0.12
Disease Activity	Change in Treatment					
	No treatment change	56	52	1		
	Step up in treatment	52	23	3.20	1.20 – 8.50	0.02
Disease Severity	Drugs					
	No Immuno./ Biologics	47	38	1		
	Immuno./ Biologics	61	37	2.15	0.79 – 5.82	0.13
Internet Use	Hours/week	16.3 (13.0)	14.7 (13.5)	1.00	0.97 – 1.04	0.97
Internet Access	Number of devices					
	<4 Devices	77	62	1		
	+4 Devices	31	13	1.41	0.45 – 4.48	0.55
Confidence in using Internet	Scale (1-10)	9.1 (2.7)	8.6 (4.4)	1.05	0.71 – 1.55	0.79
Trust in Internet	Scale (1-10)	7.1 (3.3)	6.6 (4.4)	1.04	0.81 – 1.31	0.78
Knowledge	CCKNOW score (0-24)	10.8 (5.0)	9.4 (4.3)	1.14	1.01 - 1.28	0.03
Patient Engagement	PAM-13 score (0-100)	62.7 (12.9)	58.3 (11.7)	1.03	0.98 - 1.08	0.23
	LTC-6 score (0-18)	14.3 (12.9)	13.9 (11.0)	0.99	0.83 – 1.14	0.73
Medication Adherence	MMAS-8 scale					
	Low Adherence	36	25	1		
	Med/High Adherence	70	47	0.85	0.35 – 2.05	0.71
Illness Beliefs	BIPQ-9 scale (1-10)					
	Affect Life	6.4 (2.1)	6.4 (2.5)	1.01	0.67 – 1.52	0.95
	Continued Length	9.1 (1.7)	9.5 (1.1)	0.81	0.55 – 1.19	0.28
	Control	5.5 (1.9)	5.3 (2.3)	0.92	0.72 – 1.17	0.49
	Treatment helps	7.7 (1.7)	7.6 (1.8)	1.01	0.75 – 1.36	0.96
	Experience Symptoms	5.9 (2.3)	6.2 (2.4)	0.91	0.69 – 1.30	0.76
	Concerns	6.9 (2.3)	7.1 (2.4)	0.86	0.65 – 1.13	0.28
	Understanding	7.4 (1.8)	7.1 (1.9)	0.91	0.66 – 1.24	0.54
	Emotional affect	6.2 (2.6)	6.5 (2.7)	0.97	0.72 – 1.30	0.84

48 dropped observations

Deviance goodness of fit chi-square = 142.576354 df = 113 P = 0.03

The results of this elimination process showed disease activity was the most significant predictor of use, with an adjusted odds ratio of 2.3 ($p=0.02$). Baseline patient activation levels (OR 1.03, $p=0.03$) and knowledge (O.R 1.08, $p=0.02$) were also predictive of use. Collinearity between these variables needs to be taken into account as there was a modest correlation between these variables. ($r=0.29$). Male gender ($P=0.06$) and those participants newly diagnosed (within 2 years $p=0.09$) showed a non-significant association in predicting use. Both age and disease severity were removed following this elimination model.

Table 17. Predictors of use logistic regression model following backward elimination

Predictor	Variable	Odds Ratio	C.I. (95%)	P Value
Gender	Female	1		
	Male	1.78	0.94 – 3.37	0.08
Duration	<2 years	1		
	+2 years	0.41	0.14 – 1.14	0.09
Activity	No change in Rx	1		
	Change in Rx	2.3	1.15 – 4.62	0.02
Knowledge	CCKNOW score (Scale 0-24)	1.08	1.00 – 1.16	0.04
Engagement	PAM-13 score (Scale 0-100)	1.03	1.00 – 1.06	0.03

3.12 Objective C: Healthcare outcomes

Due to the experimental design of the study without a randomised control group, it was not possible to measure the causal effect of the intervention on the proposed healthcare outcomes. However, analysing the baseline and 6-month data enabled the evolution of outcomes to be revealed and associations related to use and other variables to be analysed. Previous studies have shown multiple and complex behavioural factors can influence patient knowledge, engagement and medication adherence.

Table 18 shows the changes in the measured healthcare outcomes on an intention-to treat analysis in the study population at baseline and at 6-months. The paired t-test was used for parametric data and the Mann-Whitney U test for non-parametric data. This analysis showed there was a significant increase in disease knowledge over the 6-months in the sample population. No other variable showed a significant change over this time period.

Table 18. The change in health outcomes over the study period

Outcome	Measure	0 months	6 months	Change	P Value	95% C.I.
Knowledge	CCKNOW Mean (SD)	10.2 (4.8)	12.3 (4.9)	+2.1	P < 0.001	1.5 to 2.7
Patient Engagement	PAM-13 Mean (SD)	60.8 (12.6)	61.2 (13.6)	+0.4	P=0.46	-2.2 to 2.4
	LTC-6 Median (IQR)	15 (12-17)	15 (13-17)	0	P=0.78*	0 to 1
Medication Adherence	MMAS-8 Median (IQR)	7 (5.25-8)	7 (5.75-8)	0	P=0.65*	0 to 0.25

*Mann-Whitney U-test

To explore the impact of use of the IBD Portal on the proposed outcomes further sub-group analyses were conducted comparing changes within the user and non-user group. Table 19 on the following page demonstrates the changes in knowledge, engagement and medication adherence following this categorisation at baseline and 6-months. Initially, univariate analyses were performed to examine differences between the groups. Finally, to control for postulated predictors that may have also influenced change in the measured outcomes, multiple linear regression analyses were conducted. Below is a description of the findings for each health outcome.

Table 19. The change in health outcomes in user and non-user groups.

Outcome	Users			Non-Users		
	Baseline	End of Study	Change	Baseline	End of Study	Change
Knowledge						
CCKNOW Questionnaire (n)	107	82		75	44	
Mean (SD)	10.8 (5.0)	13.0 (5.1)	+2.2	9.4 (4.2)	10.9 (4.4)	+1.5
Median (IQR)	11 (7-14)	13.5 (9-17)	+2.5	9 (7-12)	10 (8-14)	+1
Engagement						
PAM-13 Questionnaire (n)	107	82		75	43	
Mean (SD)	62.7 (12.9)	63.8 (13.46)	+1.1	58.3 (11.73)	56.4 (12.5)	-1.9
Median (IQR)	63.2 (52.9-70.8)	63.2 (52.9-73.1)	0	56.4 (49.9-66.0)	56.4 (47.4-66.0)	0
Stages of Activation (n/%)						
Stage 1	13 (12.2%)	12 (8.5%)	-3.7%	9 (12.0%)	10 (23.3%)	+11.3%
Stage 2	17 (15.9%)	23 (22.0%)	+6.1%	20 (26.7%)	11 (25.6%)	-1.1%
Stage 3	38 (33.5%)	26 (25.6%)	-7.9%	31 (41.3%)	12 (27.9%)	-13.4%
Stage 4	39(36.4%)	42 (43.9%)	+7.5%	15 (20.0%)	10 (23.2%)	+3.2%
Engagement						
LTC-6 Questionnaire (n)	107	82		75	40	
Mean (SD)	14.28 (3.60)	14.95 (2.38)	+0.67	13.93 (3.32)	12.3 (3.86)	-0.63
Median (IQR)	15 (13-17)	15(13-17)	0	15 (12-16)	13 (11-15)	-2
Sub-Total- Mean (SD)						
1. Discuss what is important	2.40 (0.79)	2.46 (0.76)	+0.06	2.19 (0.98)	2.13 (0.94)	-0.06
2. Involved in decisions	2.42 (0.76)	2.53 (0.61)	+0.10	2.29 (0.94)	2.15 (0.86)	-0.14
3. Received enough info	2.50 (0.71)	2.62 (0.56)	+0.12	2.29 (0.83)	2.45 (0.78)	+0.16
4. Level of support	2.64 (0.61)	2.72 (0.51)	+0.06	2.59 (0.64)	2.53 (0.69)	-0.06
5. Care joined up	2.41 (0.63)	2.42 (0.52)	+0.01	2.43 (0.62)	2.33 (0.86)	-0.10
6. Confident in managing	2.17 (0.62)	2.16 (0.64)	-0.01	2.11 (0.69)	1.90 (0.63)	-0.21
Adherence						
(MMAS-8) (n)	106	79		72	40	
Mean (SD)	6.41 (1.77)	6.57 (1.74)	+0.16	6.17 (1.80)	6.15 (1.77)	-0.02
Median (IQR)	7 (5.5-8)	7 (5.75-8)	0	7 (5-7.75)	7 (5.75-7)	0
Frequency (%)						
Low Adherence (%)	36 (34.0%)	21 (26.6%)	-7.4 %	25 (34.7%)	13 (32.5%)	-2.2 %
Med/High Adherence (%)	70 (66.0%)	58 (73.4%)	+7.4 %	47 (65.3%)	27 (67.5%)	+2.2 %

3.12.1 Knowledge

At the start of the study, the mean CCKNOW score in the user-group was higher (10.8) than in non-users (9.4). This difference between the two groups approached significance when compared using the unpaired t-test ($p=0.06$) and correlated with the previous finding when assessing predictors of use.

At the end of the study both users and non-users knowledge scores increased. The mean change was greater in users (difference +2.2 points) compared to non-users (difference +1.5 points). Univariate analysis comparing the mean change in knowledge scores between the two groups at 6-months was not statistically significant (unpaired t-test $p=0.37$).

Many factors could be postulated to influence a change in knowledge within the study population other than use of the intervention. For example prior knowledge at the start of the study will likely impact future scores. Educational factors and age may alter understanding

and retention of information. Disease characteristics including type, duration and activity could all effect knowledge gained during the study. A number of items within the CCKNOW questionnaire are specific to Crohn's disease, despite its generic use across the IBD population. Newly diagnosed patients may show a greater increase in knowledge over a shorter period of time. Also, patients with active disease are more likely to search for solutions to their symptoms than those in remission.

To assess the potential factors predicting a change in knowledge, including use of the intervention, a multiple regression analysis was performed. The response variable was defined as the change in knowledge score over the six months. The following factors were included as independent predictors; use, age, gender, education, disease type, disease duration and disease activity. Table 20 shows the results of the model. After controlling for the above predictors, patients in the study who left education after 18 years demonstrated a significantly greater increase in knowledge than those leaving before 18 ($p=0.03$). Use of the intervention showed a positive relationship with an improvement in knowledge (regression coefficient 0.71) that was not statistically significant ($p=0.29$).

Table 20. Regression model assessing predictors of change in knowledge

Predictor	B Coefficient	95% C.I.	P Value
Intercept	2.31		0.10
Use User vs. Non-user	0.716	-0.631 to 2.064	0.29
Age Years	0.022	-0.023 to 0.067	0.33
Gender Male vs. Female	-0.082	-1.373 to 1.209	0.90
Education +18 vs <18	1.433	0.138 to 2.727	0.03
IBD Type UC/IBD-U vs. CD	-0.175	-1.371 to 1.022	0.77
IBD Duration Years	0.003	-0.064 to 0.070	0.22
Disease Activity Active vs. Inactive	0.794	-0.474 to 2.061	0.93
Baseline Score CCKNOW	-0.251	-0.397 to -0.106	<0.001

3.12.2 Patient engagement

Table 19 on page 143 shows the changes in patient engagement, measured using the PAM-13 and LTC-6 questionnaires between users and non-users. Comparing the two groups before the introduction of the intervention showed patient activation levels were significantly higher in future users (mean 62.7, median 63.2) than non-users (mean 58.3, median 56.4) (unpaired t test $p=0.02$). At the end of the study, the users-group mean activation score increased (mean difference +1.1) and non-user group mean activation score decreased (mean difference -1.9). Univariate analysis of this change between users and non-users at the end of the study was non-significant (unpaired t-test $p=0.41$).

Perceived support levels, measured using the LTC-6 questionnaire, were not normally distributed and were similar at baseline between users (median 15, mean 14.3) and non-users (median 15, mean 13.9). At the end of the study no significant changes in scores were found when the groups were compared (Mann-Whitney U test $p=0.51$). In the non-user group the results followed a similar pattern to the patient activation scores, with a decrease in perceived support from baseline (median score change -2, mean score -0.63). User group scores at the end of 6-months remained comparable to baseline scores (median score change 0, mean +0.67). Univariate analysis of this change in support comparing the two groups was again non-significant (Mann-Whitney U test $p=0.35$).

Regression analyses were performed to examine potential factors leading to the changes in patient engagement seen during the study, including use of the web-based care package. Predictive factors again included use, age, gender, disease type, disease duration, education and disease activity. The response variable was the change in patient engagement scores (post score – pre score) for both the PAM-13 and LTC-6 measures. Table 21 on the following page shows the results of these two models of changes in patient engagement.

The results show that use of the intervention was associated with a positive increase in patient engagement when including these other predictive factors. The result was significant

for the patient activation (regression coefficient 5.21, $p=0.04$) and close to significance for perceived support (regression coefficient 1.06, $p=0.06$). The model suggests that overall users activation scores increased 5.21 points compared to non-users (scale 0-100) and users levels of perceived support increased 1.06 points (scale 0-18) compared to non-users after the 6-month period. Other positive but non-significant relationships that correlated between the two different measures of patient engagement were increased levels in males and older patients. Participants with ulcerative colitis and active disease engagement decreased.

Table 21. Predictive factors associated with a change in patient engagement

Patient Engagement	Patient Activation Measure (PAM-13)			Perceived Support (LTC-6)		
	Coefficient	95% C.I.	P Value	Coefficient	95% C.I.	P Value
Intercept	29.24	16.82 to 41.65	<0.01	8.02	5.19 to 10.87	<0.01
Use User vs. Non-user	5.26	0.35 to 10.16	0.04	1.06	-0.06 to 2.18	0.06
Age Years	0.05	-0.12 to 0.21	0.57	0.03	-0.01 to 0.07	0.09
Gender Male vs. Female	0.08	-4.67 to 4.82	0.97	0.90	-0.19 to 1.99	0.11
Education +18 vs. <18 years	-0.57	-5.11 to 3.98	0.81	0.17	-0.87 to 1.22	0.74
IBD Type UC vs. CD	-3.22	-7.61 to 1.16	0.15	-0.32	-1.33 to 0.70	0.53
Disease Activity Active vs. Inactive	-2.57	-7.17 to 2.03	0.27	-0.36	-1.42 to 0.68	0.49
Disease Duration Years	-0.03	-0.26 to 0.21	0.83	0.01	-0.05 to 0.06	0.82
Baseline Score PAM-13/LTC-6	-0.51	-0.69 to -0.34	<0.01	-0.71	-0.87 to 0.56	<0.01

3.12.3 Adherence

Medication adherence scores, as measured using the self-report MMAS-8 scale, were not normally distributed. Scores at baseline were similar between users (median 7, mean 6.41) and non-users (median 6.75, mean 6.17). This was confirmed following categorisation into low and medium/high adherers, with 34.0% low adherers in the user group and 34.7% in the non-user group. After the 6-month period, median adherence scores did not change in either group. The mean adherence score increased in the user-group (+0.16) and was virtually unchanged in the non-user group (-0.02). Using the split categories, levels of medium/high medication adherers increased in both groups during the period, with a greater change in

users (+7.7%) compared to non-users (+ 2.2%). Comparing the differences between the two groups at the end of the study was non-significant (Mann-Whitney U test p=0.87)

A regression model assessing for predictors of a change in medication adherence is shown in table 22. Predictors in the model included; use, age, gender, disease type, disease duration, medications prescribed, education and disease activity.

Table 22. Predictors of a change in medication adherence score

Predictor	B Coefficient	95% C.I.	P Value
Intercept	1.67	0.36 to 2.98	0.01
Use User vs. Non-user	0.21	-0.37 to 0.79	0.48
Age Years	0.006	-0.013 to 0.025	0.57
Gender Male vs. Female	-0.046	-0.601 to 0.510	0.87
Education +18 vs <18	-0.107	-0.635 to 0.420	0.69
IBD Type UC/IBD-U vs. CD	0.155	-0.395 to 0.705	0.58
IBD Duration Years	0.003	-0.024 to 0.030	0.81
Disease Activity Active vs. Inactive	-0.323	-0.876 to 0.230	0.25
Medication Immunomodulator/Biologic	0.47	-0.09 to 1.02	0.10
Baseline Score MMAS-8 scale	-0.346	-0.397 to -0.106	<0.001

Use of the intervention showed a positive relationship with an increase in medication adherence (regression coefficient +0.21) but this difference was non-significant (p=0.48). There was a trend that participants on either an immunomodulator or biologic showed an increase in medication adherence (regression coefficient 0.47) compared to patients not on these therapies during the study (p=0.10).

3.12.4 Healthcare resource use

As previously described, the primary aim of the study was to evaluate the acceptability of the service to patients. However a preliminary analysis of potential health resource implications was also considered to be necessary. A full costing of the intervention was not attempted but data were collected on outpatient appointments, IBD helpline use, hospital admissions, investigations and frequency of medication changes. The aim was to look for trends in the pattern of health resource use and secondly to help formulate future methods for data collection. Due to the studies experimental design, interpretation of the results is limited. The data were collected from the medical records for each individual participant and an exploratory analysis conducted. Table 23 shows the differences in resource use in the study population, comparing the previous 6-months to the 6-months during the study period. The resource use data was converted to the mean average per patient per year.

Table 23. Health resource use

Health Resource	Type	6 months prior to study (n) (183 patients)	Mean average per patient per year	6 months during study (n) (183 patients)	Mean average per patient per year
Outpatient Appointments	IBD Nurse	157	1.72	210	2.30
	IBD Physician	105	1.15	83	0.91
	Surgical Nurse	32	0.34	15	0.16
	Surgeon	17	0.19	24	0.26
	Total	311	3.40	332	3.63
IBD Helpline	Telephone	76	0.84	102	1.12
	Email	1	0.01	29	0.32
	Total	77	0.85	131	1.44
Hospital Admissions	Emergency	17	0.19	12	0.13
	Elective	9	0.10	7	0.08
	Number of nights	209	2.28	101	1.10
	MIU admissions	118	1.28	111	1.22
Investigations	Colonoscopy	28	0.31	27	0.30
	Sigmoidoscopy	16	0.17	13	0.14
	MRI Scan	26	0.28	24	0.26
	CT Scan	11	0.12	5	0.05
	Fluoroscopy	6	0.07	7	0.08
	Bone Density Scan	10	0.11	22	0.24
Disease Activity	Step-up in Treatment	75	41.0%	73	39.9%

The table demonstrates an increase in the total number of outpatient appointments during the study period (3.63 appointments/patient/year), compared to the preceding 6-months (3.40 appointments/patient/year). Using the paired t-test, this difference was non-significant ($p=0.47$). This higher number of outpatient appointments appeared directly related to an increase in IBD nurse-led appointments during the study (pre-study 1.72 visits/patient/year versus post-study 2.30 visits/patient/year).

The number of contacts to the IBD helpline significantly increased following the introduction of the intervention (paired t-test $p<0.01$). In the 6-months prior to its introduction, there was a mean average use of 0.85 IBD helpline contacts/patient/year. This increased to 1.44 contacts/patient/year during the study.

Hospital admissions and investigation data were closely matched in both periods. There was a trend for an increased length of stay in the preceding 6-months (paired t-test $p=0.12$). Reviewing the raw data showed this was related to a small number of very long admissions, suggesting the sample size was too small to accurately estimate this parameter.

A marginal difference in the surrogate marker used to measure disease activity was noted when comparing the two periods. 41.0% of patients in the preceding 6 months required an escalation of medical or surgical therapy in contrast to 39.8% during the study. When compared using the paired t-test this difference was non-significant ($p=0.80$).

To further explore health resource use, the data were again split into users and non-users. Table 24 on the following page presents the results of this categorisation. The table shows that in the 6-months prior to recruitment, patients that went on to use the Portal were more likely to have been seen in clinic (users mean average 3.72 visits/patient/year versus 2.93 visits/patient/year). Univariate analysis showed this association was non-significant (unpaired t-test $p=0.14$).

After introduction of the intervention, the users-group total number of appointments further increased to an average of 4.44 visits/patient/year. This compared to a decrease in the non-user group, with an average of only 2.93 visits/patient/year. At this end-point, the difference between the two groups was highly significant ($p < 0.01$)

Table 24. Health resource use comparing users versus non-users pre- and post-study

Health Resource	Type	6 months prior to study				6 months during study			
		User (n=108)		Non-User (n=75)		User (n=108)		Non-User (n=75)	
		Total (n)	Mean patient/yr	Total (n)	Mean patient/yr	Total (n)	Mean patient/yr	Total (n)	Mean patient/yr
Outpatient Appointments	IBD Nurse	97	1.80	60	1.60	156	2.89	54	1.44
	IBD Physician	74	1.37	31	0.83	58	1.07	25	0.67
	Surgical Nurse	20	0.37	12	0.32	12	0.22	3	0.32
	Surgeon	10	0.19	7	0.19	14	0.26	10	0.27
	Total	201	3.72	110	2.93	240	4.44	92	2.45
IBD Helpline	Telephone	45	0.83	31	0.83	86	1.59	16	0.43
	Email	0	0	1	0.03	27	0.50	2	0.05
	Total	45	0.83	32	0.85	113	2.09	18	0.48
Hospital Admissions	Emergency	10	0.19	7	0.19	7	0.13	5	0.13
	Elective admissions	6	0.11	3	0.08	5	0.09	2	0.05
	No. of nights	114	2.11	95	2.53	85	1.57	16	0.43
	Day-case admissions	79	1.46	39	1.04	90	1.67	21	0.56
Investigations	Colonoscopy	18	0.33	10	0.27	19	0.35	8	0.21
	Sigmoidoscopy	12	0.22	4	0.11	9	0.17	4	0.11
	MRI Scan	13	0.24	13	0.35	15	0.28	9	0.24
	CT Scan	6	0.11	5	0.13	3	0.06	2	0.05
	Fluoroscopy	5	0.09	1	0.03	5	0.09	2	0.05
	BD Scan	5	0.09	5	0.13	19	0.35	3	0.08
Disease Activity	Step-up in Therapy	52	48.1%	23	30.7%	54	50.0%	19	25.3%

Reviewing use of the IBD helpline showed contact was exactly the same in both the user and non-user groups in the 6-months preceding recruitment (0.83 contacts/patient/year). Before the introduction of the intervention only one participant was documented to have contacted the IBD team by email. During the study period, the user-group demonstrated an increase in contacts to the IBD helpline (2.09 contacts/patient/year) versus non-users (0.43 contacts/patient/year). This difference between the two groups at the end of the study was

highly significant (unpaired t-test $p < 0.01$) with approximately a third of user communications via email.

Comparing the hospital admission data revealed few differences except for a trend in users requiring more day-case visits prior to (1.46 visits/patient/year) and during the study (1.67 visits/patient/year). Day-case admissions in non-users nearly halved in the study period (pre-study 1.04 visits/patient/year versus. post-study 0.56 visits/patient/year). Investigations showed a similar but less pronounced pattern with similar levels in users in both periods and a decrease in non-users.

A variety of possible factors may explain the increase in resource use seen within the user-group during the study. The greatest changes were the associated increase in outpatient visits and IBD helpline contacts. The most prominent factor that could account for these differences is likely to be changes in disease activity. Using the surrogate marker of an escalation in medical or surgical therapy as a predictor of current active disease demonstrated twice as many participants in the user-group required a step-up in treatment compared to the non-users group during the study.

Participants with more severe disease are also reviewed more frequently for monitoring. Again, there was a difference between the two sub-groups. Using the surrogate marker of severity as classes of drug prescribed, a higher proportion of users (56.5%) were prescribed an immunomodulator or biologic compared to non-users (49.3%).

To further explore the use of health resources in relation to use and to control for possible confounders, regression analyses were conducted independently for both outpatient visits and IBD helpline use. Control variables in each model included use, disease activity, drug use, age, gender, length of illness, education and baseline contacts. Results of these analyses are shown on the following page in Table 25.

The model demonstrated that after controlling for the predictors, use of the intervention was associated with an increase in the total outpatient appointments but this was non-significant (b coefficient 0.34, p=0.17). Predictive factors associated with a significant increase in outpatient visits included participants with active disease (b coefficient 1.86, p<0.0001) and Crohns disease (B coefficient -0.59, p=0.03). There was also a trend in participants that left school after 18 (b coefficient 0.37, p=0.13), as well as immunomodulator and biologic use, being associated with more frequent appointments (b coefficient 0.40, p=0.11).

Table 25. Regression models exploring predictors of IBD outpatient and helpline use

Health Resource Use	Outpatient Visits (n)			IBD Helpline Contacts (Phone & Email) (n)		
	B Coefficient	95% C.I.	P Value	B Coefficient	95% C.I.	P Value
Intercept	-0.005	-1.06 to 1.05	0.99	-0.15	-0.93 to 0.62	0.70
Use User vs. Non-user	0.34	-0.15 to 0.83	0.17	0.59	0.22 to 0.96	0.002
Age Years	0.01	-0.01 to 0.03	0.41	0.01	-0.01 to 0.02	0.31
Gender Male vs. Female	0.19	-0.29 to 0.66	0.44	-0.20	-0.56 to 0.16	0.28
Education +18 vs. <18 years	0.37	-0.12 to 0.85	0.13	-0.13	-0.50 to 0.24	0.49
IBD Type UC vs. CD	-0.59	-1.12 to -0.07	0.03	0.01	-0.38 to 0.40	0.96
Disease Activity Active vs. Inactive	1.86	1.36 to 2.36	<0.0001	1.00	0.61 to 1.38	<0.0001
Disease Duration Years	-0.01	-0.03 to 0.02	0.58	-0.02	-0.04 to 0.01	0.13
Drug Use (Imm/biol. vs. nil)	0.40	-0.10 to 0.90	0.11	-0.05	-0.42 to 0.33	0.80
Baseline OP appts.	0.23	0.10 to 0.37	0.001	0.31	0.24 to 0.64	<0.0001

The regression model used to explore IBD helpline use, showed users of the Portal were significantly more likely to contact the IBD helpline than non-users (b coefficient 0.59, p=0.002). Other significant predictors of IBD helpline use again included active disease as well as previous IBD helpline use. There was a non-significant trend that participants with a shorter disease duration contacted the helpline more frequently (b coefficient -0.02, p=0.13)

3.13 Summary of key health outcome results

Overall, the findings from the intention-to treat analysis showed that knowledge was the only health outcome that improved significantly during the study period. Patient engagement and adherence levels did not change. Total outpatient visits increased following introduction of the IBD portal but this difference was not statistically significant. Use of the IBD helpline increased from 0.85 contacts/patient/year to 1.44 contacts/patient/year ($p < 0.001$). There was no other significant change in health resource use observed.

Sub-group analyses comparing the user and non-user group were performed to further explore associations linked with the introduction of the intervention. Univariate analyses were initially conducted to review potential differences between the groups. The change in knowledge, engagement and adherence scores were not significantly different when comparing users to non-users without controlling for predictive variables. Both outpatient appointment and IBD helpline use showed a significant increase within the user-group. Although the changes in knowledge, patient engagement and medication adherence were non-significant, positive trends were observed in the user-group with an increase in the mean scores of all these postulated outcomes. Within the non-users-group, the mean knowledge score showed a small increase. However, a decrease was observed in the mean patient activation, perceived support and adherence scores during the study.

It was clear a number of confounding factors other than use of the IBD portal may have influenced the observed changes in each of the measured outcomes. To more accurately estimate the relationship between use of the system, the outcomes observed and controlling for predictive variables, a series of regression analyses were conducted. Each change in outcome was regressed against a set of measured factors. These included use, age, gender, disease activity, duration and type as well as baseline scores.

The regression model used to explore for changes in IBD knowledge showed use was not associated with a significant improvement in the CCKNOW score. Higher educational

achievement, measured as participants leaving school after 18 years, was associated with an improvement in the disease knowledge score over the 6-months.

Analysing changes in patient engagement demonstrated that use of the IBD portal was associated with higher levels of both patient activation and perceived support. Crohn's disease patients also showed a trend towards a greater improvement in patient activation. Use of the web package was not associated with a significant improvement in medication adherence following regression.

Finally, regression analyses of health resource use demonstrated a non-significant trend for more frequent outpatient visits and a significant increase in IBD-helpline use. The method of communication with the IBD team also changed significantly with nearly a third of patients using email.

4.0 Discussion

4.1 Introduction

There is a growing body of evidence showing the potential benefits of e-health technologies in supporting patients to manage chronic disease. [80] Greater patient involvement has become an area of focus amongst healthcare policy makers. This trend is obvious given the majority of healthcare decisions are taken by individuals without HCP contact.

Supporting patients to manage their IBD enables patients to be better educated about their health needs and equipped in making decisions. Despite this, most studies have shown education alone is insufficient in changing patient behaviour and further specific training is required. [28] This training should be tailored to each person's individual lifestyle and preferences.

To realise the potential of e-health technologies to improve the quality of care, implementation in routine clinical practice is required to sustain adoption. There is an increasing volume of literature evaluating such technologies. Many reported studies have shown promise but there is considerable heterogeneity of the findings.

Following the construction and implementation of the IBD portal, the primary objective was to evaluate the patient experience. Secondary objectives were to investigate characteristics predicting use and explore its potential impact on healthcare outcomes. To the author's knowledge, this is the first comprehensive study examining the introduction of an IBD portal in a large cohort within the UK.

Overall, the project clearly demonstrated that an e-health IBD portal could be successfully implemented within the NHS setting. During this process inevitable issues were encountered, delaying the design and occasionally affecting the delivery of the service. When the fully working system was implemented, a majority of recruited participants used the intervention, perceived it supported their management and expressed a desire to

continue to access the service. Further work to develop the current application and explore its impact is required both at the pilot NHS Trust and in other secondary care settings.

Section 4.2 below provides a detailed account of factors affecting the design and implementation of the project. Section 4.3 discusses the study design. Section 4.4 provides discussion on the findings from the study and its limitations. Section 4.5 offers possible future work and finally section 4.6 concludes with a summary.

4.2 Factors affecting design and implementation of the IBD portal

Major weaknesses of many e-health interventions are their labour intensive nature and time constraints placed on users. Many studies have reported poor adherence and high attrition levels. [144] There are many reported factors that can lead to these findings, including the design of the service, perceived benefit and relevance to users. Any combination of these factors can significantly impact the generalisability of the findings.

In an attempt to mitigate these issues, considerable patient and HCP involvement was sought throughout the design process. This process highlighted aspects that mattered most to patients. Challenges faced included unrealistic expectations of the proposed service and limits to the technology available at the time of development, as well as keeping within the constrained budget.

In order to successfully set up the IBD portal, a number of different IT companies were approached. This took a considerable amount of time, with advantages and disadvantages of each option evaluated. The importance placed on this process was considerable, as the decision made had the potential to impact the feasibility of the whole project. The influence of the IT department at the host Trust affected this choice, owing to a previous unfavourable experience with one of the tendering companies.

After weighing up each variable, including cost, the developers of the Renal Patient View system (RPV) were without doubt the best choice. Partnering with this service helped

enormously in breaking down many technical and organisational factors that often delay or prevent the implementation of e-health applications. However, using their services limited some of the desired functionality as in order to control costs, the IT infrastructure was kept virtually identical to their original model. After reviewing their application, it was clear from the patient focus group that the design of the interface required a complete update. This revision took more time and resources than anticipated and a number of unforeseen challenges were faced.

Part of this development involved producing information in a 'web-enabled' format, allowing patients direct links to the educational material. As these resources were not developed, this aspect of the project took considerably longer than anticipated. Following permission, the charities information booklets were converted from Adobe® pdf files to html format. This enabled patients' immediate access to the information, through one click directly from the interface (www.myibdportal.org). These resources were connected to specific sections of the system, tailoring links to each individual's condition. During this phase it became clear there were major gaps in the resources available and further educational material was written and verified by the local clinical IBD team. Once more, this additional work impacted upon the proposed budget and timescale originally set out.

A further challenge that occurred during development was a change in the Trusts' EPR provider. The switch from an old version in use for over 10 years, to an entirely new system occurred during recruitment (September 2013). This led to significant technical problems over a two-week period. Recruited participants data failed to upload and unfortunately this led to some mistrust regarding the reliability of the intervention and hence some disengagement within the affected group of participants (14 patients). Another technical issue encountered was a 'bug' in the system in recognising certain symbols. If any of the data transferred contained an ampersand (&) symbol, all data failed to transmit for that individual.

4.3 Study design and data collection

4.3.1 Study protocol

To ensure the research design and governance of the study met the highest standards, appropriate ethical and protocol approval was sought from the National Research Ethics Service. This approval ensured the research methods, questionnaires, information booklets and consent process were fully authorised prior to recruitment. Minor modifications were required to the questionnaires and information booklet during the review process, leading to some time delays. The benefit of seeking formal approval through this process provided extra support from the clinical research nurse at the Trust, aiding recruitment. For the author it provided a greater understanding of the necessary administrative requirements needed to gain approval for a NIHR-sponsored portfolio study. This will hopefully support future research studies.

To evaluate the service, a pre-post observational study was designed to examine its use, acceptability and impact. A review of the potential effect on health utilisation was also incorporated. Originally proposed and in ideal circumstances, a pilot randomised controlled trial would have been performed. This would have resulted in a more rigorous method to evaluate the effectiveness of the system. However, it was not feasible to perform owing to time delays incurred and budget restrictions. This research design would have also resulted in less patients being recruited. The pre-post study design enabled twice as many participants to evaluate the system and could help refine procedures for future studies. Even with randomisation, the difficulty in blinding participants creates weaknesses in removing potential bias.

4.3.2 Data collection

An unexpected issue that affected data collection and demonstration of the service was in recording participants' symptoms. The original protocol planned to demonstrate the 'Enter Symptoms' chart to each recruit and record their disease activity at baseline. It became clear during early recruitment that this was not feasible. The symptom chart required data on each individual to be transferred to the IBD portal. This function was reliant on the system

knowing the individuals' specific diagnosis. This process was delayed for at least 24 hours and resulted in a proxy measure for disease activity to be used in the analysis (escalation in therapy).

Although comparing users to non-users helped explain possible associations of the impact of the intervention, the findings may not accurately reflect changes seen in the general IBD population. The non-user group by nature was self-selected. A control group of future users that were not given access would provide a more precise match. To further investigate the effects a randomised controlled study needs to be conducted.

Finally, the proposed study design was to include formal qualitative semi-structured interviews. Once again, given the time constraints that occurred during development and additional costs of this process, this aspect of work was limited to developing open-comments within the exit questionnaire.

4.4 Findings

4.4.1 Recruitment and Participation

A strength of the study was the ability to successfully recruit a large number of participants. The sample represented a significant proportion of the target population available during the study. Over 75% of patients approached were successfully recruited. Only a small proportion of those eligible refused to participate. In fact a number of patients were unable to be recruited owing to time pressures that were encountered, with a high number of positive responses at the clinics. This relative ease of recruitment demonstrated the attractiveness of the intervention to the patient population.

Demographics and disease characteristics were very similar to the IBD cohort at the Trust but differed from the general IBD population. This is owing to the tertiary nature of the pilot centre. As expected, the exit questionnaire completion rate was lower in the non-user group. For participants, the entrance and exit questionnaires were perceived to be time consuming to complete. This may have further affected completion rates. In hindsight on reviewing the

information gathered, not all data were essential. Specifically, the CCKNOW knowledge questionnaire was perceived to be challenging and lengthy. Although a less accurate source of data, the self-reported statistics correlated closely with the hospital record data and if used in future studies could potentially decrease administrative time.

4.4.2 Patient Experience

The primary objective of the study was to evaluate patient experience of the IBD portal. Three inter-related themes were measured and included individual usage data, usability and patient satisfaction. Open comments provided greater context to the quantitative findings.

The results demonstrated that a majority of participants accessed the service, with two-thirds returning twice or more during the study period and were defined as regular users. A mean of 11.4 logins per user were recorded, with individual visits lasting on average over 5 minutes. Usage was highly variable. Approximately a quarter did not use the service despite enrollment, with an equal proportion classified as heavy users (>10 logins over the 6-months).

Despite the interface not being specifically designed for mobile or tablet devices, nearly half of all logins were through these devices. With further development of applications for these technologies, the usability could be further improved. Even though there are major differences between the demographics and patterns of renal and inflammatory bowel disease, as well as the technical changes made to the interface, usage data were similar between the two disease groups. [174]

Not all the interactive tools developed were used as widely as anticipated. A number of individuals commented that the symptom chart scores failed to represent disease severity. The care plan section was under-utilised and will require further revision and HCP training. Formal care planning is predominantly used in the primary care setting and further exploration is required to understand the potential benefit in IBD. Without formal review by

the IBD team, patient data entry will generally be carried out only by the most active participants.

The usability of the interface was shown to be excellent and exploring the open comments supported this finding. Participants using the service perceived improved support with approximately a third reporting the service helped with decision-making. A higher proportion than expected shared their records with family members. This could cause concern regarding data protection, although this trend has been observed in other cohorts. Patient satisfaction amongst users that responded was high, with a user response rate of 75%. The vast majority expressed a desire to continue using the IBD portal. Negative comments and concerns were less prevalent than anticipated, despite the technical issues that affected a proportion of users. Obviously satisfaction amongst non-responders is likely to be lower and needs to be considered when interpreting the findings.

Reviewing test results was the most common reason to login to the IBD portal, accounting for 23% of pages visited. The interpretation of the findings by patients without formal training and outside of the formal care setting often raises significant concerns. Without support, there is the possibility of misinterpreting results, leading to psychological distress. Results of no direct clinical relevance may heighten anxiety. [175] To mitigate this possibility and to help patient understanding, information links describing each test were created. This resource was also used frequently. Furthermore, when analysing the open comments, no concerns were raised amongst respondents in interpreting their results. Indeed, a general theme for even greater access to information was noted.

Another concern prior to adoption was the IBD nurses being overwhelmed with contacts, following the provision of easier access. Despite a statistically significant increase in IBD helpline contacts, the absolute volume was perceived to be manageable. Indeed, participants appeared to appropriately use the improved access. There was little evidence of frequent unnecessary contact. The majority of communication was for active disease. As

previously reported attrition was seen and the number of logins diminished each month (see table 13). This effect will require further evaluation over a longer timescale.

4.4.3 Predictors of use

Previous literature suggests younger, white and male patients are more frequent users of e-health technologies.

The exploratory analysis of factors predicting use was limited by the sample size. Further analysis after a longer time period may reveal further predictive factors other than disease activity. Gender is difficult to interpret given nearly a third of participants allowed partners to view their record.

Reviewing the raw data and exploring the predictors of use demonstrated that a number of confounding variables influenced use of the Portal. Logistic regression modelling was used to analyse data. A complication in the interpretation is that many of the parameters are correlated, and not discrete, e.g. engagement and knowledge. The results showed participants with active disease were more likely to use the service. This finding may help future uptake, by targeting recruitment in those with active disease.

Using a larger sample size and further qualitative analysis may provide greater clarity and context. Other reported studies have suggested the patient–HCP relationship may play an important role in determining use. [176] This is a further area that could be analysed in the future.

4.4.4 Healthcare Outcomes

The final objective of the study was to explore the potential impact of the IBD portal on a number of postulated behavioural and clinical outcomes. Previous studies have demonstrated that e-health applications have the potential to affect patient knowledge, engagement, adherence and health resource use. [152] The findings from this proof of

concept study on the impact on these outcomes were limited due to the observational nature of the study.

Following the initial intention-to-treat analysis, over the 6-month period, IBD knowledge significantly improved in the study population. Adherence and perceived support levels did not change, with a positive but non-significant change in patient activation.

To identify trends in the evolution of the proposed outcomes, further sub-group analyses were conducted comparing users to non-users. The raw data showed a positive trend in users knowledge, engagement and adherence compared to non-users. Univariate analysis revealed no significant changes in any of the proposed outcomes between the two groups.

After the analysis of factors predicting use, it was clear a number of confounding variables could have impacted upon changes in the measured parameters. A series of regression analyses were then conducted in an attempt to control for known possible variables. The results of this process showed the web-based care package was associated with an improvement in patient activation ($p=0.02$) and a close to significant improvement in perceived support ($p=0.06$), when comparing users to non-users. This difference was predominantly a result of a decrease in non-users engagement scores, with only a minimal increase in users. Many underdetermined factors other than use of the IBD portal could explain the differences between these two sub-groups but this observation requires further investigation. Currently, there is limited data available on the PAM within an IBD population and no data on the use of the LTC-6 questionnaire. In addition, the effects of a relapsing/remitting disease on longitudinal changes of patient engagement, has not been studied. Although attempts were made to control for disease activity as a confounding variable, further chronological data are required.

Following the regression analyses, an increase in IBD knowledge was not significantly different between users and non-users over the study period, with a positive trend observed. (B coefficient 0.72, $p=0.29$). Following regression, medication adherence showed no

significant difference between users and non-users. In retrospect, this finding is not surprising as many other factors are reported to influence changes. The majority of previous studies measuring the impact of patient access on adherence have also not observed major changes.

Exploring the health resource data on an intention-to-treat basis, demonstrated a non-significant trend ($p=0.47$) for an increase in total IBD outpatient appointments following introduction of the IBD portal. This trend was observed because of an increase in specialist nurse appointments. Univariate analysis comparing users to non-users, revealed a non-significant increase in outpatient appointments in the user-group prior to recruitment. However, the difference between the two groups became significant during the study period ($p<0.01$). After regression and controlling for known confounders, this trend in increased outpatient visits amongst the user group was still observed but the difference was statistically non-significant ($p=0.17$).

On an intention-to treat analysis, providing enhanced access to the IBD team through the portal was associated with a significant increase in patient contact through the IBD helpline (pre 0.85 contacts/patient/year versus. post 1.44 contacts/patient/year). Further sub-group analyses comparing IBD helpline contacts amongst the user-group confirmed this pattern, in both univariate and regression analyses. The method used for communication also changed significantly with a third of participants using the email facility provided compared to only one participant in the 6-months prior to recruitment.

No other significant changes were revealed when examining the other measured health resources. Whether this trend in resource use continued over a longer time period and was present in a controlled study, requires further evaluation.

4.4.5 Strengths and Limitations

4.4.5.1 Design

Although the findings from this pilot study are limited by the nature of its design, the results indicate further development work and assessment are warranted.

A strength of the study was the ability to successfully recruit a large number of participants. The recruited participants match closely to the hospital cohort in terms of disease characteristics and patient demographics. In fact, a number of patients were unable to be recruited due to time pressures, owing to the positive response at clinics. This relative ease of recruitment demonstrated the attractiveness of the intervention and led to the observed group representing a significant proportion of the target population. Only a small number of eligible recruits refused to participate. The major factor that limited recruitment was lack of access to the Internet. Although this small sub-group of patients may continue to diminish over time, it could be suggested that those without Internet access need the greatest support in managing their health.

Selection bias may have influenced the outcome findings with the exit response rate of 68.9%. Another limitation was the validity of the questionnaires used in measuring the proposed outcomes. A number of the measures have never, or only rarely been used in an IBD population.

The IBD Portal is intended to support patients and provide the skills and confidence needed for long-term control of disease. The short time period used for follow-up is a potential major weakness, whilst attempting to measure the impact of the application. It is clear that self-management support is intended to grow over time. To demonstrate a clear effect in 6-months is unrealistic, given this is only a small fraction of participants' life with the disease. We cannot foresee if the service has small incremental benefits over many years or in fact may have continuous attrition, leading to an ever-diminishing impact.

Due to time and budgetary constraints it was not possible to complete semi-structured interviews from a sample of users and non-users. Using this qualitative method would have provided a much greater understanding of the potential impact of the IBD portal. Changing to a qualitative open-questionnaire format did provide further context to the perceived benefits, concerns and reasons for non-use but to a less rigorous degree.

4.4.5.2 Environment

There are several limitations that need to be considered when interpreting the results of the study. The findings reflect the introduction of the service in a highly specialist centre with sufficient human, technical and organisational resources available to enable its development and evaluation. The pilot site provides tertiary IBD care and the disease characteristics of patients' differ from the general IBD population, with a higher proportion of more complex disease. Testing the service in other NHS Trusts will no doubt lead to new challenges and issues with implementation. Despite potential barriers to adoption in other settings, this single centre project has shown that the design and implementation of such a service is entirely feasible and can be achieved within a relatively short space of time.

The overall benefits of the system are highly related to the organisational structure of the whole IBD service, including clinic time and continuity. If there are weaknesses in the delivery of the service, use of the IBD portal will quickly fall apart. This has the potential to undermine the effectiveness of the system. For example, not all of the HCPs providing IBD care at the Trust used the system when reviewing enrolled patients. Participants that provided self-reported information may have been disappointed with a lack of acknowledgement and review of this data, affecting engagement.

A further limitation was that the author delivered the intervention under trial conditions. In order to corroborate the findings, the study would need to be repeated with a larger sample size and in routine clinical practice. Furthermore, with the potential trend of increased health resource use, a more detailed economic impact is required including consideration of reimbursement methods.

4.4.3.3 Maintenance

A potential challenge with e-health systems is the need to continuously update and fix 'bugs'. Constant work is required to monitor and test the system from a technical standpoint. The service needs to be easily adaptable to enable diverse IT systems, set up by local NHS Trusts, to operate within the service. Furthermore, the information links provided by the charity will need continuous revision to provide the latest advice about treatments.

It is not practical to maintain continuous records from the participants to monitor the various parameters measured, but it will be useful to periodically aggregate login data amongst the sample population. This data will provide greater information on use of the service over time.

4.5 Future work

At present there is a political drive to improve and modernise healthcare, through use of innovative IT systems. Therefore it was timely to construct the IBD portal and perform the proof of concept study. Although the results were limited by the nature of the study design, the positive impact on patient experience indicates further development work and evaluation is warranted. Future work could include a more detailed assessment of HCPs attitudes to the service. A number of studies have reported less enthusiasm amongst healthcare providers for patient portal applications. [177] Concerns are often expressed about increased workload and a perceived lack of time. A further area of potential interest is the impact of the patient-HCP relationship. For example, does a lack of trust between patients and providers result in increased or decreased use of a system such as this?

In general, implementation of such technologies inevitably raises questions of security, cost effectiveness, medico-legal issues, maintenance costs and responsibilities. Greater use of e-health may impact more on clinical staff, service delivery and consequently reimbursement needs. Addressing these challenges in an effort to improve patient satisfaction and safety is essential to fulfil the potential of such technologies.

Further prospective and more rigorously designed studies, exploring the clinical and cost effectiveness of e-health portals in IBD would help identify their potential value and benefit. Ideally, a large multi-centre cluster randomised controlled trial could be performed evaluating the IBD portal in the future.

4.6 Conclusion

The aim of this project was to develop, implement and test a web-based application to support adult IBD patients in managing this long-term condition. The design of the system was based on principles highlighted in other patient-focused e-health interventions. This involved sharing with patients' details of their treatment and monitoring. This new web-based care package was evaluated in a proof of concept study involving 183 participants over a 6-month period at Salford Royal Foundation NHS Trust.

The project demonstrated that the development of the intervention was both feasible and accepted by the majority of participants. High levels of satisfaction were reported by users, the vast majority expressing a desire to continue to use the service in future. The system was perceived to be clear, easy to use and helpful in supporting participants to manage their illness. The qualitative data provided further subjective evidence of benefits. Changes in healthcare outcomes were not clearly demonstrated and were limited by the study design. A number of potential confounders to changes in these parameters were identified.

The authors' priority was to develop a service that was practical to use, had limited impact on routine clinical practice and could potentially be rolled out across further sites. The design intended to provide a service that was simple to adopt, easy to maintain and required limited training. Its potential impact requires further investigation over a longer time period and in other NHS Trust healthcare settings.

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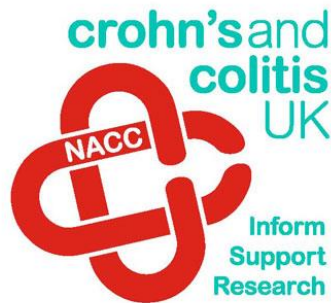
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Appendices

Appendix 1

IBD Patient Portal Specification for



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Salford Royal 
NHS Foundation Trust

23 April 2012

Development and testing the acceptability of an IBD specific Web-Portal

An interactive secure IBD web-portal that will provide both a personalised health record of their condition, email and text alerts for disease monitoring and a computer assisted self-management tool for patients appropriate for self-care.

Hypothesis for Research

We hypothesise that the web-portal will be beneficial to a majority of IBD patients and the outcomes of having an online personalized IBD record will be collected to provide evidence of acceptability, feasibility and operational use.

Once fully developed with strong patient-group support, participants will be randomised over a 6-month period, into either receiving access to the 'My IBD Portal' following training or to continue the normal standard of care and follow up. Further measures of its impact will be measured, including its effect on quality of life, knowledge, patient reported outcome measures and adherence to medications.

Why Salford?

This pilot study will be based at Salford Royal Foundation Trust, an ideal site for the web-portals development; having established patient electronic records for over 10 years and with a cohort of 1500 people with IBD. We aim to build upon previous extensive work around developing patient-orientated care and guided self-management. We envisage 'My IBD Portal' will provide a future model of care for many individuals with IBD.

Background to the Reasons for developing the IBD Patient Portal

Inflammatory bowel disease (IBD) is a chronic illness with often unpredictable symptoms that can have a profound effect on an individual's quality of life. Typically when IBD becomes acutely active, access to specialist healthcare advice is vital to initiate interventions to settle flare-ups. Any delays or barriers to this access may increase stress and worsen disease control.

The condition predominantly affects young people, with patients frequently diagnosed in teenage years or early twenties. This is often at a time when they are establishing their adult lives, either through education or finding their first job. Variations in IBD care were recognized through national auditing. In 2009 the IBD Standards working group produced a comprehensive document with the aim of ensuring IBD patients receive consistent, excellent care. Six standards were agreed after studying evidence with the aims to provide high quality care and deliver this locally. Maintain a patient-centred service, provide education and support, deliver evidence-based treatment, support research and use IT effectively, to optimise clinical management. This innovative proposal aims to enhance IBD care through these guiding principles.

This online programme aims to empower patients and promote a team approach to disease management, enabling patients to be better equipped to take a more active role in managing their IBD, whilst greatly improving communication between GPs and hospitals.

Following success, the aim would be to roll out the service to other hospitals with the necessary IT infrastructure, in an incremental fashion and to develop the site in conjunction with the developing National IBD registry. The aim is to provide a patient-focused database to help monitor IBD and improve future research recruitment, facilitating a better understanding of this often life-long chronic condition.

Portal Specific Requirements

- The web-portal needs to be hosted via a secure login with data encrypted in compliance with the strictest NHS information governance standards and in accordance with the Data Protection Act, 1998.
- Patients need to be able to access the web-portal securely via a login from any ISP in the world
- The web-portals functionality and design (look and feel) is a very high priority and the web lay out needs to be user-friendly with real thought put into the screenshots.
- The portal must have a clear structure and easy identifiable log-in.
- Compliant with NHS corporate style guidelines.
- Navigation through the system should be swift and responsive to user input and be used on Windows and Apple operating systems.
- The portal needs to be fully functional by 1st July 2012 for pilot testing prior to going 'live' on the 1st August 2012

Details of the Web-Portal Design

1. Specific datasets identified from previous patient-focus groups will be extracted from the Salford Royal Foundation Trust Electronic Patient Record (EPR) system 'Sunrise iSoft Clinical Manager'.
2. This data extraction will be published daily in a CSV file and will be available in excel or delimited format or can be marked up to XML.
3. The data will be made available via a secure IP address to the web-portal's successful developer.
4. The web-portal developer will take legal responsibility for the security and encryption of the data to standard that conform to the highest levels of the NHS information governance and Data Protection Act.
5. The EPR datasets will be used to populate the specific pages of the web-portal as highlighted below.
6. Data that is unable to be extracted from the EPR but deemed necessary for the delivery on an interactive web-portal, will be inputted within the secure web-portal by the trial participant, via a user-friendly interface.
7. The combined data and contacts with the IBD clinical team at Salford will be anonymised and stored on a secure database during the length of the research trial in order to evaluate the impact of the IBD specific web-portal. A full audit trail of any interactions with the web-portal will need to be available.
8. The IBD specific web-portal will combine both content and functionality to deliver relevant information in a patient-orientated format.
9. A high priority will need to be applied to the web design layout with a simplified user-friendly interface.
10. The following data will be made available to the web-portal developers via the EPR to populate the web-portal interface as described in the following sitemap.

Details of Web-Portal Datasets (area from within iSoft the data will be extracted)

1. Name (PAS)
2. Date of Birth (PAS)
3. NHS Number (PAS)
4. Hospital Number (PAS)
5. Address (PAS)
6. Postcode (PAS)
7. Telephone (PAS)
8. Email (Pt to enter)
9. Other conditions (Health Issues Record)
10. Diagnosis- Ulcerative colitis/Crohns Disease (IBD Flow Sheet)
11. Extent of disease- Proctitis, procto-sigmoiditis, left sided colitis, extensive colitis, ileal, ileo-colonic, colonic, gastric, oral, peri-anal. (IBD Flow Sheet)
12. Date of diagnosis (IBD flow Sheet)
13. Weight (Clinical Observations)
14. Vaccination record- Previous chickenpox, Hep B, Hep C, TB status (IBD Flowsheet)
15. Smoking history (IBD Flowsheet)
16. Family history- IBD and GI cancer (IBD Flowsheet)
17. Extra-intestinal manifestations- arthralgia, ankylosing spondylitis, uveitis, erythema nodosum, pyoderma gangrenosum, PSC (IBD Flowsheet)
18. Previous surgery – Yes/No and Date (IBD Flowsheet)
19. Name of GP, GI Consultant (PAS)

Medications

20. Allergies (Alert)

Investigations

21. Bloods- FBC, UE, LFT, CRP (Results section)
22. Faecal Calprotectin, stool cultures
23. Imaging- AXR, CXR, CT, MRI, SBFT, Dexa scan (EPR results)
24. Endoscopy- Colonoscopy (last Colonoscopy/next colonoscopy), sigmoidoscopy (EPR/Dates)

Care Plan

25. Clinic letters for Gastroenterology (Medisec)
26. Clinic letters from Surgery (Medisec)
27. Clinic letters from dietetics (Medicsec)

Data to be inputted by Participant to populate correct field of web interface.

1. Current Medications
2. Previous Medications- Date stopped and Reason

The secure web-portal will host the following web-pages:

Homepage

Welcome comment
Explain Trial Aims
How the data is secure
Contacts
Search Facility of site

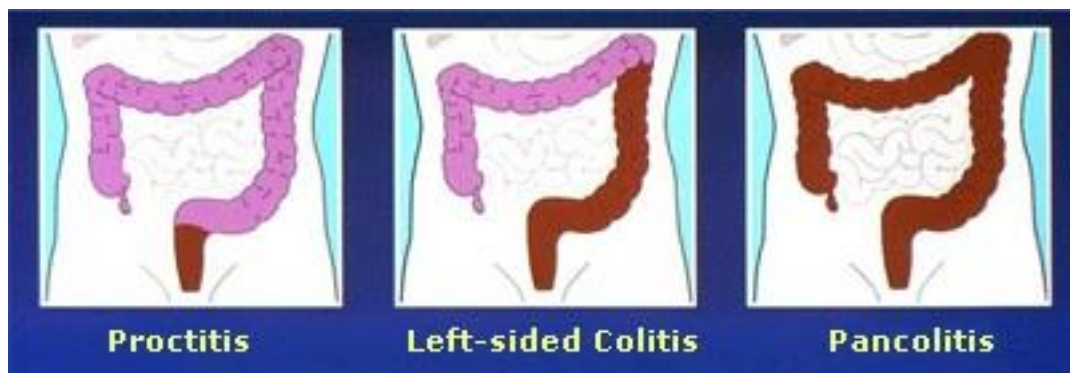
Tabs across Top for links

- a. Login
- b. My Details
- c. My IBD
- d. Medications
- e. Investigations
- f. Care Plan
- g. Calendar
- h. Nutrition
- i. Learning Centre
- j. Contact
- k. Help

See example of sitemap below.

The site will combine content from the datasets and incorporate the data into the relevant area of the site for viewing. Functionality will need to be built in to convert the data into diagrams where needed.

E.g. The extent of disease data from the extract will convert the data into a schematic diagram of this data in a pictorial representation.



a. Login

b. My Details

- Option to download passport style photo
- Name
- DOB
- Age
- NHS Number
- Address
- Telephone
- Email
- Disease Type
- Other Conditions

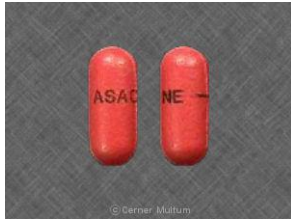
c. My IBD

- Disease type (Crohns/Ulcerative Colitis, IBD unspecified)
- Date of diagnosis
- Extent of disease in pictorial format. (This data combined with date of diagnosis could generate an alert in the calendar for surveillance endoscopies. i.e. Patients with history of 10 years of colitis need an alert to remind them they need a colonoscopy)
- Weight
- Current medications populated from more detailed list under medication section. This data would need to be populated from list entered by patient in medication tab (see d. Medications)
- Vaccination record
- Smoking history
- Family History (IBD and GI cancer)
- Extra-intestinal manifestations- arthralgia, ankylosing spondylitis, uveitis, erythema nodosum, pyoderma gangrenosum, PSC
- Surgical record- Date, type of operation. Hyperlink to surgery information
- Named GP, Consultant and IBD Nurse

d. Medications

- Patients will need to enter in this data, as the fields are not populated from the EPR extract.
- Current Medications will be created in a box format in the following categories
 - 5ASAs
 - Steroids
 - Immunomodulators
 - Biologics

- Drop down boxes to record drug, dose, frequency, date started. (Is it possible to show drugs in pictorial format when this data has been completed?)
- Hyperlink to information on taking enemas/suppositories



- Allergies

e. Investigations

- a. Bloods to include- FBC, UE, LFT, CRP with normal values when hovered over.
- b. Stool- Faecal Calprotectin and stool cultures
- c. Imaging- AXRs, CTs, MRIs, SBFT, Dexa scans- data on dates and reports.
- d. Endoscopy- type and date

f. IBD Care Plan

- Clinic letters
- What questions would I like answered- free text box to answer questions at appointments or via email.
- Timeline- This would combine data of date of diagnosis, previous medications, current medications, surgery record to present data in schematic diagram to show chronology of their disease.
- Self-management web-based tool to input data on the occurrence of a flare up and a knowledge management tool to provide advice about what to do with recording of symptoms that the data can be extracted.

UC Self-Management tool (linked to educational content)

Data will include start date of flare:

1. Frequency- Number of times bowel open a day, number of times bowels open at night
 2. Urgency- hurry, immediately, any accidental soiling
 3. Is there any Blood?- trace, occasional red blood , frank red blood seen
 4. How I feel- very well, slightly below par, poor, very poor, terrible
 5. Extra features- arthritis, uveitis, pyoderma gangerosum and erythema nodosum
- This will create a score and advice on medication, need for faecal calprotectin and when to seek medical advice

Symptom	Score
Bowel frequency (day)	
1—3	0
4--6	1
7--9	2
>9	3
Bowel frequency (night)	
1—3	1
4--6	2
Urgency of defecation	
Hurry	1
Immediately	2
Incontinence	3
Blood in stool	
Trace	1
Occasionally frank	2
Usually frank	3
General well being	
Very well	0
Slightly below par	1
Poor	2
Very poor	3
Terrible	4
Extracolonic features	1 per manifestation

R S Walmsley, R C S Ayres, R E Pounder, R N Allan A simple clinical colitis activity index GUT 1998;43:29-32

Crohn's self-management tool-

Based on the HBI to provide guidance on symptoms and treatment. Need to record data in visual analogue scale format that is user friendly. This will be combined with a digital self-guide management booklet and will record data by date and in a format that then can create a recorded report. Bloods and faecal Calprotectin may need to be incorporated.

General well-being	very well +0
	slightly below par +1
	poor +2
	very poor +3
	terrible +4

Abdominal pain	none +0
	mild +1
	moderate +2
	severe +3

Number of liquid stools per day	0-8+
---------------------------------	------

Abdominal mass	none +0
	dubious +1
	definite +2
	definite and tender +3

Complications	none +0
	arthralgia +1
	uveitis +1
	erythema nodosum +1
	aphthous ulcers +1
	pyoderma gangrenosum +1
	anal fissure +1
	new fistula +1
	abscess +1

g. Calendar (for Appointments with reminder function)

- Patient to self-input diary of appointments, blood monitoring schedule, Dexa scan and endoscopy surveillance with text/email links before appointments and alarm links triggered if data suggests they are late for bloods, endoscopy. This could show up flashing in IBD passport and linked to triggering an email to the Unit.

h. Nutrition

- Weight chart from clinical observations with date. Ideally need to create graph from data or possible to download graph from within graphs from the EPR.
- Height
- Current BMI- Calculation from weight and height (kg/height in m²)
- Food Diary- Pts to self-record food that may be causing an effect and can make a list of problem foods.

i. Learning Centre (Living with IBD/Education Links/Library and mention of research trials

- Hyperlinks to all relevant information on IBD from :
 - NHS choices
 - Crohns and Colitis, UK
 - NHS evidence
 - Crohns and colitis Foundation of America, USA
 - Abbott info on Adalumimab
 - MSD on infliximab
 - Research trials

j. Contacts, helpdesk and feedback

- Contact for Unit named
- FAQs
- Email contact
- Phone number for GI Unit and contracted IT company

k. Security

- The system must provide user logon ID & password security.
- The application should only allow records to be viewed across primary, secondary and tertiary care if patient consent has been granted and recorded.
- A security audit trail must be in place logging access to the system.
- The application must be secure to ensure no unlawful access to patient records.

- It must be possible for the security system to disable/enable specific functions based upon category group(s).
- There must be an automatic lock-out from the system after a defined period of inactivity. When the system is in lock-out status pressing save must require user re-authentication to unlock to that position, as opposed to closing down the application.

Education (as described above)

- Hyperlinks to Crohns and colitis UK starter pack in web format and other legitimate patient information tools need to be provided.
- This patient information needs to be available in easy to print format through a clear link to print.
- A web-based self- management tool needs to be developed with the ability for the patient to record data to help manage self-care with conversion of a previously validated paper IBD self-care book, formatted into a user – friendly web tool.
- The application must support various calculators and questionnaires including but not limited to CDAI, Harvey-Bradshaw index, QOL and IBDQ.

Alerts/Reminders

- Easy to use email and text function to contact the IBD team via the secure NHS email address at Salford Royal Foundation Trust.
- Consent from the patient to be contacted via SMS or email must be recorded.
- SMS or email appointment and repeat prescription reminders to be able to be sent to patients to decrease DNA's. These should be patient-initiated.

Data Outputs

- The system must generate an audit trail recording each action committed to the application (to individual field level is a must), the date and time and the user. The audit trail must be viewable by the system manager, but not amendable or editable in any way and the data contained within it must be available for extraction into reports.

Vision

We envisage that all patients with IBD can benefit from this future model of healthcare delivery. 'My IBD Portal' will:

- Provide patient information and education at all stages, increasing the individual patient's confidence to manage their condition.
- Improve communication between the patient, primary and secondary care in a seamless service.
- Enable primary care practitioners and patients to be rapidly informed about test results.
- Enable patients to input data about their health prior to appointments through a web-based format.
- Promote patient-guided self-management. This will obviate the need for unnecessary hospital appointments.

Our previous work around guided self-management demonstrated a reduction in scheduled outpatient appointments (and consequently time off school or work) as well as increased patient satisfaction. Psychological adaptation to diagnosis was also improved. It is envisaged that 'My IBD Portal' will surpass these findings and provide an improved and advanced model of patient-centred care.

Appendix 2

My IBD Portal Data and Security

How the Caldicott Guardian requirements are met

MY IBD Portal introduces a new information flow that contains patient identifiable information: from the hospital electronic medical record system 'iSoft Clinical Manager' to the website www.myibdportal.com so that patients can access relevant and appropriate elements of their patient record.

In the following pages we have outlined how this information flow is kept both confidential and secure.

We consider that these protocols are in keeping with national guidance, policy and law. Integral to our approach is the explicit informed consent of the patients involved.

How the data protection requirements are met

Following are statements of how the MY IBD Portal service meets the requirements of the Data Protection Act.

Fairly and lawfully processed	Subjects will give explicit consent in the manner agreed
Processed for limited purposes	The purposes are clearly defined in the consent form signed by patients
Adequate, relevant and not excessive	Only a selected, relevant dataset will be downloaded from the comprehensive clinical database kept in the Electronic Medical Record.
Accurate	Data is derived from the existing clinical information system which has ongoing policies for data quality assurance. Patients are able to report errors back to the research team.
Kept no longer than necessary	The longitudinal patient record will be held on the website accessed by the patient for their use only. If the patient wishes no longer to use the MY IBD Portal service then their patient record will be deleted from the website within 24 hours of the request, setting the data extract field to 'remove'.
Processed in accordance with the data subjects rights	Subjects will give explicit consent, as agreed with the Caldicott Guardian. The purpose for processing is for the patient to have access to their record
Secure	Security features are provided below.
Not transferred to countries without adequate protection	Registered users may view the selected data which they have permission to see from anywhere with internet access. Otherwise data will not be exported without additional consent from patients.

Justification and configuration

Requirement

A necessary feature of the Service is that patients are able to access their records outside of hospital or other NHS sites. Consequently, the solution when implemented involves sending extracts of information from the patient records of enrolled patients on at least a daily basis (rolling last 10 items from a changed record, or any new items if identifiable) from a clinical information system resident in the Hospital Trust. This data is sent, again on a daily basis, to a server hosted by a commercial Internet Service Provider. This data is then processed and made available through www.myibdportal.com

Security Features

The security precautions we have taken we believe are consistent with current policy. The system uses the security features of Renal Patient View and these were approved following consultation with the Security team at the NHSIA and with representatives of national authorities in Scotland and Wales. Since then we have taken note of further developments in data security standards in the NHS and more widely, and continue to keep this under regular review. The security features implemented in the solution are detailed below.

The key features are:

- Only registered users have access. Access for individual users is restricted to their data
- Data security policy is designed to ISO/IEC 27001/27002 (BS7799) standards
- The website data and applications are in a secure physical location with limited access
- Software, hardware and firewall controls used are catalogued to appropriate NHS standards
- All data transferred across networks is encrypted using a minimum of 256-bit encryption
- Security risks will be analyzed and reviewed, and any appropriate additional measures identified and implemented
- Security will be monitored and audited

Physical Security

The server is located at the Interxion data center in East London. More information can be found at: <http://www.interxion.com/Data-Centres/Facilities/>

The facility is state of the art with N+1 redundancy throughout, 24x7x365 security, climate protection and fire protection and water detection.

Within Hospital Trusts, the application server for the I,M&T Directorate at Salford Royal Foundation Trust and the PC used for encrypting patient data (if separate) is within the control of Trust IT staff.

Transport Security

Data is encrypted using PGP® solutions built on the recognized OpenPGP (RFC 2440 & 3156) standard. A timed routine extracts data from the Electronic Medical Record application server. The same server within the I, M&T Directorate ('gateway PC') encrypts the data. This is then sent using sFTP to the IP address of the commercially hosted website. The data is then decrypted on the root server and the website database populated.

Application Security

Once explicit patient consent has been given, a field is set on the Hospital IT system to 'include' ('remove' and 'suspend' are other options). The demographic data for the patient must include NHS/CHI Number. The system administrator then creates a login for the patient. This username and password is given to the patient or sent to their registered address.

The patient subsequently uses the username and password but must change the password on first use so that it is not known to members of staff on the unit. The patient only sees his/her data.

If the patient subsequently decides to no longer use the website or suspend their use of the website, then a research system administrator sets the field to 'remove' or 'suspend'. In the case of remove, the patient data is deleted from the website at the time of the next data upload. In the case of suspend, no new data is sent to the website. In both cases, the system administrator disables the login and password on behalf of the patient.

The developer of the software, Worth Solutions Ltd., is the system administrator for the website and has root server permissions. Worth Solutions is subject to a Service Level Agreement with Salford Royal Foundation Trust. Any additional contractors are subject to the same agreement. The application security features applied to the website:

- SSL implemented
- IP tables firewall implemented
- Unnecessary services shutdown
- Inward messages via sFTP
- Software tools updated to include latest patches: pertinent software includes httpd, Tomcat, openssh, openssl, mysql, Java.

Penetration Testing

Security testing is undertaken by an independent external penetration testing company. Repeat testing is undertaken periodically, and after every major software upgrade. A copy of the most recent security report is available on request; please contact us if you have any questions.

Port Request data

Outgoing files from Hospital Trusts are sent via sFTP (port 22) to IP 85.118.234.56.

Appendix 3

Department of Gastroenterology
IBD Services
Stott Lane
Salford
M6 8HD
Tel no: 0161 2061442
Email: chris.calvert@srft.nhs.uk

**Assessing the impact of a web-based care package to in adults with
inflammatory bowel disease (IBD)**

DEAR SIR / MADAM,

I would like to ask you to consider taking part in a research study my colleague Dr Chris Calvert is undertaking. We have developed a new computer based system called 'My IBD Portal' that may be of use to patients, like yourself who have inflammatory bowel disease.

Dr Calvert is running a study designed to see if this system is acceptable and useful and how it might be improved before it is put into wider use.

Before you decide, it is important for you to understand why the research is being done and what the study will involve. I have attached an information leaflet with this letter providing the reasons for the study and what involvement would be required from you. Please take time to read the information carefully. If you are interested in taking part or have any further questions please contact the lead researcher at the address: chris.calvert@srft.nhs.uk or on the telephone number on the top of the letter.

If you are interested in participating in this study, we ask that you attend your outpatient clinic **30 minutes before your next scheduled appointment so that we can have further discussion about participation**. We appreciate your time and thank you for reading the attached information.

Many thanks,



Dr Andrew Robinson, Consultant Gastroenterologist

Appendix 4

Patient information sheet

Department of Gastroenterology
IBD Services
Stott Lane
Salford
M6 8HD
Tel no: 0161 2061442
Email: chris.calvert@srft.nhs.uk

Assessing the impact of a web-based care package in adults with inflammatory bowel disease (IBD)

Invitation

On behalf of the IBD team at Salford Royal Foundation NHS Trust, we would like to invite you to take part in a research study, that we believe may be of interest to you. To help you understand what the research is about, we are providing you with the following information.

Part 1 explains the purpose of the study, to help you fully understand what you would need to do if you agree to take part.

Part 2 gives more detailed information about the conduct of the study.

If you have any questions after reading this information sheet, please contact us and we will do our best to explain and provide any further information you need.

Part 1

The purpose of the study

This study is designed to find out more about the usefulness and acceptability of a new secure web-based care package that aims to improve the way inflammatory bowel disease is managed.

The web package is secure and has been designed with the support of people with inflammatory bowel disease. It provides users with; online access to relevant blood tests, clinic letters, and symptom-monitoring charts, personalised to your condition. Accredited information is also provided, as well as secure email contact with the hospital.

Approximately 150 people will be needed for the study. We want to find out if the new system offered is acceptable, useful and improves how people feel about the way they manage their condition.

We need to measure how often the site is used, who uses it, is it useful and whether it makes you feel more involved in your care. We also need to look into whether the care package has an impact on your knowledge about inflammatory bowel disease and how often you are in contact with the hospital and your GP.

Why have I been invited?

You have invited to take part in this study because you are a patient of the IBD service at Salford Royal Foundation NHS Trust and are due to have an outpatient appointment in the next few months. This study will look at:

- Ways to make information about your condition more convenient to you
- Ways to help you manage your condition better

Do I have to take part?

It is entirely up to you to decide whether to take part in the study. Below we will describe the study in more detail, to provide you with more information. If you agree to take part, we will then ask you to sign a Consent Form when you attend clinic. You are free to withdraw at any time from the study, without giving a reason. This would not affect the standard of care or medical treatment you receive.

What happens if I decide to take part?

- You will be in the study for around 6 months; all people who agree to take part in the study will be given access to the new secure Internet IBD package at the start of the study.
- If you decide to take part, you will be asked to attend your outpatient clinic for your IBD **30 minutes** earlier than the scheduled appointment to answer any further questions you may have, sign a Consent Form, complete a questionnaire and to be given secure access to the Internet IBD package.
- The questionnaire will ask questions about your disease, medications, how you feel in managing your IBD and your knowledge.
- We will ask you to commit to using the website once a month to record your symptoms and to keep the information up-to-date.
- We will ask you to complete **one** further questionnaire. This will be sent after 6 months from the start of the study.
- Around twelve of the users of the Internet IBD package will be invited for an interview at the hospital that will last 30-60 minutes to seek people's views on the new service.

Expenses and Payments

You should not incur any additional costs as a participant in the study. Those invited for an interview at the end of the study will be offered travel expenses to cover transport and parking at the hospital.

What will I have to do?

- For the study to be successful we will need you to complete the questionnaires before your appointment and after 6 months.
- After being provided access to the Internet IBD Package you will be expected to use the site on a monthly basis to record your symptoms and keep a list of your medications up-to-date.

- If you are invited to be interviewed, we would ask that you attend the hospital at a mutually convenient time and that you participate in a face to face interview relating to your experiences of using the system. This interview would be digitally recorded and we would seek permission for this in addition to the consent that you have already given.

What are the possible disadvantages, inconveniences and risks in taking part?

We hope that the new service provides a better way to find information about the condition and to manage your disease. However it is important that you are aware of the possible risks and inconveniences.

Privacy and Security

One of the main concerns will be the security of the information.

To protect your information, we use two methods:

- Every time any information is sent across the Internet, it is coded (encrypted). The codes used are almost impossible to break.
- Everyone that uses the new IBD web-based package will have their own username and password. The first time you use the service, you will be asked to change your password, so that only you know it. It is important to keep your password safe, but you can choose to share your password with other people that you trust. You can change your password at any time if you think someone else may have discovered it.

Together these create a very safe system. However if someone learnt your password or if you are very worried about part of your health record been used in this way, you should not take part in the study. Please note:

- The system will only show **some** of the information that is in your notes and in the computer system at the hospital.
- Only staff directly looking after your IBD will be able to see your information.
- None of your information goes onto the secure Internet site unless you sign up to the study.
- You can choose to leave the study at any time and your information from the site will be removed.
- We will do our best to be sure that all of the information we hold is accurate. But if you spot any errors, you can ask for changes to be made.

Technology Difficulties

Web-based systems are occasionally prone to 'unexpected events' There is a small risk that there is a problem with the Information and Technology (IT), meaning the Service does not fully function for part of the study.

Inconveniences

If you take part in the study we would ask that you access the service at least once a month. You will also be asked to complete a questionnaire after 6 months. It may take up to 30 minutes to complete this. You may also be asked to return to hospital to attend an interview. These would be in addition to the standard care that you receive.

What are the possible benefits of taking part?

We do not envisage that there will be significant direct benefits for you at this stage as the system is being developed. However, you will have access to information and advice relating to your condition.

What happens when the research stops?

When the study ends we hope to continue to offer the service to IBD patients at Salford Royal Foundation Trust. The results from the study will help decide on the benefits of this new package of care and what needs to be improved.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. Further details are included in Part 2.

Part 2**What will happen if I don't want to carry on with the study?**

- If you decide to withdraw from the study this will not affect your medical care in any way.
- If you are using the IBD Internet package and decide you want your information removed from the secure site, this data will be removed on your request.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Please contact Dr Chris Calvert by email chris.calvert@srft.nhs.uk or telephone on 0161 2061442. You can also speak to Rachel Georgiou, Associate Director of Research and Development, Salford Royal NHS Trust. Rachel.georgiou@manchester.ac.uk, tel. 0161 206 7032

If you remain unhappy and wish to complain formally, you can do this through the normal NHS complaints mechanism of the Patient Advice and Liaison Service (PALS). The local contact number is 0161 2062003 or email pals@srft.nhs.uk

Will my taking part in the study be kept confidential?

If you agree to take part in the study all information collected will be strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised. The Internet package has been approved by Salford Royal Foundation Trust Information Governance Committee as secure and meets the requirements for NHS security and the Data Protection Act, 1998. In order to check how the study is being conducted it may be necessary for staff from the R and D department, other approved organisations or regulators to have access to your records and the information from the study.

Involvement of your General Practitioner (GP)

Your GP will be informed by letter, if you agree to take part in the study. Your GP Practice may be contacted at the end of the study to review how often people have needed to visit their GP Practice about their condition and their medical prescriptions.

What will happen to the results of the research study?

We will aim to publish the results of the study after completion of the study. Feedback on the Internet package will be used to improve how it works for people in the future. The study is being conducted as part of a higher degree for Dr Calvert.

Who is organising and funding the research?

The study has been organised and sponsored by the Research and Development Department at Salford Royal Foundation NHS Trust. The study is funded by the charity Crohn's and Colitis, UK, registered in England Number 1117148.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by North Riverside Research Ethics Committee.

Further information and Contact Details

If you have any further questions, please contact :

Dr Chris Calvert, Clinical Research Fellow

Address: Office D 424,
3rd Floor Clinical Science Building,
Salford Royal Foundation Trust,
Salford,
M6 8HD

Email: chris.calvert@srft.nhs.uk

Phone: 0161 2061442

Further Details

Further details are also available on CIT Scientist website, please see <http://www.citizenscientist.org.uk/>

Appendix 5

Assessing the impact of a web-based care package in adults with IBD

Baseline Questionnaire

Dear Participant,

I would be very grateful if you would complete this questionnaire.

Please answer all the questions.

If you have any problems completing this form, please contact by email: chris.calvert@srft.nhs.uk or via the telephone on 061 2061442 and we will be happy to assist.

All information you provide will be treated with the strictest confidence.

Many thanks for your help,



Dr Chris Calvert
Clinical Research Fellow,
Room D424 Research Department,
Clinical Sciences Building,
Salford Royal Foundation Trust,
Stott Lane,
Salford,
M6 8HD

Section A: PERSONAL DETAILS

(Please tick the boxes)

1: What is your age? Gender: Male Female

2: How old were you when you left full time education?

3: Do you have a degree or equivalent professional qualification?

Yes No

4: Which of these best describes your current work situation?

In paid work (including part-time and self-employed) <input type="checkbox"/>	Looking after the family home <input type="checkbox"/>
Unemployed <input type="checkbox"/>	In full-time education or training <input type="checkbox"/>
Retired <input type="checkbox"/>	Voluntary work <input type="checkbox"/>
Unable to work because of long-term disability or ill health <input type="checkbox"/>	Other (please specify) <input type="checkbox"/>

If other please describe _____

5: Over the last 12 months, have you needed to take time off work or study for your IBD? (include all contact with the GP, hospital visits and sickness)

No Yes → If Yes, how long would you estimate ___ hours or ___ Days

6: Are you a member of the Crohn's and Colitis UK (NACC)?

No Yes

7: What are your current medications?

If you are taking any complementary / alternative treatments please list them here as well

Medication Name	How often do you take it in a day	Dose of Medication if known
1.		
2.		
3.		
4.		
5.		
6.		

8: Do you have any drug allergies or intolerances?

No Yes

Section B: YOUR IBD

If Yes, which drugs:

1: What type of IBD do they have?

Crohn's disease Ulcerative Colitis Unknown type

2: What year were you diagnosed with IBD? please estimate

3: Have you needed any operations for your IBD?

No Yes If Yes, can remember the year & type of your operation(s)

Operation(s):

4: Does your IBD affect any parts of your body away from your gut?

None Skin Joints Eyes

5: Have any of your relatives got either Crohn's disease or ulcerative colitis?

No Yes If Yes, which relative e.g. Sister, Uncle _____

6: Are you:

A current smoker A previous smoker Someone who has never smoked

7: Have you visited your GP about your IBD in the last 12 months?

No Yes If Yes, how many visits have you made _____

8: Other than this visit, have you needed to be seen at the hospital for your IBD in the last 12 months?

No Yes If Yes, how many visits have you made _____

9: Have you contact the IBD Helpline in the last 12 months?

No Yes If Yes, how many calls have you made _____

10: Have you had a flare-up in the last 12 months?

No Yes If Yes, how many visits have you made _____

11: To manage your last flare-up what did they do? (please tick multiple boxes if needed)

Contacted GP	Started treatment myself	Rang the hospital IBD helpline	Didn't get treatment	Did something else
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If they did something else please can you explain:

Section C: HOW YOU FEEL ABOUT MANAGING YOUR HEALTH

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say. If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I am confident I can help prevent or reduce problems associated with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell whether I need to go to the Doctor or whether I can take care of a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can tell a doctor's concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I understand my health problems and what causes them	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I know what treatments are available for my health problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12. I am confident I can figure out solutions when new problems arise with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13. I am confident that I can maintain lifestyle changes, like eating right and exercising during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Section D: INFORMATION AND IBD

1: Do you feel you have received enough information about IBD? (please circle)

No Information 1 2 3 4 5 6 7 8 9 10 Full information

2: Do you ever find health information or leaflets difficult to understand? (please circle)

All of the time 1 2 3 4 5 6 7 8 9 10 None of the time

3: How much knowledge do you feel you have about IBD? (please circle)

No knowledge 1 2 3 4 5 6 7 8 9 10 Complete knowledge

4: Do you use the Internet? (please tick the box)

Yes No (If No, please go directly to next page-section C)

If Yes, how often do you use it on average? (please insert number)

- (i) _____ hours a day
- (ii) _____ hours a week
- (iii) _____ hours a month

5: How do you access the Internet? (please tick multiple boxes if you use more than one device)

Home computer	Work computer	Laptop	Mobile Phone	Tablet / iPad	Other
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6: How confident do you feel in using the Internet? (please circle)

Not at all confident 1 2 3 4 5 6 7 8 9 10 Extremely confident

4: Have you ever used the Internet to search for IBD information?

Yes No

If yes, how much do you trust the health websites you have visited? (please circle)

No trust at all 1 2 3 4 5 6 7 8 9 10 Total Trust

Section E: HOW YOU FEEL ABOUT YOUR IBD

For the following 8 questions please circle the number that best corresponds to your views.

1. How much does your IBD affect your life?

1	2	3	4	5	6	7	8	9	10
No affect at all									Severely affects my life

2. How long do you think your IBD will continue?

1	2	3	4	5	6	7	8	9	10
A very short time									Forever

3. How much control do you feel you have over your IBD?

1	2	3	4	5	6	7	8	9	10
Absolutely no control									Extreme amount of control

4. How much do you think your treatment can help your IBD?

1	2	3	4	5	6	7	8	9	10
Not at all									Extremely helpful

5. How much do you experience symptoms from your IBD?

1	2	3	4	5	6	7	8	9	10
No symptoms at all									Many severe symptoms

6. How concerned are you about your IBD?

1	2	3	4	5	6	7	8	9	10
Not at all concerned									Extremely concerned

7. How well do you feel you understand your IBD?

1	2	3	4	5	6	7	8	9	10
Don't understand at all									Understand very clearly

**8. How much does your IBD affect you emotionally?
(e.g. does it make you angry, scared, upset or depressed)**

1	2	3	4	5	6	7	8	9	10
Not at all affected emotionally									Extremely affected emotionally

Section F: YOUR MEDICATIONS

1: Questions about your IBD medications

We know it is often not easy to take medications, especially when feeling well.

Please circle the answers to indicate how you are in taking your IBD medications

Do you sometimes forget to take your medication?	Yes	No		
People sometimes miss taking their medications for reasons other than forgetting. In the last 2 weeks, was there any day when you did not take your medication?	Yes	No		
Have you ever stopped taking your medications or decreased the dose without first warning your doctor because you felt worse when you took them?	Yes	No		
When you travel or leave the house, do you sometimes forget to take your medications?	Yes	No		
Did you take your medication yesterday?	Yes	No		
When you feel your IBD is controlled, do you sometimes stop taking your medications?	Yes	No		
Taking medications everyday is a real inconvenience for some people. Have you ever felt stressed for strictly following your IBD treatment plan?	Yes	No		
How often do you have difficulty to remember taking all your IBD medications?				
Rarely / Never	Once in a while	Sometimes	Usually	Always

Section G: YOUR CARE AND SUPPORT

Think about the last 12 months when you have received care and support for your IBD

1: Did you discuss what was most important for you in managing your IBD?

Not at all

Rarely

Some of the time

Almost always

2: Were you involved as much as you wanted to be in the decisions about your care or treatment?

Not at all

To some extent

More often than not

Almost always

3: How would you describe the amount of information you received to help you manage your health?

I didn't receive any information

I rarely received enough information

I sometimes received enough information

I always received enough information

4: Have you had enough support from the hospital and your GP to help you manage your IBD?

I have had no Support

I have not had enough support

I have sometimes felt supported

I have always felt supported

5: Do you think the support and care you get is joined up and working for you?

Never

Rarely

Sometimes

Always

6: How confident are you that you can manage your own health?

Not at all confident

Not too confident

Somewhat confident

Very confident

Section H: YOUR KNOWLEDGE ABOUT IBD

These questions have previously been used to look at an individual's general knowledge of inflammatory bowel disease (IBD). They are known to be difficult. Answers will help us know which topics we may need to provide more information to help make treatment more effective. Please answer them as best as you can by **ticking only one answer for each question**. Thank you.

1. People with inflammatory bowel disease are never allowed to eat dairy products:

- a) True
- b) False
- c) Don't know

2. Elemental feeds are sometimes used to treat Crohn's disease and ulcerative colitis. They:

- a) Always contain a lot of fibre
- b) Are very easy to digest
- c) Come in the form of tablets
- d) Don't know

3. Proctitis:

- a) Is a form of colitis that affects the rectum or back passage only
- b) Is a form of colitis that affects the whole of the large bowel
- c) Don't know

4. Patients with inflammatory bowel disease are probably cured if they have been symptom free for 3 years:

- a) True
- b) False
- c) Don't know

5. Inflammatory bowel disease runs in families:

- a) True
- b) False
- c) Don't know

6. Patients with inflammatory bowel disease can get inflammation in other parts of the body as well as the bowel:

- a) True
- b) False
- c) Don't know

7. A fistula:

- a) Is an abnormal track between 2 pieces of bowel or between the bowel and skin
- b) Is a narrowing of the bowel which may obstruct the passage of the contents
- c) Don't know

8. The terminal ileum:

- a) Is a section of the bowel just before the anus
- b) Is a section of the bowel just before the large intestine
- c) Don't know

9. During a flare up of inflammatory bowel disease:

- a) The platelet count in the blood rises
- b) The albumin level in the blood rises
- c) The white cell count in the blood falls
- d) Don't know

10. Steroids (such as prednisolone/prednisone/budesonide/hydrocortisone):

- a) Can only be taken by mouth
- b) Can be given in the form of an enema into the back passage
- c) Cannot be given directly into the vein
- d) Don't know

11. Immunosuppressive drugs are given to inflammatory bowel disease patients to:

- a) Prevent infection in the bowel by bacteria
- b) Reduce inflammation in the bowel
- c) Don't know

12. Sulphasalazine:

- a) Controls the level of sulphur in the bloodstream
- b) Can be used to reduce the frequency of flare ups
- c) Cannot be used to prevent flare ups
- d) Don't know

13. An example of an immunosuppressive drug used in inflammatory bowel disease is:

- a) Sulphasalazine
- b) Mesalazine
- c) Azathioprine
- d) Don't know

14. If a woman has Crohn's disease:

- a) She may find it more difficult to become pregnant
- b) She should not have children
- c) Her pregnancy will always have complications
- d) She should stop all medication during her pregnancy
- e) Don't know

15. Which one of the following statements is false?

- a) Ulcerative colitis can occur at any age
- b) Stress and emotional events are linked with the onset of ulcerative colitis
- c) Ulcerative colitis is least common in Europeans and North Americans
- d) Patients with ulcerative colitis have an increased risk of developing bowel cancer
- e) Don't know

16. Male patients who take sulphasalazine:

- a) Have reduced fertility levels that are reversible
- b) Have reduced fertility levels that are not reversible
- c) The drug does not have any effect on male fertility
- d) Don't know

17. The length of the small bowel is approximately:

- a) 2 feet
- b) 12 feet
- c) 20 feet
- d) Don't know

18. The function of the large bowel is to absorb:

- a) Vitamins
- b) Minerals
- c) Water
- d) Don't know

19. Another name for an ileorectal anastomosis operation with formation of a reservoir is:

- a) Purse
- b) Pouch
- c) Stoma
- d) Don't know

20. If a part of the bowel called the terminal ileum is removed during surgery the patient will have impaired absorption of:

- a) Vitamin C
- b) Vitamin A
- c) Vitamin B12
- d) Don't know

21. Patients with IBD need to be screened for cancer of the colon. Which one of the following statements about screening is false?

Screening should be offered to all patients with ulcerative colitis:

- a) Which affects only the rectum
- b) Which has lasted for 8–10 years
- c) Which started before the age of 50
- d) Don't know

22. There are millions of tiny "hairs" in the small bowel to increase the absorptive surface. They are called:

- a) Villi
- b) Enzymes
- c) Bile salts
- d) Crypts
- e) Don't know

23. Which one of the following is not a common symptom of inflammatory bowel disease? a)

- Abdominal pain
- b) Change in bowel habit
- c) Headache
- d) Fever
- e) Don't know

24. If a child has inflammatory bowel disease; he/she probably will not:

- a) live beyond the age of 45
- b) be as tall as his or her friends
- c) be as intelligent as his or her friends
- d) Don't know

Section I: FURTHER DETAILS

Please write in today's date below

Day Month Year

To contact me about future questionnaires for this study after 6 months:

I would prefer to be emailed the follow-up questionnaire

I would prefer to be posted the follow-up questionnaire

If you have any comments on the questionnaire or any other aspects of the research, please write them here. Once again many thanks for completing this questionnaire.

If there are any problems completing this form, please email me at: chris.calvert@srft.nhs.uk

Appendix 6 (information Leaflet for My IBD Portal)

How does it work?

My IBD Portal takes information from your IBD unit's computer system at least once a day and links it to useful information about your IBD and its treatment. Your blood tests and clinic letters are among some of the items for you to view. See the inside picture for more details.

Who can read it?

As well as you, your GP can and some staff from your IBD unit will also have access. If you want you can share your password with relatives or if you want to show your information to others healthcare professionals or become ill on holiday, you can access your record anywhere in the world.

Is it safe?

It is very safe. It uses security systems like the ones used for internet shopping. If you think someone may have discovered your password, you can change it at anytime. Your information only goes onto My IBD Portal at your request and you can have all the information removed if you change your mind. If you do not want to use the system, it will not affect your records held at the hospital or your care.

How do I get to join?

My IBD Portal is being tested as part of a research trial to assess its impact within the NHS. If you would like to consider enrolling in the study contact us below.

What if I do not use the internet?

Maybe you have a friend or family member that does? Often internet access is available in public libraries. Please ensure if using a public computer that you always safely log out of the portal and close the web browser.

What does it cost?

It is free for patients and the early development of this project has been funded by Crohn's and Colitis, UK.



Would you like to:

- Find out your latest bloods and read your clinic letters?
- Create an IBD plan to help support and manage your condition
- Read online information about your IBD and treatment
- Monitor your symptoms and get advice

www.myibdportal.com

Where can I find out more?

For more information visit:
www.myibdportal.org/about-the-project

Contact us at: myibdportal@srf.nhs.uk

Getting Started with My IBD Portal

My Details contains basic information from your hospital records

My IBD contains a summary of your IBD with tailored information links

Enter Symptoms helps you chart your disease over time and provides advice



Care Plan helps you think about how you are managing your IBD, where you may need more support and can provide a plan to improve your health

Diagnostics lists your previous imaging and endoscopy tests and provides useful information about investigations

Contact provides a secure link to email the hospital about your health or any other questions

Information provides reliable and trusted links for IBD resources

Letters provides the latest clinic letters from your IBD unit

Results helps you monitor your latest blood tests from the hospital and you can click for more info over the links

Nutrition provides helpful links and a personal food diary

Date	Meal	Time	Notes	Weight	Temp
08/12/12	10:30	10:30		65	37.5
09/12/12	10:30	10:30		65	37.5
10/12/12	10:30	10:30		65	37.5
11/12/12	10:30	10:30		65	37.5

Medicines helps you keep your own personal record of your current and previous treatment

- **Login** to get started at www.myibdportal.com
- Click on the tabs to navigate the site
- Click on the links to find further info
- Monitor your symptoms and manage your IBD
- Read your letters and access your latest bloods
- Contact the IBD unit

Appendix 7a

Assessing the impact of a web-based care package in adults with IBD

Exit Questionnaire

Dear Participant,

I would be very grateful if you would complete this questionnaire.

Please answer all the questions.

If you have any problems completing this form, please contact by email: chris.calvert@srft.nhs.uk or via the telephone on 061 2061442 and I will be happy to assist.

All information you provide will be treated with the strictest confidence.

Many thanks for your help,



Dr Chris Calvert
Clinical Research Fellow,
Room D424 Research Department,
Clinical Sciences Building,
Salford Royal Foundation Trust,
Stott Lane,
Salford,
M6 8HD

Section A: USING 'MY IBD PORTAL'

1: Overall, how satisfied were you with 'My IBD Portal'? (please circle)

Very satisfied Satisfied Dissatisfied Very dissatisfied

2: How would you rate the content of the information on the site? (please circle)

Very Clear Clear Unclear Very Unclear

3: Do you think using 'My IBD Portal' helps support you to manage your IBD?

No Yes

Please comment:

4: Did you use My IBD Portal prior to any: (please tick)

Hospital appointments? GP Visits?

5: Did you allow anyone else to use the Portal?

No Yes If Yes who? (Family member/GP/Friend)

6: Please answer the following questions to assess the way the Portal functions

Questions about My IBD Portal	Strongly disagree	<u>(please circle)</u>			Strongly agree
1. I thought the IBD Portal was easy to use	1	2	3	4	5
2. I found the IBD Portal unnecessarily complex	1	2	3	4	5
3. I think that I would like to continue to use the IBD portal frequently	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use the system	1	2	3	4	5
5. I found the various functions in the IBD Portal were well integrated.	1	2	3	4	5
6. I thought there was too much inconsistency in the IBD Portal	1	2	3	4	5
7. I would imagine that most people would learn to use the IBD Portal very quickly	1	2	3	4	5
8. I found the IBD Portal very cumbersome to use	1	2	3	4	5
9. I felt very confident using the IBD Portal	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with the IBD Portal	1	2	3	4	5

Section B: USING 'MY IBD PORTAL'

1: Do you have any concerns about the site?

No Yes

If Yes, please comment:

2: Has using the Portal helped you make any decisions about your treatment?

No Yes

Please comment:

3: Do you want to continue to use 'My IBD Portal' in the future?

No Yes

4: What are the most useful features of the service?

5: What are the least useful features of the service?

6: Are there any changes to the Portal that you would you like to see?

7: Are there any other ways we could improve the care for people with IBD?

If you have any further comments on 'My IBD Portal' or any other aspects of the research please write them in the comment box below.

Section C: HOW YOU FEEL ABOUT MANAGING YOUR HEALTH

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say. If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I am confident I can help prevent or reduce problems associated with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell whether I need to go to the Doctor or whether I can take care of a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can tell a doctors concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I understand my health problems and what causes them	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I know what treatments are available for my health problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12. I am confident I can figure out solutions when new problems arise with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13. I am confident that I can maintain lifestyle changes, like eating right and exercising during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Section D: FLARE-UPS & MEDICATIONS

1: Have you had a flare up in the last 6 months?

No Yes →If Yes, how many flares have you had in 6 months _____

2: When was your last flare-up?

3: What did you do about it?

4: Have you visited your GP in the last 6 months about your IBD?

No Yes →If Yes, how many visits have you made _____

5: Over the last 6 months have you needed to take time off work or study for your IBD?
(include all contact with the GP, hospital visits and sickness)

No Yes →If Yes, how long would you estimate ___ hours or ___ Days

6: Have you made any changes to your IBD medications in the last 6 months?

No Yes →If Yes, what changes have you made?

7: Questions about your medications

We know it is often not easy to take medications, especially when feeling well.

Please circle the answers to indicate how you are, in taking your IBD medications

Do you sometimes forget to take your medication?	Yes	No		
People sometimes miss taking their medications for reasons other than forgetting. In the last 2 weeks, was there any day when you did not take your medication?	Yes	No		
Have you ever stopped taking your medications or decreased the dose without first warning your doctor because you felt worse when you took them?	Yes	No		
When you travel or leave the house, do you sometimes forget to take your medications?	Yes	No		
Did you take your medication yesterday?	Yes	No		
When you feel your IBD is controlled, do you sometimes stop taking your medications?	Yes	No		
Taking medications every day is a real inconvenience for some people. Have you ever felt stressed for strictly following your IBD treatment plan?	Yes	No		
How often do you have difficulty to remember taking all your IBD medications?				
Rarely / Never	Once in a while	Sometimes	Usually	Always

Section E: HOW YOU FEEL ABOUT YOUR IBD

For the following 10 questions please circle the number that best corresponds to your views.

1. How much does your IBD affect your life?

No affect at all	1	2	3	4	5	6	7	8	9	10	Severely affects my life
---------------------	---	---	---	---	---	---	---	---	---	----	--------------------------------

2. How long do you think your IBD will continue?

A very short time	1	2	3	4	5	6	7	8	9	10	Forever
----------------------	---	---	---	---	---	---	---	---	---	----	---------

3. How much control do you feel you have over your IBD?

Absolutely no control	1	2	3	4	5	6	7	8	9	10	Extreme amount of control
--------------------------	---	---	---	---	---	---	---	---	---	----	---------------------------------

4. How much do you think your treatment can help your IBD?

Not at all	1	2	3	4	5	6	7	8	9	10	Extremely helpful
---------------	---	---	---	---	---	---	---	---	---	----	----------------------

5. How much do you experience symptoms from your IBD?

No symptoms at all	1	2	3	4	5	6	7	8	9	10	Many severe symptoms
--------------------------	---	---	---	---	---	---	---	---	---	----	-------------------------

6. How concerned are you about your IBD?

Not at all concerned	1	2	3	4	5	6	7	8	9	10	Extremely concerned
-------------------------	---	---	---	---	---	---	---	---	---	----	------------------------

7. How well do you feel you understand your IBD?

Don't understand at all	1	2	3	4	5	6	7	8	9	10	Understand very clearly
-------------------------------	---	---	---	---	---	---	---	---	---	----	----------------------------

8. How much does your IBD affect you emotionally?

(e.g. does it make you angry, scared, upset or depressed)

Not at all affected emotionally	1	2	3	4	5	6	7	8	9	10	Extremely affected emotionally
---------------------------------------	---	---	---	---	---	---	---	---	---	----	--------------------------------------

9: Do you feel you have received enough information about IBD? (please circle)

No Information	1	2	3	4	5	6	7	8	9	10	Full information
-------------------	---	---	---	---	---	---	---	---	---	----	---------------------

10: How much knowledge do you feel you have about IBD? (please circle)

No knowledge	1	2	3	4	5	6	7	8	9	10	Complete knowledge
-----------------	---	---	---	---	---	---	---	---	---	----	-----------------------

Section F: YOUR CARE AND SUPPORT

Think about the last 6 months when you have received care and support for your IBD

1: Did you discuss what was most important for you in managing your IBD?

Not at all

Rarely

Some of the time

Almost always

2: Were you involved as much as you wanted to be in the decisions about your care or treatment?

Not at all

To some extent

More often than not

Almost always

3: How would you describe the amount of information you received to help you manage your health?

I didn't receive any
information

I rarely received enough
information

I sometimes received
enough information

I always received
enough information

4: Have you had enough support from the hospital and your GP to help you manage your IBD?

I have had no
Support

I have not had enough
support

I have sometimes felt
supported

I have always felt
supported

5: Do you think the support and care you get is joined up and working for you?

Never

Rarely

Sometimes

Always

6: How confident are you that you can manage your own health?

Not at all confident

Not too confident

Somewhat confident

Very confident

Section G: YOUR KNOWLEDGE ABOUT IBD

These questions have previously been used to look at an individual's general knowledge of inflammatory bowel disease (IBD). They are known to be difficult. Answers will help us know which topics we may need to provide more information to help make treatment more effective. Please answer them as best as you can by **ticking only one answer for each question**. Thank you.

1. People with inflammatory bowel disease are never allowed to eat dairy products:

- a) True
- b) False
- c) Don't know

2. Elemental feeds are sometimes used to treat Crohn's disease and ulcerative colitis.

They:

- a) Always contain a lot of fibre
- b) Are very easy to digest
- c) Come in the form of tablets
- d) Don't know

3. Proctitis:

- a) Is a form of colitis that affects the rectum or back passage only
- b) Is a form of colitis that affects the whole of the large bowel
- c) Don't know

4. Patients with inflammatory bowel disease are probably cured if they have been symptom free for 3 years:

- a) True
- b) False
- c) Don't know

5. Inflammatory bowel disease runs in families:

- a) True
- b) False
- c) Don't know

6. Patients with inflammatory bowel disease can get inflammation in other parts of the body as well as the bowel:

- a) True
- b) False
- c) Don't know

7. A fistula:

- a) Is an abnormal track between 2 pieces of bowel or between the bowel and skin
- b) Is a narrowing of the bowel, which may obstruct the passage of the contents
- c) Don't know

8. The terminal ileum:

- a) Is a section of the bowel just before the anus
- b) Is a section of the bowel just before the large intestine
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9. During a flare up of inflammatory bowel disease:

- a) The platelet count in the blood rises
- b) The albumin level in the blood rises
- c) The white cell count in the blood falls
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- b) Can be given in the form of an enema into the back passage
- c) Cannot be given directly into the vein
- d) Don't know

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- a) Prevent infection in the bowel by bacteria
- b) Reduce inflammation in the bowel
- c) Don't know

12. Sulphasalazine:

- a) Controls the level of sulphur in the bloodstream
- b) Can be used to reduce the frequency of flare-ups
- c) Cannot be used to prevent flare-ups
- d) Don't know

13. An example of an immunosuppressive drug used in inflammatory bowel disease is:

- a) Sulphasalazine
- b) Mesalazine
- c) Azathioprine
- d) Don't know

14. If a woman has Crohn's disease:

- a) She may find it more difficult to become pregnant
- b) She should not have children
- c) Her pregnancy will always have complications
- d) She should stop all medication during her pregnancy
- e) Don't know

15. Which one of the following statements is false?

- a) Ulcerative colitis can occur at any age
- b) Stress and emotional events are linked with the onset of ulcerative colitis
- c) Ulcerative colitis is least common in Europeans and North Americans
- d) Patients with ulcerative colitis have an increased risk of developing bowel cancer
- e) Don't know

16. Male patients who take sulphasalazine:

- a) Have reduced fertility levels that are reversible
- b) Have reduced fertility levels that are not reversible
- c) The drug does not have any effect on male fertility
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- b) 12 feet
- c) 20 feet
- d) Don't know

18. The function of the large bowel is to absorb:

- a) Vitamins
- b) Minerals
- c) Water
- d) Don't know

19. Another name for an ileorectal anastomosis operation with formation of a reservoir is:

- a) Purse
- b) Pouch
- c) Stoma
- d) Don't know

20. If a part of the bowel called the terminal ileum is removed during surgery the patient will have impaired absorption of:

- a) Vitamin C
- b) Vitamin A
- c) Vitamin B12
- d) Don't know

21. Patients with IBD need to be screened for cancer of the colon. Which one of the following statements about screening is false?

Screening should be offered to all patients with ulcerative colitis:

- a) Which affects only the rectum
- b) Which has lasted for 8–10 years
- c) Which started before the age of 50
- d) Don't know

22. There are millions of tiny "hairs" in the small bowel to increase the absorptive surface. They are called:

- a) Villi
- b) Enzymes
- c) Bile salts
- d) Crypts
- e) Don't know

23. Which one of the following is not a common symptom of inflammatory bowel disease?

- a) Abdominal pain
- b) Change in bowel habit
- c) Headache
- d) Fever
- e) Don't know

24. If a child has inflammatory bowel disease; he/she probably will not:

- a) live beyond the age of 45
- b) be as tall as his or her friends
- c) be as intelligent as his or her friends
- d) Don't know

Section H: FEEDBACK

Please write in today's date below:

Day Month Year

Once again many thanks for completing this questionnaire.

A small number of people are needed to attend an interview to look in more detail about My IBD Portal. If you would be happy to be contacted about this please tick the box below:

Yes, I would be happy to attend an interview lasting 30-60 minutes at the hospital

If you have any comments on future improvements to 'My IBD Portal', the questionnaire or any other aspects of the research please write them in the comment box below.

Comments

If there are any problems completing this form, please email me at:

chris.calvert@srft.nhs.uk

Appendix 7b

Assessing the impact of a web-based care package in adults with IBD

Exit Questionnaire

Dear Participant,

I would be very grateful if you would complete this questionnaire.

Even if you have not managed to use 'My IBD Portal' it is important for the study that you please complete this exit questionnaire and answer all the questions as much as possible.

If you have any problems completing this form, please contact by email at: chris.calvert@srft.nhs.uk or via the telephone on 061 2061442 and I will be happy to assist.

All information you provide will be treated with the strictest confidence.

Once again many thanks for your help,



Dr Chris Calvert
Clinical Research Fellow,
Room D424 Research Department,
Clinical Sciences Building,
Salford Royal Foundation Trust,
Stott Lane,
Salford,
M6 8HD

Patient ID:

Section A: USING 'MY IBD PORTAL'

1: Overall, how satisfied were you with 'My IBD Portal'? (Please circle)

Very satisfied

Satisfied

Dissatisfied

Very dissatisfied

2: Do you think using 'My IBD Portal' will help support you to manage your IBD?

Yes

No

Please comment:

3: Would you want to continue to use 'My IBD Portal' in the future?

Yes

No

4: If you did not use or were not able to use the service I would be very grateful if you could write the reasons for this in the box below. This information is really important to understand why people didn't access the website and what could be done to make better use of the services for people with IBD at Salford.

Your honest opinions will improve the care in the future. Many thanks

I did not use the Portal because:

To improve the IBD service I would:

Section B: HOW YOU FEEL ABOUT MANAGING YOUR HEALTH

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say. If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I am confident I can help prevent or reduce problems associated with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell whether I need to go to the Doctor or whether I can take care of a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can tell a doctors concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I understand my health problems and what causes them	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I know what treatments are available for my health problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12. I am confident I can figure out solutions when new problems arise with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13. I am confident that I can maintain lifestyle changes, like eating right and exercising during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Section C: FLARE-UPS

1: Have you had a flare up in the last 6 months?

No Yes →If Yes, how many flares have you had in 6 months _____

2: When was your last flare-up?

3: What did you do about it?

4: Have you visited your GP in the last 6 months about your IBD?

No Yes →If Yes, how many visits have you made _____

5: Over the last 6 months have you needed to take time off work or study for your IBD?
(Include all contact with the GP, hospital visits and sickness)

No Yes →If Yes, how long would you estimate ___ hours or ___ Days

5: Have you made any changes to your IBD medications in the last 6 months?

No Yes →If Yes, what changes have you made?

6: Questions about your medications

We know it is often not easy to take medications, especially when feeling well.

Please circle the answers to indicate how you are, in taking your IBD medications

Do you sometimes forget to take your medication?	Yes	No		
People sometimes miss taking their medications for reasons other than forgetting. In the last 2 weeks, was there any day when you did not take your medication?	Yes	No		
Have you ever stopped taking your medications or decreased the dose without first warning your doctor because you felt worse when you took them?	Yes	No		
When you travel or leave the house, do you sometimes forget to take your medications?	Yes	No		
Did you take your medication yesterday?	Yes	No		
When you feel your IBD is controlled, do you sometimes stop taking your medications?	Yes	No		
Taking medications every day is a real inconvenience for some people. Have you ever felt stressed for strictly following your IBD treatment plan?	Yes	No		
How often do you have difficulty to remember taking all your IBD medications?				
Rarely / Never	Once in a while	Sometimes	Usually	Always

Section D: HOW YOU FEEL ABOUT YOUR IBD

For the following 10 questions please circle the number that best corresponds to your views.

1. How much does your IBD affect your life?

No affect at all	1	2	3	4	5	6	7	8	9	10	Severely affects my life
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2. How long do you think your IBD will continue?

A very short time	1	2	3	4	5	6	7	8	9	10	Forever
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3. How much control do you feel you have over your IBD?

Absolutely no control	1	2	3	4	5	6	7	8	9	10	Extreme amount of control
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4. How much do you think your treatment can help your IBD?

Not at all	1	2	3	4	5	6	7	8	9	10	Extremely helpful
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5. How much do you experience symptoms from your IBD?

No symptoms at all	1	2	3	4	5	6	7	8	9	10	Many severe symptoms
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6. How concerned are you about your IBD?

Not at all concerned	1	2	3	4	5	6	7	8	9	10	Extremely concerned
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7. How well do you feel you understand your IBD?

Don't understand at all	1	2	3	4	5	6	7	8	9	10	Understand very clearly
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8. How much does your IBD affect you emotionally? (e.g. does it make you angry, scared, upset or depressed?)

Not at all affected emotionally	1	2	3	4	5	6	7	8	9	10	Extremely affected emotionally
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9: Do you feel you have received enough information about IBD? (Please circle)

No Information	1	2	3	4	5	6	7	8	9	10	Full information
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10: How much knowledge do you feel you have about IBD? (Please circle)

No knowledge	1	2	3	4	5	6	7	8	9	10	Complete knowledge
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Section E: YOUR CARE AND SUPPORT

Think about the last 6 months when you have received care and support for your IBD

1: Did you discuss what was most important for you in managing your IBD?

Not at all

Rarely

Some of the time

Almost always

2: Were you involved as much as you wanted to be in the decisions about your care or treatment?

Not at all

To some extent

More often than not

Almost always

3: How would you describe the amount of information you received to help you manage your health?

I didn't receive any
information

I rarely received enough
information

I sometimes received
enough information

I always received
enough information

4: Have you had enough support from the hospital and your GP to help you manage your IBD?

I have had no
Support

I have not had enough
support

I have sometimes felt
supported

I have always felt
supported

5: Do you think the support and care you get is joined up and working for you?

Never

Rarely

Sometimes

Always

6: How confident are you that you can manage your own health?

Not at all confident

Not too confident

Somewhat confident

Very confident

Section F: YOUR KNOWLEDGE ABOUT IBD

These questions have previously been used to look at an individual's general knowledge of inflammatory bowel disease (IBD). They are known to be difficult. Answers will help us know which topics we may need to provide more information to help make treatment more effective. Please answer them as best as you can by **ticking only one answer for each question**. Thank you.

1. People with inflammatory bowel disease are never allowed to eat dairy products:

- a) True
- b) False
- c) Don't know

2. Elemental feeds are sometimes used to treat Crohn's disease and ulcerative colitis.

They:

- a) Always contain a lot of fibre
- b) Are very easy to digest
- c) Come in the form of tablets
- d) Don't know

3. Proctitis:

- a) Is a form of colitis that affects the rectum or back passage only
- b) Is a form of colitis that affects the whole of the large bowel
- c) Don't know

4. Patients with inflammatory bowel disease are probably cured if they have been symptom free for 3 years:

- a) True
- b) False
- c) Don't know

5. Inflammatory bowel disease runs in families:

- a) True
- b) False
- c) Don't know

6. Patients with inflammatory bowel disease can get inflammation in other parts of the body as well as the bowel:

- a) True
- b) False
- c) Don't know

7. A fistula:

- a) Is an abnormal track between 2 pieces of bowel or between the bowel and skin
- b) Is a narrowing of the bowel, which may obstruct the passage of the contents
- c) Don't know

8. The terminal ileum:

- a) Is a section of the bowel just before the anus
- b) Is a section of the bowel just before the large intestine
- c) Don't know

9. During a flare up of inflammatory bowel disease:

- a) The platelet count in the blood rises
- b) The albumin level in the blood rises
- c) The white cell count in the blood falls
- d) Don't know

10. Steroids (such as prednisolone/prednisone/budesonide/hydrocortisone):

- a) Can only be taken by mouth
- b) Can be given in the form of an enema into the back passage
- c) Cannot be given directly into the vein
- d) Don't know

11. Immunosuppressive drugs are given to inflammatory bowel disease patients to:

- a) Prevent infection in the bowel by bacteria
- b) Reduce inflammation in the bowel
- c) Don't know

12. Sulphasalazine:

- a) Controls the level of sulphur in the bloodstream
- b) Can be used to reduce the frequency of flare-ups
- c) Cannot be used to prevent flare-ups
- d) Don't know

13. An example of an immunosuppressive drug used in inflammatory bowel disease is:

- a) Sulphasalazine
- b) Mesalazine
- c) Azathioprine
- d) Don't know

14. If a woman has Crohn's disease:

- a) She may find it more difficult to become pregnant
- b) She should not have children
- c) Her pregnancy will always have complications
- d) She should stop all medication during her pregnancy
- e) Don't know

15. Which one of the following statements is false?

- a) Ulcerative colitis can occur at any age
- b) Stress and emotional events are linked with the onset of ulcerative colitis
- c) Ulcerative colitis is least common in Europeans and North Americans
- d) Patients with ulcerative colitis have an increased risk of developing bowel cancer
- e) Don't know

16. Male patients who take sulphasalazine:

- a) Have reduced fertility levels that are reversible
- b) Have reduced fertility levels that are not reversible
- c) The drug does not have any effect on male fertility
- d) Don't know

17. The length of the small bowel is approximately:

- a) 2 feet
- b) 12 feet
- c) 20 feet
- d) Don't know

18. The function of the large bowel is to absorb:

- a) Vitamins
- b) Minerals
- c) Water
- d) Don't know

19. Another name for an ileorectal anastomosis operation with formation of a reservoir is:

- a) Purse
- b) Pouch
- c) Stoma
- d) Don't know

20. If a part of the bowel called the terminal ileum is removed during surgery the patient will have impaired absorption of:

- a) Vitamin C
- b) Vitamin A
- c) Vitamin B12
- d) Don't know

21. Patients with IBD need to be screened for cancer of the colon. Which one of the following statements about screening is false?

Screening should be offered to all patients with ulcerative colitis:

- a) Which affects only the rectum
- b) Which has lasted for 8–10 years
- c) Which started before the age of 50
- d) Don't know

22. There are millions of tiny "hairs" in the small bowel to increase the absorptive surface. They are called:

- a) Villi
- b) Enzymes
- c) Bile salts
- d) Crypts
- e) Don't know

23. Which one of the following is not a common symptom of inflammatory bowel disease?

- a) Abdominal pain
- b) Change in bowel habit
- c) Headache
- d) Fever
- e) Don't know

24. If a child has inflammatory bowel disease; he/she probably will not:

- a) live beyond the age of 45
- b) be as tall as his or her friends
- c) be as intelligent as his or her friends
- d) Don't know

Section G: FEEDBACK

Please write in today's date below:

Day Month Year

Once again many thanks for completing this questionnaire.

A small number of people are needed to attend an interview to look in more detail about My IBD Portal. If you would be happy to be contacted about this please tick the box below:

Yes, I would be happy to attend an interview lasting 30-60 minutes at the hospital

If you have any comments on future improvements to 'My IBD Portal', the questionnaire or any other aspects of the research please write them in the comment box below.

Comments

If there are any problems completing this form, please email me at:

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