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ABSTRACT

A realist evaluation of an integrated care pathway for inflammatory bowel disease in the North East of England

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April 2015

A mixed-methods non-participant evaluation of an integrated care pathway for adult inflammatory bowel disease patients in a North East of England health economy was undertaken utilising a realist evaluation framework. The evaluation commenced at an early stage in the pathway's life in October 2009 and closed two and a half years later in March 2012. The evaluation identified internal and external enablers and inhibitors to the pathway, primarily in the design and implementation phases as opposed to the operational phase. Inferences were made to contemporaneous evaluations of integrated care projects which served to validate this evaluation and identify the additional value of the evaluation to the health services research field. Contextual enabling and inhibiting factors were identified along with their associated mechanisms and actual or potential outcomes. An additional pilot project identified the scope for, and potential nature of, a role for community pharmacy in the management of adult IBD patients.

A realist evaluation of an integrated care pathway for inflammatory bowel disease in the North East of England

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School of Medicine, Pharmacy and Health

Durham University

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Chapter 1: Introduction

1.1 Inflammatory bowel disease

Inflammatory bowel disease (IBD) is not a single diagnosis and the term covers a number of different aetiologies. The most common single diagnoses are Crohn's disease and ulcerative colitis typically accounting for over 90% of IBD diagnoses. The principal effects of the disease are inflammation and ulceration in the colon and rectum (ulcerative colitis) or anywhere in the gastrointestinal tract (Crohn's disease). [1]

1.1.1 Epidemiology

Inflammatory bowel disease (IBD) is a chronic and, for most patients, lifelong condition estimated to affect nearly a quarter of a million people in the UK. [1] The prevalence of IBD within an English primary care population was estimated at 0.4%, with ulcerative colitis accounting for the majority of diagnoses (0.25%) than Crohn's disease (0.15%). [2] Annual incidence rates were estimated at 0.014% for ulcerative colitis and 0.008% for Crohn's disease. [2] These figures are broadly in-line with epidemiological reports from other localities. [3] The prevalence of IBD is generally highest in areas of Caucasian populations, specifically Northern Europe including the UK, Ireland, Scandinavia, France and the low countries, and North America, Australia and New Zealand. The incidence and prevalence of IBD appears to be increasing over time in all localities with some, particularly in the developing world, experiencing rapid growth. [3] The ratio of ulcerative colitis to Crohn's disease is generally slightly in favour of ulcerative colitis in UK populations [2, 4] although this is not true in all localities. [3]

Age at diagnosis is bimodal, with a first peak presenting in the teenage years or the third decade of life and a second less pronounced peak in the 6th decade. [1] The median age at diagnosis is 29 years. [2] IBD affects males and females in similar proportions. [2] Paediatric IBD, typically defined by patient age less than 18 or 16 years, is estimated to account for between 7% and 20% of all IBD cases. [3]

1.1.2 Aetiology and causes

The aetiology of IBD is not entirely clear. [5, 6] Both Crohn's disease and ulcerative colitis appear to be triggered by an unknown, possibly environmental, factor affecting genetically susceptible individuals. [6] An immunological mechanism in the pathogenesis of the condition appears to be triggered in these individuals. [5] Evidence for a genetic component to the disease comes from a recognised greater incidence of IBD in first-degree relatives of IBD patients which may be slightly stronger for Crohn's disease than ulcerative colitis. [5, 6]

1.1.3 Symptoms and natural course

General symptoms common to Crohn's disease and ulcerative colitis include feelings of bowel urgency, frequent and excessive defecation, diarrhoea, pain, anaemia and fatigue. Malnutrition and weight loss are common consequences associated with IBD. [1, 5-7]

Symptoms which are more specific to the individual diagnoses of IBD can help in distinguishing between Crohn's disease and ulcerative colitis. For example, bloody diarrhoea is more typical of ulcerative colitis than Crohn's disease, and effects in the right lower quadrant such as the presence of an abdominal mass with or without constant pain are more typical of Crohn's disease than ulcerative colitis. [5] However, a diagnosis can only be confirmed following colonoscopy, biopsy and histological tissue classification. [7]

The frequency, severity and duration of symptoms and disease episodes show considerable inter-patient variation, and intra-patient variation over time. [1]

The course of the condition, in common with other conditions considered to have a significant autoimmune and inflammatory aspect, typically results in patients experiencing periods of 'remission' during which symptoms are well controlled or even absent, possibly with the aid of medication and dietary modification. Periods of remission vary in frequency and duration but can be prolonged extending to several years or longer. However, and often with no discernible aggravating or precipitating factor, patients may experience an acute exacerbation of the condition known as a relapse or 'flare-up', particularly patients with ulcerative colitis. [3, 5-7]

About 50% of ulcerative colitis patients have a relapse in any year [7] compared with less than 40% in Crohn's disease. [8]

Not all patients experience a remitting-relapsing disease course with a significant proportion experiencing constant, persistent or progressive symptoms. Crohn's disease in particular is more likely to follow a progressive pattern from the outset compared with ulcerative colitis. [3, 5-7]

The symptoms and consequences associated with an IBD relapse may include profuse, painful, and bloody diarrhoea, sudden and drastic weight loss, and loss of appetite, dehydration, rectal bleeding and painful cramps. [5, 6] Such flare-ups will often require urgent specialist attention to manage the acute phase and regain symptom control. [7]

Due to faecal blood loss, malabsorption, dietary restrictions and other reasons anaemia is a common longer-term consequence of the condition. [9]

Fatigue, which can be severe, is also relatively common in IBD patients. It may occur either as a consequence of anaemia, malnutrition, or for other reasons. [7, 9]

Osteoporosis is common in IBD patients and may be influenced by the effects of the condition on an individual's nutritional status but also adverse effects from commonly used steroid drugs. Screening and, where appropriate, treatment is recommended. [7]

Extra-intestinal symptoms are more commonly seen with Crohn's disease than with ulcerative colitis. [7] The most prevalent extra-intestinal symptoms are arthritis, erythema nodosum, iritis, uveitis, aphthous stomatitis, ankylosing spondylitis and pyoderma gangreosum. [1, 7]

A more serious feature of Crohn's disease is the emergence of strictures, fistulae and abscesses. Often these can go unnoticed by the patient but once symptomatic will usually require surgery to resolve. [7]

IBD is also associated with an increased risk of developing cancer, primarily in the colon. The risk of colorectal cancer in ulcerative colitis is increased with the extent and severity of the disease, the age of onset and duration of the disease. Evidence has demonstrated that colorectal cancer rates are slightly less in Crohn's disease than in ulcerative colitis. [1]

1.1.4 Psychological impact

IBD is associated with psychological effects such as depression and anxiety. Patients with IBD are estimated to have a greater than two-fold incidence of depressive illness compared with control populations. In IBD patients the lifetime prevalence of depressive illness is estimated at about 27% and annual prevalence at 15%. Anxiety has also been found to be more common in IBD patients than matched control populations. [7]

As is the nature of mental illnesses it is difficult to identify causality; mood disorders may not solely be a consequence of the disease but could also be related to treatment, for example steroid therapy and surgery. Knowledge of the associated health risks of IBD such as cancer, and the associated measures such as cancer surveillance, may also contribute to the increased risk of psychological disorders in IBD patients. [10]

An interesting and repeated finding has been that psychological stress and even the way in which IBD patients cope with it can impact on their IBD-related health. For example, greater levels of stress can worsen the course of IBD, and 'low-avoidance' behaviour when employed as a coping strategy (i.e. keeping themselves to themselves) is associated with greater rates of sustained disease remission than other coping strategies such as high-avoidance (distraction) behaviour. [11]

1.1.5 Quality of life in IBD

Several studies have reported that patients with IBD have lower quality of life compared with age and sex matched controls without IBD. [12, 13]

A survey of IBD patients in the North East of England found that lower quality of life was associated with female gender, lower socioeconomic status, Crohn's disease, and being under specialist care which itself may act as a proxy for disease severity. [14] However, in a wider review of the literature, age was not consistently found to be associated with quality of life in IBD. [15] The factors which were found to be more clearly associated with lower quality of life in IBD patients were female gender, lower socioeconomic status, lower education levels and lower levels of IBD knowledge. [15]

Disease severity and disease activity have themselves been found to be inversely correlated with quality of life in patients with IBD. [12, 13, 16]

IBD affects other parts of a patient's life in some obvious and some more subtle ways. For example, a number of reports have found that patients with IBD, particularly female patients, have concerns and issues regarding self-image, sexuality and the ability to engage in personal and sexual relationships. [15]

Another report, again using a North East of England patient population, found that people with IBD and low quality of life scores perceived their illness as embarrassing, taboo and misunderstood. Patients tended to make social comparisons with other IBD patients and non-patients and appraised their situation relative to those. Patients would seek, fight for, or adapt to achieve normality based on what they perceived as normal through these comparisons, which were somewhat dynamic. [17]

The evidence demonstrates that the effects of IBD on an individual patient will often extend well beyond the direct manifestations of the disease, impacting upon education, employment, personal relationships, social and family life. Social functioning and self-esteem can be adversely affected and patients adapt to and accept undesirable and unnecessary constraints in their everyday lives. [1]

1.1.6 Treatment

1.1.6.1 Management

IBD patients may experience different models of care provision depending on disease activity, local facilities and personal preferences. [18]

Specialists working in the acute sector, i.e. hospital-based consultant gastroenterologists, have a key role in the care of IBD patients. [19]

However in the NHS, and many other healthcare systems, general practitioners act as a first point of access and gatekeepers to specialist care for most health problems including IBD. [20] This can create problems for example with delay in diagnosis stemming from inadequate assessment in primary care or prolonged waiting times for specialist consultation. [1, 21] Once under the care of a specialist patients may remain there for a prolonged period of time or indefinitely. Where patients are discharged back to their GP (general medical practitioner) care will often continue under guidance from the specialist and the patient may still see the specialist periodically for review even if well. [21]

Increasingly specialist IBD nurses are being employed in hospitals for a range of roles in the care of IBD patients. [22] The role of specialist IBD nurses is supported by clinical evidence where a number of positive effects have been demonstrated, such as improved patient satisfaction and reduced costs of healthcare. [23] Consequently, the role of specialist IBD nurse is endorsed in guidelines [7] and practice standards. [1]

1.1.6.2 Nutritional therapies

Although specific and general malnutrition are relatively common features of IBD, the use of specific nutritional and dietary strategies to alleviate the symptoms of IBD is associated, at best,

with only limited efficacy. Short-term enteral nutritional feeding may be particularly useful in managing severe active Crohn's disease. Enteral nutrition diets can be used as an alternative to steroid therapy to induce remission in Crohn's disease. [7]

Exclusion diets such as gluten-free and dairy-free diets can alleviate some symptoms but only where there is a specific intolerance. [7] Numerous other exclusion and special diets have been evaluated in IBD but have not been proven to be of clinical benefit. [24]

Patients may require specific supplements or types of feeds such as liquid feeds and enteral nutritional therapy. For severely ill patients, long-term intravenous parenteral nutrition may be required. There is limited clinical evidence to support use of microbiological preparations, often called 'probiotics' in the maintenance [25] and induction [26] of remission in ulcerative colitis. The clinical evidence does not support the use of microbiological preparations to induce remission in Crohn's disease. [27]

1.1.6.3 Medical therapies

The mainstay of long-term treatment in all forms of IBD is the use of aminosalicylate anti-inflammatory drugs typified by mesalazine. These drugs liberate anti-inflammatory entities predominantly in the lower gastrointestinal tract and therefore exert a local anti-inflammatory action. [7] A number of drugs are available in a large range of formulations including for rectal administration. [28]

One problem with long-term medical therapy in IBD is adherence to the prescribed medication regimen with typical non-adherence rates estimated at about 30 to 45%. [29] Psychological distress, patient's beliefs about medicines, and discordance in the doctor-patient relationship have been consistently associated with non-adherence of IBD patients. [29, 30]

Steroid therapy such as oral prednisolone is frequently used to manage acute exacerbations of IBD, i.e. relapses or flare-ups. At high-doses steroids are effective at gaining rapid symptomatic control but long-term use, even at lower doses, is avoided due to concerns about adverse effects. Other routes of administration of steroids include rectal preparations which may be used in the longer-term due to reduced systemic absorption, and parenteral formulations for very ill patients. [29]

For longer-term steroid-sparing medical management immunosuppressive drugs such as azathioprine, mercaptopurine, ciclosporin and methotrexate are used. Although these drugs are not associated with some of the troublesome adverse effects seen with steroids they are associated with their own distinct adverse effect profiles and must be closely monitored. [7]

Biological therapies targeted against specific components of the immune system have become available for treating both Crohn's disease and ulcerative colitis. These include infliximab (1999) and adalimumab (2006). Some of these indications have been approved by the National Institute for Health and Clinical Excellence under specific criteria. [31, 32] Due to the positioning of biological therapies in treatment pathways and, in the case of infliximab the need for intravenous administration, these drugs remain in the specialist domain. [1, 7] The UK IBD biological therapy audit found that infliximab and adalimumab are usually prescribed according to the recommendations from NICE and that use in ulcerative colitis is low, especially relative to use of infliximab in Crohn's disease. The audit also revealed that the expected efficacy based on clinical studies appeared to be borne out in practice and that few adverse events had been reported. [33]

1.1.6.4 Surgery

A large proportion of IBD patients, particularly those with Crohn's disease, are still treated surgically at some point in the natural course of their condition. The historical lifetime probability for surgery may be as high as 70-80% for Crohn's disease and 20-30% for ulcerative colitis, depending on disease severity and location. A number of different surgical techniques are used in IBD ranging from the relatively conservative to extensive and radical surgery. [7]

Surgery in Crohn's disease is not curative and is only used to achieve symptomatic relief where conservative treatment options have failed. [7] UK-based data has demonstrated that surgery is less commonly used now than in the past, potentially due to increased medical therapy. [34] The UK national IBD audit found that, of more than 3,000 in-patient admissions for Crohn's disease in 2010, 17% were elective admissions for surgery. [22] It is estimated that 70% of Crohn's disease patients who do have surgery develop further disease within 15 years. [5]

Depending on the extent of surgery, surgical treatment of ulcerative colitis can be curative although patients will be left with lasting consequences due to the total absence of their colon, for example reduced bowel transit time, reduced faecal storage capacity, and potentially the permanent use of stoma. [7] The UK national IBD audit found that, of more than 3,000 in-patient admissions for ulcerative colitis in 2010, 16% were elective admissions for surgery. In addition, the audit found that ulcerative colitis patients were more likely to receive surgery following an emergency admission compared with Crohn's disease patients. [22]

1.1.7 Healthcare utilisation

Patients with IBD require a substantial level of healthcare, which increases with disease severity. [35] One UK study found that 1 in 7 of all patients known to a hospital IBD service were hospitalised in a six-month period. [36] Although in any given time period a minority of patients require hospital in-patient care, hospital care accounts for the majority of costs associated with

IBD. [36] The cost of IBD in the UK, based on 2006 data, has been estimated at £720 million per year. [35] Crohn's disease appears to be consistently slightly more costly to healthcare providers and patients than ulcerative colitis due to greater use of surgical interventions and greater hospital in-patient stays. [36]

Of all hospital admissions for IBD in 2010, nearly two-thirds were emergency admissions, and 1 in 6 were elective admissions for surgery. The median length of stay for IBD patients was about one week (7 days) with more than one-fifth of patients staying for at least 14 days. [22] There may be a minority of patients with particularly high healthcare requirements, for example one-third of patients with ulcerative colitis admitted to hospital in 2010 had been admitted in the preceding two years. [22]

Clinical care of IBD patients is fairly equally shared between gastroenterologists and GPs. In the first 12 months after diagnosis patients had a mean of 3.9 specialist consultations and 3.3 GP consultations specifically related to IBD. Patients with duration of diagnosis ≥ 2 years had a mean of 1.02 specialist and 1.04 GP consultations in the preceding 12 months. [2] It is estimated that about two-thirds of IBD patients visit their GP regarding IBD in any given year with nearly one-third making at least three visits.[37]

Prescription medication is widely used by IBD patients, identified at over 85% in a local IBD adult patient population. [38]

1.2 The IMAGE project

The Improving Management in Gastroenterology (IMAGE) project was a national quality improvement study funded by the Health Foundation in the UK. Thirty-nine general medical practices in England were involved. Quality criteria, derived from the views of patients and recommendations in evidence-based clinical practice guidelines, were incorporated into decision support software to guide primary care clinicians towards better management of four common gastrointestinal disorders including IBD. [39] The project commenced in 2007 and was completed in 2010. [40] One of the key outputs of the project was a comprehensive, evidence-based and 'road-tested' template for conducting annual reviews with IBD patients. This template was developed in primary care but is equally suitable for review of any IBD patient with stable disease in remission, including, for example, patients who are reviewed in secondary care.

1.3 The IBD Standards of Care

The IBD Standards of Care were developed through a collaboration of six healthcare professional representative organisations and one leading patient charity. [1] They were published in 2009 as part of a wider strategy to improve services and care for patients with ulcerative colitis or Crohn's

disease, the two most common inflammatory bowel diseases. The standards are broken down into six categories, each further sub-categorised in greater detail. The six categories related to clinical care, local delivery, patient-centred services, patient education and support, information technology and audit, and evidence-based practice & research. [1]

The IMAGE project is referred to in the IBD standards as an important project which could potentially improve the management of IBD by using established approaches which have delivered improvements in the management of other chronic health conditions within the NHS. [1]

1.4 Integrated care

Integrated care is not consistently defined and multiple definitions exist in an extensive literature base. [41] The Royal College of General Practitioners has defined it as ‘care that places patients at the centre of its design and delivery, meeting their needs in a co-ordinated and individually tailored way’. This is further qualified as being ‘patient centred, primary care-led, shared working with multi-professional teams where each profession retains their autonomy but works across professional boundaries ideally with a shared electronic GP record’. [42] A report from the Nuffield Trust defined integrated care more loosely as ‘an approach that seeks to improve the quality of care for individual patients, service users and carers by ensuring that services are well co-ordinated around their needs’. [43]

Irrespective of the definition of integrated care the provision of generalist and specialist healthcare (primary and secondary care, respectively) within the NHS is distinguished by boundaries or ‘interfaces’, both tangible and intangible.

Integrated healthcare is often described as being vertically or horizontally integrated. [44] Vertical integration will typically involve disease-specific care plans or pathways which negotiate the boundaries across generalist (primary) and specialist (secondary) care. Horizontal integration involves broader collaborations often with non-health organisations such as local authorities or charities to improve overall health. [44]

These healthcare boundaries, or interfaces, have been broadly differentiated into three non-exclusive levels; patient and provider, organisational, and system-based. Some of the problems which arise from delivery of care across the primary-secondary care boundary, or interface, are described in box 1. [45]

Better integration of care is often presented as a potential solution to some or even all of the problems arising from the primary-secondary care interface. This can be delivered in many ways including integrated care pathways. [46]

As with 'integrated care' there is also no single universally accepted definition of what an 'integrated care pathway' is. A particular and thorough description is provided in box 2.

Box 1. Problems observed with the boundaries between primary and secondary care [45]

Patient and provider level boundaries

Poor communication characterised by transfer of patient information via hard copy (i.e. paper), separate information management and technology systems, separate consultations and locations resulting in additional transport and temporal impositions for patients, separate personnel.

Organisational level boundaries

Absence of agreed pathways and associated standards of care and service leading to variation in patient experiences, different levels of access to or provision of non-treatment interventions, cumbersome referral pathways leading to temporal delays to appropriate care.

System level boundaries

Separate funding arrangements leading to a purchaser-provider relationship and potential power imbalance.

Box 2. Integrated care pathways [47]

Integrated care pathways are structured multidisciplinary care plans which detail essential steps in the care of patients with a specific clinical problem and describe the expected progress of the patient.

They aim to facilitate the introduction into clinical practice of clinical guidelines and systematic on-going audit into clinical practice. They can provide a link between the establishment of clinical guidelines and their use.

They help in communication with patients by giving them access to a clearly written summary of their expected care plan and progress over time.

The functions of integrated care pathways have also been defined as: 'An integrated care pathway determines locally agreed, multidisciplinary practice based on guidelines and evidence, where available, for a specific patient/client group. It forms all or part of the clinical record, documents the care given and facilitates the evaluation of outcomes for continuous quality improvement.' [48]

1.4.1 The Darzi Review

The NHS next stage review 'High Quality Care For All', more commonly known as the 'Darzi review' after the lead author, was published in June 2008. [49] This review supported the case for 'integrated care' although it did not explicitly define what was meant by this term. The report built upon numerous earlier NHS and department of health reports and reviews, all of which supported the process of integrated care. [50, 51] For example, the practice guidance 'Implementing care closer to home: Convenient quality care for all patients', published in 2006 by the Department of Health, emphasised patient-centred care and used examples of integrated care pathways to illustrate good practice. [51]

1.4.2 Integrated Care Pilots

As a direct consequence of the Darzi review the Department of Health for England launched a competitive initiative in autumn 2008 entitled the Integrated Care Pilots. [52] Applications were invited for integrated care projects within the English NHS to become one of a number of pilot sites within an integrated care pilots programme. For the successful projects, inclusion within the programme would result in automatic participation in an independent comprehensive evaluation programme commissioned by the Department of Health. [52] The evaluation was designed to run for three years and would objectively and independently report on several aspects of the pilots. [53]

1.5 The locality

The locality of interest to the research project is a predominantly urban conurbation in the North East of England characterised by former industrial sites and urban sprawl, interspersed with rural areas. [52] Eighty-six per cent of the population is classified as living in 'urban areas' compared with the English average of 73%. [53]

The population of the health district conurbation is between 100,000 and 250,000. The area demonstrates higher than average overall deprivation within England. [54] and contains a high concentration of areas which are amongst the most deprived in England. [55] The locality displays a number of measures indicative of greater social and community deprivation compared with national and regional averages. [54, 55]

The health of people in the locality is worse than the national average for England as described by several public health criteria. Although the all-cause mortality rate has decreased over the preceding decade it remains slightly greater than the average for England. [54] Life expectancy is slightly less than the average for England for males and females [53] although there is considerable variation in life expectancy across different areas within the locality. [54]

The locality was served by a single commissioning healthcare organisation, known at the time as a Primary Care Trust (PCT). This contained between 20 and 30 general medical practices governed by the PCT. The practices ranged in scale and size from a small single GP practice with about 1,000 patients to a large multi-professional practice with several GP's and over 20,000 patients. [56] The PCT and local authority boundaries were closely but not identically aligned. [57]

The locality was served primarily by one hospital of the district general hospital model located in the main conurbation of the locality. The hospital principally served the local community. [58]

Prior to the introduction of the integrated care pathway for IBD there was no defined pathway for patients with IBD in the locality. Instead care was based on a historical system of referral from GPs to hospital-based consultant-led care. The majority of specialist care of IBD patients residing within the locality was delivered by the gastroenterology department at the main hospital site located in the main conurbation. A minority of IBD patients within the locality received their care from neighbouring hospital trusts in other major conurbations.

1.5.1 A local healthcare programme

In 2007 two neighbouring PCTs, including the locality PCT, formed a partnership with the hospital trust which principally served their populations. One of the aims of the programme was to serve as a national exemplar for the provision of modern integrated healthcare. [59, 60]

One of the key components of the programme was to deliver as much care as possible in primary and community settings. The strategic aim of the programme was described as:

"... the provision of a new acute hospital to replace the existing two along with a redesign of the health care system across primary, community and secondary care ...". [61]

The programme was described in its own literature as developing a vision for future healthcare: [59]

A patient-centred and clinically driven local NHS that is responsive to the needs of local people, that can deliver the best quality health and social care available in an integrated and efficient way, provided in first rate facilities that are as close to home as possible by well trained professionals using state of the art equipment.

The programme included clinicians, patients, staff, public, carers and other partners, and was expected to run between April 2007 and March 2014. [59, 60] There were six projects within the overall programme, one of which related to long term conditions. [60]

1.5.1.1 Long-term conditions

The management of long term conditions was considered as a separate project within the programme. A report on the initial findings of the long term conditions project was published in 2008.[60] This part of the project focused on ten long term conditions for which data was collected and presented. Although IBD was not listed among the ten long term conditions covered in the 2008 report the data collected and presented, and the corresponding conclusions, were described as being generalisable to the local management of all long term conditions.

Regarding local service models for long term conditions, the report made several conclusions: [60]

- There were some good examples of care for patients with long term conditions
- Access routes to services was variable and caused confusion and delay
- Delays were inherent in the current model
- The focus was on management of chronic disease
- There was lack and/or inconsistency of patient information
- Links between services and service providers were not fully coordinated
- The role of voluntary, charitable and independent organisations was not explicit
- The current model of care was not patient-centred
- There were more reactive care services than proactive care services

The report concluded that the future management of long term conditions should be via a single point of access, be proactive via disease management programmes, feature integrated data systems, ensure workforce development, utilise multidisciplinary working to reduce variations in care, and include prospectively defined audit and review. [60]

1.6 Aims and objectives of this thesis

In this thesis a combination of qualitative and quantitative research methods have been used to evaluate the design, implementation, operational processes and outcomes of an integrated care pathway for IBD. Qualitative and quantitative data have been combined to identify convergent findings in the context of a complex evaluation in the expectation that the combination of the two different types of data would be greater than the sum of the parts. [62]

The over-arching evaluation utilises the technique of realist evaluation, first described in detail by Pawson & Tilley. [63] Embedded within this are more focused evaluation techniques applied to specific data components, for example, a framework analysis of interview transcripts and summary statistics relating to quantitative outputs and metrics. A fundamental aspect of realist evaluation is the elucidation of the contextual factors in which a programme operates to deliver observable outcomes via specific mechanisms. This evaluation used diverse data sources including minutes of meetings, official publications and reports, electronic mail correspondence, observational notes, and interview transcripts. [63] Quantitative data was also obtained from a range of different sources including those integral to the pathway such as the collection of symptom scores, and also from sources which are routinely generated by the NHS such as prescribing and hospital episodes statistics data. Control or reference groups were utilised where these could be reliably identified.

A complementary exploratory investigation of the potential role of community pharmacy in the care of patients with IBD was performed in tandem with the pathway evaluation.

1.7 Structure of this thesis

Chapter 2 of this thesis is a comprehensive literature review which examines the current evidence base for the use of realist evaluation in healthcare, disease-specific models of integrated healthcare, and examples of other pathways for IBD. Chapter 3 describes the methodologies used in the conduct of the research. Chapter 4 constitutes provides the results obtained to support the findings of the thesis, utilising extensive qualitative and quantitative sources. Chapter 5 brings together the various components of the thesis and considers them within the context of an in-depth discussion and relationship to the wider evidence base. Chapter 6 draws conclusions based on the previous chapters and other relevant work.

1.8 Personal statement of interest

My first degree is in pharmacy and I have worked for several years at the patient interface in different fields of pharmacy. However, I was drawn from the outset of my career towards more reflexive and enquiring aspects of healthcare, particularly in terms of optimising patient care and experience with fixed resources. Initially this focused on the application of evidence-based medicine with respect to specific drug treatments. For this purpose I undertook a diploma in statistics, which proved invaluable when interpreting and understanding often complex statistical data. In order to maintain my clinical knowledge I also undertook a diploma in medicines management. During this time I developed an interest in the more general field of health economics and I recognised that health economics was becoming increasingly important in healthcare systems throughout the world as well as the NHS. This led to my undertaking a Master's degree in health economics.

Of course, seldom is a treatment or intervention made in isolation of what are usually complex interactions between carers, patients, and organisations. These interactions, combined with the inherent properties of each, can influence the health outcomes of individual patients and by extension whole patient groups and communities. It was to develop a better understanding of how these interactions exist in a programme of healthcare development for a defined chronically ill patient group that I was drawn to undertake a doctoral research degree. My existing educational and research background, and extensive experience in the commissioning side of the NHS, provided a useful starting point to undertake a long term, observational, and objective evaluation of a new service in a specific locality. The specific condition for which the service had been developed, IBD, lay within the same therapeutic field of gastroenterology in which the host research department has particular expertise and recognition. In addition, compared with several other long term conditions, IBD has a limited profile both amongst the public and within the media. Indeed, it is somewhat neglected by healthcare organisations and governmental departments, as exemplified by the continued omission of IBD from the national quality outcomes framework programme. However, in the context of the external relevance of this thesis, I hope that the lessons learned and findings can be extended to other long term conditions specifically or generally.

Chapter 2: A review of the relevant literature

This literature review considers the published literature on the key points relevant to this thesis.

The first section reviews the published literature regarding the use of realist, or realistic, evaluation as an evaluation technique of healthcare interventions as well as considering the broader evidence base for change, and specifically pathway redesign, in the context of large healthcare organisations such as the NHS.

The next section considers the use of specific integrated care pathways to achieve changes and the outcomes produced. First it is important to define what is integrated care, what is a care pathway, and is an integrated care pathway. Identifying the relevant evidence is confounded by a variations in the terminology used to describe integrated care pathways. Over time integrated care appears to have been increasingly associated with models of healthcare which are examples of horizontal integration across different healthcare providers at the same level of need. For example, traditional primary care healthcare providers integrating with social care providers to deliver community-based patient care. This is a shift from early intimations of integrated care which more often related to vertical healthcare integration across boundaries defined largely by the level of patient care required, for example integration between primary and secondary care. [64] The IBD integrated care pathway which is the focus of this evaluation is an example of vertically integrated care and this will be the focus of the evidence considered in this section. A vertically integrated care pathway is increasingly described as 'disease management', which does at least help to distinguish it from horizontal models of integrated care. In addition, disease management adds some detail to the descriptor as vertically integrated care pathways are usually focused on a single morbidity whereas horizontally integrated models of care are usually more holistic. A further distinction must be drawn between the morbidity (illness, disease, condition) which is the focus of the vertically integrated care pathway. The integrated care pathway in this evaluation related only to IBD, an example of a chronic morbidity. Pathways which deal with time-limited morbidities such as an acute or one-off intervention (e.g. orthopaedic or surgical procedures), an acute medical emergency, terminal or palliative care, rehabilitation, or infections and wound care, are better and more often described as critical care pathways. The evidence reviewed in this section therefore relates specifically to vertically integrated care pathways for chronic conditions, such that the evidence may be relevant to the IBD integrated care pathway. Evidence specific to IBD will be identified and considered with relevance to the IBD pathway of this project.

2.1 Realist evaluation

2.1.1 What is realist evaluation?

Realist, or realistic, evaluation was formally described only in the 1990's and yet, due to its flexible nature and applicability to multifaceted and complex programmes of change, it was rapidly adopted by researchers and others in healthcare and other fields. Fundamentally it is a pragmatic, naturalistic and comprehensive evaluation not just of the traditional causes (mechanisms) and effects (outcomes) of an intervention but one which also, crucially, includes identification of contextual factors. [63]

Context is itself something of an abstract and often subtle concept which can exist in many forms, for example the policy background, the prevailing economic situation, geographical, socio-economic, political, social, inter-personal, institutional or other. [63] In realist evaluation it is the elucidation of unique combinations of contexts, mechanisms and outcomes (CMO) which is important and should be one of the key aims of the evaluation. [65] The following schematic is useful to conceptualise the process.

Context + mechanism = outcome

The same mechanism, if applied in a situation with different contextual attributes, may therefore lead to different outcomes. Observation of mechanisms alone can be misleading about the outcomes which might be expected and it is important to identify what these contextual attributes, both enablers and inhibitors, might be. The actual details about how each mechanism is evaluated is not explicitly defined within the realist evaluation framework but, because 'context' and the many forms it can take are relatively abstract concepts, qualitative techniques are a common feature of realist evaluations. However this does not preclude the use of quantitative evaluation techniques and these are often employed alongside qualitative techniques in realist evaluations.

Realist evaluation has amongst its founding principles the theory of critical realism, first described formally by Bhaskar in 1975. [66] In critical realism actors have to operate in an environment of structural constraints and possibilities which they neither created nor are able to exert any obvious control upon. It is the role of realist evaluation to try and identify some of these unseen constraints and influences which may manifest as unintended consequences, tacit skills, unacknowledged conditions, unconscious motivations, and other subtleties of a social construct.

More simply, the basic tenet of realist evaluation is that the observed outcomes in a real, social, world, are not the sole consequence of the mechanisms which have been, presumably, put in place or otherwise identified as causal. The critical realist will recognise that the same

mechanisms, when transferred to a new but almost certainly different social environment will be unlikely to yield the same outcomes. If considered prospectively, implementation in a real social environment of a specific mechanism from which there is an expectation of a set of specific outcomes is in fact likely to yield outcomes other than those intended or expected due to the very nature of the social environment in which the mechanisms existed. It is the details of the social environment which have a tangible effect on the mechanisms, which are collectively labelled as 'context' by Pawson and Tilley, which a realist evaluation seeks to identify.

Context can therefore take many forms across single, to few, to many attributes. Context in this respect can vary from the overt and objective to the subtle and abstract. It is the nature of realist evaluations that the source of contextual attributes are more often of the subtle, unseen, abstract and inherently subjective nature, elucidated after several iterations and refinements. It is for the realist evaluator to demonstrate their skill in elucidating these contextual abstracts and making a case accordingly.

2.1.2 The evolution of healthcare programme evaluation

The evaluation of healthcare and related programmes has had an interesting and at times controversial modern history. [67-69] Pawson and Tilley provided an thorough history of evaluation in the first chapter of their seminal text on realist evaluation. [63] Initially healthcare programme evaluations, in common with programme evaluation in general, were founded in positivist objective traditions, often referred to as 'goal-bound'. [69] These evaluations tended to have a predominant emphasis on the quantitative outcomes or outputs of programmes and sought to identify causality within a programme through experimental design. Evaluations of this nature have included randomised controlled studies, [70, 71] cluster-randomised studies [72, 73] and other variations of randomised [74] and non-randomised comparative studies. [75] Such evaluations are still performed and are useful to present neater and easier to understand conclusions of cause and effect. [76] However, many healthcare programmes are complex interventions which exist in the real world. There are often ethical and practical limitations to conducting experimentally designed evaluations of such complex interventions.

After a prolonged period where experimental positivism reigned unchallenged, qualitative techniques and less scientifically focused evaluation techniques emerged. Various new terminologies and specialities emerged from the social sciences field, all with a common qualitative thread. [63, 77] These were collectively known as constructivist [63, 76, 77] and included a now familiar and largely standardised range of qualitative research techniques. Taking this new qualitative approach was considered by its proponents to offer a different and more enlightened view of not just what happened and what were the causes, but also why certain outcomes occurred and explanations for those outcomes. Examples of qualitative evaluation of healthcare programmes include the use of grounded theory to identify social phenomena, [78] action research used to evaluate the impact of new working practices, [79] and an ethnographic study of professional relationships [80] to name but a few. Qualitative and quantitative evaluation techniques do not have to be mutually exclusive and there are numerous examples of healthcare programme evaluations which have used both approaches to deliver an array of reported outcomes. Developing this theme further, quantitative and qualitative research methods can be combined, and not just reported alongside each other, to yield an evaluation which is greater than the sum of its components. Such a combination of evaluation or research methods is more commonly referred to as a mixed methods study. Mixed methods research combines qualitative and quantitative data to produce convergent findings with data from each paradigm informing the other. Tensions between these different methods can generate new insights. The mixed methods descriptor may also refer to a mix of different qualitative techniques and outcomes and not only a combination of qualitative and quantitative techniques and outcomes.[62]

Contemporary to the emergence of qualitative techniques in programme evaluation was the emergence of theory-based evaluation. [81] As with much of the evaluation and research literature the terminology is variable. Theory-based, -driven or -oriented evaluation was developed primarily as a response to problems of the generalisation of other, particularly positivist, evaluations to new situations or environments. It marked an important departure from previous debates in the field of evaluation research in which developments had been largely methodological of the quantitative (positivist) vs. qualitative (constructivist) nature. The seminal text in this field was the publication of Chen's 'Programme Evaluation' in 1990. [81] Programme theory deals with 'the assumptions that guide the way specific programmes, treatments, or interventions are implemented and expected to bring about change'. [82] Such theories are seldom explicit within healthcare programmes or interventions and often require careful and somewhat subjective identification by evaluators.

Most of the key authorities in programme theory evaluation make a distinction between theories which explain how certain activities are expected to produce specific outcomes, and other theories which explain how certain mechanisms which are released or enabled by a programme are causally linked to specific outcomes (i.e. how, why and to what extent different individuals and stakeholder groups will respond to an intervention). In common with much of the programme theory field, these two distinct theoretical perspectives go by a number of different and sometimes similar descriptions but are described herein as implementation and programme theory respectively. The way in which the theories identified are then incorporated into the evaluation process will vary depending on the programme evaluation theory framework which is utilised by the evaluators. The programme theory evaluation field is dominated by two frameworks; 'theories of change' and 'realist evaluation'. Table 1 highlights key methodological and functional differences between the two approaches. [83]

The transformation in approach to the evaluation of healthcare programmes has emerged in official guidance. The Medical Research Council (MRC) has published guidance on developing and evaluating complex interventions [84] although there was still a preference for randomised study designs and a more conventional, or positivist, elicitation of cause and effect. This was only guidance and it explicitly stated that it was not intended to be prescriptive. The authors have stated that understanding processes [of complex interventions] is important but does not replace evaluation of outcomes. [85] Other commentators have expressed disappointment at this positivist stance. [86] In an editorial published in the same year, Freeman claimed that a study of a health promotion intervention, which was evaluated by means of a randomised controlled trial, may have been better served if it had been evaluated within a realist evaluation framework. [86]

Table 1. Summary of methodological and functional differences between two related evaluation frameworks

Framework attribute	Theories of change	Realist evaluation
Identification and nature of theories	Much preferred at programme design or commencement. More suited to uncovering implementation theory.	Preferred at programme design or commencement, but can be adequately incorporated within any stage of programme. Primarily concerned with uncovering the programme theory.
Validation or approval of theories	Each stakeholder must validate and agree the theories. Conflict between stakeholders must be resolved by the evaluation team.	Validated and approved by evaluation team through observations, prior research and the relevant literature.
Theories' impact on evaluation		Used to identify mechanisms by which the theories are realised.
Impact of contextual attributes	Incorporated into the evaluation, often implicitly	Explicitly identified and combined with mechanisms to yield 'context + mechanism = outcome' combinations.
Level of evaluator involvement and interaction with programme	High, often intricate.	Variable. Can operate as a passive observer with minimal influence but framework can incorporate various levels of evaluator involvement.
Resource requirements	Generally quite high due to intricate nature of involvement with programme.	Generally lower than other evaluation frameworks, often relying on existing outputs and sources of data.

2.2 Evaluation of healthcare programmes

Health and healthcare interventions such as new or redesigned services are by their nature complex, due not least to the number of different agents and agencies which are often involved. [87, 88] As well as involving different groups or operating across different organisational levels, health service programmes must exist in a real world situation where numerous external variables are difficult, impractical or impossible to control. [89]

2.2.1 Realist evaluation in healthcare

Most research labelled as 'realist' or 'realistic' evaluation in the healthcare field has been published since the year 2000, with increasing numbers year on year. [90] A review of realist evaluations in health systems research, published in 2012, identified eighteen published articles which met the strict inclusion criteria out of an initial cohort of over 1,000. [90] The main findings of the review were that there were few examples of self-styled realist evaluations which met the inclusion criteria, that those which did were the more recent, that realist evaluation had been applied in a variety of fields within health systems research, that there was considerable diversity in the application of the underpinning principles of realistic evaluation, and that all researchers encountered challenges in applying the principles in practice. The review identified seemingly indiscriminate use of related but distinct terms such as theory-driven evaluation, theories of change and realist evaluation which confounded the analysis. Other common issues identified were conflicts in distinguishing between mechanisms and context, and a lack of methodological guidance for conducting realist evaluations. [90]

The specific issue of mechanism and context differentiation can present a significant interpretative and analytical hurdle. An example of the mechanism-context attribution conflict was given by Rycroft-Malone *et al* in considering whether a financial incentive which resulted in the consistent use of protocols for monitoring patient wellbeing was a mechanism which directly drove protocol use, or a contextual attribute which acted as motivation. [91] Where this problem has been identified not all evaluators were able to present solutions. However a number of different approaches have emerged. For example, Byng *et al* resolved the issue by returning to the philosophical basis of realism and accepting that there may be multiple mechanisms in operation at the same time. [92] Rycroft-Malone *et al* took a different conceptual approach by determining that some attributes can be both a mechanism and context at the same time depending on the organisational level under scrutiny. [91] This approach required a clear and explicit identification of the level, or levels, at which a programme or components thereof were operating. Even Pawson, as co-author of a realist evaluation of a large-scale health improvement initiative, found that distinguishing between a context and a mechanism could prove to be a challenge. [93] The solution in that case was found with an increasingly more abstract view of the

data so that two superficially distinct factors, exemplified by 'replacement of examination rooms with self-management pods' and 'early discharge of patients so that rehabilitation shifts to their home', each equally valid as a context or a mechanism, could subsequently be considered as being of the same mechanism described as 'redesigning the physical environment for self-care'.

As early as 2005, less than one decade after publication of the seminal text, [63] realist evaluation was specifically recommended for the evaluation of health care programmes in complex organisations or networks. [94] In order to successfully conduct a realist evaluation a detailed, multi-dimensional view of the experience of implementing the programme is required, and high-quality data on a range of agreed and standardised process measures must be prospectively collected. [94]

2.2.2 Innovation and change in healthcare organisations

Evidence for the implementation of changes in healthcare organisations, especially across multiple organisations and at different levels, has been comprehensively and systematically reviewed by Greenhalgh *et al.* [94] This review identified multiple examples of changes and innovations in various healthcare systems, organisations, and looked at the evidence for the adoption and implementation of healthcare innovations or changes. In particular the review concluded that when an organisation moves into the implementation phase this occurs in a non-linear process characterised by multiple shocks, setbacks and unanticipated events. The reviewers identified specific elements associated with successful implementation of an innovation or change in healthcare organisations and its subsequent routine adoption. [94]

- Organisational structure: Adaptive, flexible, support for devolved decision-making (e.g. strategic decisions made by departments and operational decisions made by delivery teams).
- Leadership and management: Support from senior managers and leaders, continued advocacy of the change and continued commitment. Alignment with prior goals of senior and very senior management levels with active involvement and consultation of leaders.
- Human resources: Motivated and competent practitioners, adequate system capacity, involvement of staff from all levels, and early and wide staff engagement, formal facilitation initiatives.
- Funding: Dedicated and on-going funding is associated with success compared to situations without such.
- Intra-organisation communication: A coherent narrative for change and effective communications between parties, teams, departments, etc.
- Extra-organisational networks: Of increasing significance with increasing complexity of the change or innovation.

- Feedback: accurate and timely information on impact of change increases chance of routine adoption.
- Adaptation: Where innovations are adapted to the local context they are more likely to be successful.

2.3 Integrated Care

2.3.1 What is integrated care?

Integrated care has a fluid and dynamic definition which varies depending on an individual's or organisation's perspective. [95, 96]. It has been defined by the World Health Organisation as:

'A concept bringing together inputs, delivery, management and organization of services related to diagnosis, treatment, care, rehabilitation and health promotion. Integration is a means to improve the services in relation to access, quality, user satisfaction and efficiency.' [97]

A systematic review of 'integration in health systems' identified more than 70 terms and phrases which in turn yielded about 175 definitions and concepts. The authors of the review specifically highlighted 'integrated care' as one of the more common but heterogeneous terms encountered. [96] An international conference and discussion on integrated care in 2009 concluded that 'integrated care' as it is now used is more akin to an umbrella term encompassing models which differ significantly in scope and point of view, although similarities exist with respect to the use of tools and the targeting of resembling problems. [98]

A report from the Nuffield Trust sought to answer the question 'What is integrated care?' by providing an overview of integrated care in the NHS. [41] The authors defined integrated care broadly as:

'... a term that reflects a concern to improve patient experience and achieve greater efficiency and value from health delivery systems. The aim is to address fragmentation in patient services, and enable better coordinated and more continuous care, frequently for an ageing population which has increasing incidence of chronic disease.' [41]

One perspective which has been taken when considering integrated care is to consider what care without integration would be like:

Without integration at various levels, all aspects of health care performance suffer. Patients get lost, needed services fail to be delivered, or are delayed, quality and patient satisfaction decline, and the potential for cost-effectiveness diminishes. [99]

A common theme of integrated care, especially with respect to the UK and Department of Health documents, is 'patient-centred care'. [49, 100] This has been more technically described as 'imposing the patient perspective as the organising principle of service delivery'. [101] Patient-centred care and integrated care are often used interchangeably or are used in the same context. [49, 100, 102]

2.3.2 Breadth of integration: Horizontal and vertical

A useful distinction is often made between integration of care providers within a specific setting and integration which is specific to a defined patient group. Setting-specific integration is usually within primary and community care, and patient-specific integration is usually defined by a particular disease or condition across the hierarchy of medical care. These forms of integration are known as horizontal and vertical integration respectively. [44, 95] Both descriptors relate to the breadth of integration. Vertical and horizontal healthcare integration are not necessarily mutually exclusive, although in practice it is uncommon for the two to be present in the same system. [103]

The World Health Organisation has defined vertical integration as '*integration happening across organisational boundaries to align strategic approaches to care*', and horizontal integration as '*within organisations and across departments*'. I.e. vertical integration is defined as linking different levels of care (e.g. primary, secondary, and tertiary) and horizontal integration is defined as linking similar levels of care across professional, departmental and organisational boundaries. [104]

A comprehensive definition of the breadth of integration was provided by Thomas *et al*: [44]

Vertical integration relates to the idea that diseases are treated at different (vertical) levels of specialisation. Horizontal integration relates to the idea that environments that more broadly support health require co-ordinated effort and collaborative planning at the (horizontal) level of whole people and communities. Whole system, or comprehensive, integration requires that vertical and horizontal integration develop in tune with each other. Vertical integration draws particularly on natural science, with an emphasis on laboratory (especially positivist) research and linear care pathways. Horizontal integration draws particularly on social science. [44]

Vertical integration may be perceived as a more attainable short-term objective compared with horizontal integration which can only be achieved successfully in the longer term, if at all. [105] This difference may arise due to the narrower focus of vertical compared with horizontal integration and models of vertical integration more often build on existing labour and environmental resources. [105]

There has been much attention on integrated care in the English NHS between 2000 and 2010. [43] However the focus appeared to have shifted towards horizontally integrated care as typified by Department of Health initiatives such as the Integrated Care Network [106] and the Community Health Partnerships [107]. There were no obvious equivalent central initiatives to promote and support vertically integrated care within the NHS. Despite the apparent bias towards horizontally integrated care models the sixteen pilot projects in the Department of Health Integrated Care Pilots programme did include a minority of projects described as demonstrating only vertical integration. [108]

2.3.3 Evidence for benefits of integrated care

A narrative review of systematic reviews of integrated care programmes for chronically ill patients was an important source of evidence for the effects and mode of integrated care. [109]

Ouwens *et al* identified thirteen systematic reviews of integrated care programmes for chronically ill patients. The studies included in the reviews were similar in their aims which were to reduce fragmentation of service delivery and to improve continuity and co-ordination of care. However they varied considerably in the focus and content of each programme. The authors identified some of the more common components of integrated care programmes as patient education and support to self-manage, structured clinical follow-up, case management, multidisciplinary care teams, a multidisciplinary pathway, and healthcare professional targeted interventions consisting of feedback and education. In elucidating summary findings the authors came up against issues of inconsistent definitions and poorly described interventions. Despite this they identified generally positive effects on 'quality of care' loosely defined by a number of attributes such as process outcomes (e.g. use of guidelines), functional status, specific health outcomes, and mortality and hospitalisation rates. The authors stated that consistent definitions of integrated care programmes must be used, and the component interventions must be well described to enable better comparisons between programmes and to understand their effectiveness and cost impacts. [109]

A Cochrane systematic review of shared care across the primary and secondary care interface, defined as 'the joint participation of primary care physicians and specialty care physicians in the planned delivery of care, informed by an enhanced information exchange over and above routine discharge and referral notices' included twenty studies, nineteen of which were randomised controlled trials. [110] Most studies had at least one important methodological shortcoming. The definition of shared care used has clear similarities with definitions of integrated care, especially vertically integrated care. The review, which included meta-analyses, found mixed results with no consistent improvements in physical or mental health outcomes, psychosocial outcomes, measures of disability and functioning, hospital admission rates, default or participation rates,

recording of patient risk factors, and patient treatment satisfaction. One clear benefit was identified, in prescribing, although this was only evaluated in eleven of the studies. Evidence relating to cost impacts was only available from eleven studies and could not be collectively evaluated.

A systematic review of randomised studies of integrated care including disease management programmes for long term conditions examined the evidence in the context of the UK health service. [111] The review made a distinction between models of horizontal and vertical integration and identified 76 reports, the majority of which related to horizontal integration. With respect to vertically integrated models of healthcare for long term conditions the review concluded that there was a lack of evidence of effectiveness. A potential tension within vertically integrated structures such as care pathways was identified. Conflict may exist between the patient choice and empowerment agenda, a common theme in the management of long term conditions, and the use of a prescribed pathway. The review also concluded the main challenge for the care pathway process was development and documentation as opposed to implementation and maintenance. In particular, service user ('patient') involvement in the development of care pathways was found to be weak. The authors expressed surprise that NHS policy was leading to ever greater levels of both vertical and horizontal integration in the absence of evidence of effectiveness. They acknowledged the NHS integrated care pilots could add substantial new volume to the available evidence base on integrated models of healthcare. [111]

A comprehensive updated review on the evidence specifically for models of vertically integrated healthcare was published in 2009. [112] However, the authors appear to have utilised an inflexible definition of integrated care which relied upon at least a degree of organisational merger. The report identified two main types of vertical integration; where agencies involved at different stages of the care pathway were part of a single organisation, and where payer and provider agencies were part of a single organisation. The inclusion of 'single organisation' in these examples may not reflect the depth of integrated healthcare which has been described as, or which describes that which is recognised as, vertical integration in other sources. The review identified a general lack of outcome data relating to models of vertically integrated healthcare compared with evidence for the processes of integration. [112] With respect to integration of payment and provider functions (e.g. using pooled budgets, and organisational mergers and acquisitions) the evidence demonstrated there was at least a perception of improved partnership formation, some limited evidence for increased healthcare capacity, and an increased focus on case management and use of information technology. However there was mixed evidence for an effect on hospital admission rates, length of stay in hospital, and the overall impact on costs of healthcare. [112] With respect to integration of healthcare providers, the evidence demonstrated a conflict between strengthened local partnerships and a lack of co-ordination at national policy

level. In addition, there were some reports of improved healthcare capacity, for example with freeing up labour, and an improved focus on governance and adherence to guidelines. There was, however, little evidence of an impact on health outcomes and limited evidence of an impact on costs. [112] With respect to clinical integration by formation of networks the evidence demonstrated inconsistent effects on networking, specifically communication and personnel role changes, largely non-significant improvements in care provision, and potentially some improvements in costs and health outcomes. The authors expressed concerns about potential for reporting or publication bias. [112]

Disease management programmes share a number of features with integrated healthcare interventions, particularly the narrow clinical focus. [113] A systematic review of disease management programmes, published in 2004, reviewed 102 reports of eleven chronic conditions. The review found that most disease management programmes improved patient satisfaction, patient medication adherence, and improved disease control. There was less clear evidence for the cost-effectiveness of, or reduction in expenditure associated with, disease management programmes. [114]

Additional evidence for integrated care was reported by The Nuffield Trust using examples from the English NHS and other peer-reviewed sources. [115] The conclusions were directed at the integrated care pilots which had been announced following the Department of Health 'High Quality Care for All' report ('the Darzi review'). [49] Specifically, ten salient points were highlighted with relevant examples of good practice provided. The overall tone of the document was one of cautious optimism for the integrated care pilots and the evidence they could generate for future integrated care in the NHS. [115]

Other reviews have focused on specific components of integrated care. [116] For example, a systematic review of disease management programmes, defined as '*... patient-centred approaches of co-ordinated multiple healthcare interventions that structure chronic care to a specific patient group. ... also referred to as e.g. integrated care, managed care, patient-centred care, and case management*' included 31 studies in the disease areas of diabetes, depression, heart failure and chronic-obstructive pulmonary disease. The focus of the review was the impact on healthcare expenditure. The evidence demonstrated substantial cost-savings for some programmes, although almost as many programmes demonstrated more modest cost increases. The balance was generally in favour of disease management programmes for reducing overall healthcare expenditure. [116]

2.4 Care Pathways

2.4.1 What is a care pathway?

It is important to consider first the definition of a 'care pathway'. As with 'integrated care', the description is subject to a large degree of variation in terminologies used. Several definitions exist with as many complementary as there are distinct. The definition of an integrated care pathway and other types of care pathways have varied in the literature over time, geography, and healthcare setting. [117]

Some of the more common terms in use which encompass the concept of a clinical pathway are care pathway, critical (care) pathway, integrated care pathway and care map. [118]

A review on the use of these four terms (care pathway, critical pathway, integrated care pathway, and care map) in 263 published articles found they were collectively associated with 84 different definitions. [117] Although a large degree of commonality and agreement between the various definitions was identified there still remained a considerable level of discordance. The authors generated a single definition of a clinical pathway presented as a starting point for further deliberation: [117]

A clinical pathway is a method for the patient-care management of a well-defined group of patients during a well-defined period of time. A clinical pathway explicitly states the goals and key elements of care based on evidence based medicine guidelines, best practice and patient expectations by facilitating the communication, coordinating roles and sequencing the activities of the multidisciplinary care team, patients and their relatives; by documenting, monitoring and evaluating variances; and by providing the necessary resources and outcomes. The aim of a clinical pathway is to improve the quality of care, reduce risks, increase patient satisfaction and increase the efficiency in the use of resources. [117]

The apparently now defunct National Pathways Association (UK) had defined a care pathway in 1999 as: [118, 119]

An integrated care pathway determines locally agreed, multidisciplinary practice based on guidelines and evidence where available, for a specific patient/client group. It forms all or part of the clinical record, documents the care given and facilitates the evaluation of outcomes for continuous quality improvement.

The European Pathway Association defined a care pathway as: [120]

A complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period.

Defining characteristics of care pathways include:

- *an explicit statement of the goals and key elements of care based on evidence, best practice, and patients' expectations and their characteristics*
- *the facilitation of the communication among the team members and with patients and families*
- *the coordination of the care process by coordinating the roles and sequencing the activities of the multidisciplinary care team, patients and their relatives*
- *the documentation, monitoring, and evaluation of variances and outcomes; and*
- *the identification of the appropriate resources*
- *The aim of a care pathway is to enhance the quality of care across the continuum by improving risk-adjusted patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources.*

A Cochrane review on care pathways also came up against the issue of multiple definitions and varied terminologies for what a care pathway is. [121] The authors worked around the terminological issues by opting to use a broad definition of a care pathway as being any intervention or programme which was a '*structured multidisciplinary plan of care*' and which met at least three of the four following criteria:

1. *It channelled the translation of guidelines or evidence into local structures.*
2. *It detailed the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other 'inventory of actions'.*
3. *There were time-frames or criteria-based progression (i.e. steps were taken if designated criteria were met).*
4. *The aim was to standardise care for a specific clinical problem, procedure or episode of care.*

Using these broad criteria the authors identified and screened over 3,200 article abstracts although only 28 met the inclusion criteria. [121] The definition used in the Cochrane review had been systematically elucidated using a targeted literature search. [122] However some respected commentators criticised the Cochrane definition as it did not stipulate that a pathway is a 'complex intervention'. This criticism was extended to the outcomes reported in the Cochrane review, in particular the distinction between simple pathways and pathways which were one component of a multifaceted intervention. The commentators argued that a pathway would always be part of a multifaceted intervention. [123] The same team of authors had previously asserted a view that care pathways were more than stand-alone documents or checklists but instead should be viewed as an encompassing and abstract intervention of a concept, model,

process and product. [124] In this same article the authors alluded to the term ‘integrated care pathway’ as being a UK-specific term used to describe a ‘clinical pathway’ and this is supported by the National Pathways Association’s definition of a care pathway reported in this same section. [124]

2.4.2 Aims of care pathways

The aims of care pathways are not always clear or explicit. There are many aims and uses for care pathways and these vary depending on the perspective. Care pathways have been used for multiple purposes: [119]

- Implement guidelines and evidence-based practice; standardise care and reduce variation
- Control and minimise costs
- Improve the efficiency of the healthcare system
- Improve patient documentation and providing patient education
- Widen patient choice
- Improve quality of care
- Promote, improve or support clinical audit, benchmarking, accreditation and clinical governance
- Promote, improve or support communication between different components of the pathway
- Manage risk and litigation
- Promote, improve or support the commissioning of services

The evidence that care pathways achieve these aims was described in the Cochrane review referred to previously. [121] The review assessed the overall effects of clinical pathways on health professional practice, patient outcomes, length of (in-patient) stay, and hospital costs. In addition, the review sought to identify specific factors (setting, nature of intervention, specific types of intervention, and quality of intervention development and implementation) that might contribute to the effectiveness of a clinical pathway. The review concluded that clinical pathways were associated with reduced in-hospital complications and improved documentation without impacting negatively on the inpatient length-of-stay or hospital costs. [121]

2.4.3 Other evidence for pathway redesign

A report by the Government’s Audit Commission published in 2004 reviewed the redesign, planning and delivery of care pathways, particularly at the primary-secondary care interface, in English primary care trusts. [125] The redesign of pathways was found to improve the actual care delivered, reduce waiting times, and increase the range of healthcare options available to patients. However it also found that only 7% of PCTs reported having sufficient staff available to drive

pathway redesign. Considerable challenges were identified in certain areas of pathway design and implementation, particularly with respect to communication and stakeholder engagement, notably with patients and hospital-based specialists (consultants). The generalisability of these conclusions was challenged as they were largely based on an assessment of 14 services focusing only on dermatology or orthopaedic care with a specialist practitioner working in primary care in each case. [125]

One of the drivers for integrated care has been the identification of care provided in secondary care which could be provided adequately yet more conveniently for patients in primary care. Evidence which supports the transfer of acute inpatient and day-case services from hospitals into the community and the associated impact on care quality and healthcare costs was examined in a report published by The Health Foundation. [126] The evidence demonstrated that community-based services could, under certain conditions, provide care which was at least as good as that provided by hospitals and potentially at reduced cost. Evidence for patient-oriented outcomes has been limited, with some benefits from improved access to a range of services, easier travel to physically access services, and shorter waiting times. The conclusions of the report were necessarily cautious due in part to the quality and extent of the supporting evidence. For example, a *potential* for community-based services to reduce healthcare costs was highlighted although to achieve noticeable cost savings such a policy would need to operate with active decommissioning of hospital bed provision (i.e. 'ward closures'). [126]

A briefing paper from The Nuffield Trust described three successful examples of integration between primary and secondary care in the English NHS. [127] Each example employed a different strategy to achieve integration, with models consisting of community-based specialists, as was seen in the examples cited in the Audit Commission report of 2004; [125] or primary care reaching into hospitals with GPs accompanying specialists and provision of traditionally hospital-based services in premises which are owned and staffed by primary care providers; and finally a model of partnership working in which strong relationships and organisational commitments were reinforced with some pooled budgets and the agreement of eight principles of contracting. A common feature of each of these examples was that they were developed locally with strong local leadership demonstrating initiative and commitment despite considerable challenges. Medical-profession leadership is noted as being of crucial importance to the success of these examples of integrated care. The examples demonstrate that changes take considerable time and often involve a complex path of development. National policies have both promoted and inhibited clinical integration between primary and secondary care. [127]

A review on the auditing of care pathways identified 15 care pathway audit tools although the majority of these had not been published in peer reviewed literature. Only one of the tools had

been piloted and externally validated. At the time of writing, the authors were not aware that any of the tools had been cited in a peer reviewed publication examining the effect of clinical pathways. Interestingly, the authors used a realistic evaluation framework to conduct their review of care pathway audit tools. [128]

A report published as part of an NHS improvement programme identified examples of patient benefits associated with clinical pathway redesign specifically in the therapeutic areas of cancer, heart disease, lung disease, stroke care, and diagnostics. [129] The report described the benefits collectively as enabling patients to enjoy better health and well-being due to practical service improvements. Acknowledging the limited clinical range the report concluded that there was ‘no reason why these improvements could not be applied to other [therapeutic] areas’. [129]

2.5 Integrated Care Pathways

2.5.1 Definition of an integrated care pathway

It is not clear whether an ‘integrated care pathway’ is distinct from other pathway definitions such as ‘care pathway’ and ‘clinical pathway’ etc. For example, the aforementioned care pathway definition from the National Pathways Association opened with ‘An integrated care pathway ...’. [118, 119] An editorial accompanying a special edition of the International Journal of Integrated Care on integrated care pathways stated that the term ‘integrated care pathway’ should refer especially to pathways which were integrated across various health care settings, for example across hospitals and community health services. [130] Hence, multidisciplinary collaboration within a single ward, for example, was not in itself an example of an integrated care pathway. [130] This was at odds with a review of the terminologies of pathways which set out to define ‘care pathway’. This stated that the addition of ‘integrated’ was unnecessary as a care pathway must be, by default, integrated. [131] The authors proceeded to state that the term ‘clinical pathway’ was reserved for use within a clinic or hospital department and a ‘care pathway’ would be differentiated by existing over a longer term and by including, for example, outpatient department activities, discharge from hospital and after-care. Further interrogation of the actual evidence considered in the review revealed a continued focus on acute or critical care, calling into question the validity of the authors’ terminological assertions. [131] As highlighted in the previous section, at least one team of respected pathway experts has asserted that ‘integrated care pathway’ was simply a UK-specific term which described a care / clinical pathway. [124] Nonetheless, an ‘integrated care pathway’ has been defined succinctly as:

‘... a structured multidisciplinary care plan which details essential steps in the care of patients with a specific clinical problem’ and which ‘... describes the expected progress of the patient’. [47]

2.5.2 Evidence for integrated care pathways

A state governmental report from Australia described five pilot projects as ‘integrated disease management projects’. [132] These involved models of integrated care for chronic disease, specifically diabetes (three), asthma, and hypertension. Each was funded for three years from 2001. The design of the projects required that social care and services played an important role, i.e. there was a key element of horizontal integration. In addition, there appeared to be a less defined role for specialist care with the focus on primary medical care and social care support but with an expectation that demand for acute and specialist services would be subsequently reduced. Over 1,000 patients were treated within at least one of the individual projects. In each project patients were educated and empowered to take on a degree of responsibility for their own care. Some staff members, typically nursing staff, were given the task of delivering patient education. Patients were also able to attend events at which they could meet other patients with the same health problem. Patient opinions were reported as overwhelmingly positive although a reporting bias could not be ruled out. [132]

A subsequent evaluation report of the programme sought to identify, amongst other things, the barriers and enablers to improving care for people with chronic conditions via the disease management programmes. [133] The enabling factors included:

- Use of systems and protocols based on evidence of best practice
- Building on existing resources and infrastructure
- Promotion of a centrally coordinated care pathway with clear entry points for consumers (i.e. patients)
- Resourced and stable workforce within agencies and programmes
- Identification of key opinion leaders and change agents
- Early and broad participation in planning, shared decision making and clear understanding of roles to foster ownership
- Agency leadership and high level management commitment
- Value added training and education of health care providers

A number of barriers were also identified, all of which specifically related to primary care engagement. [133]

- Competing initiatives
- Lack of primary care medical professionals or large workloads
- Reluctance to engage with untried and short-term initiatives
- Misunderstanding the benefits of patient self-management and multidisciplinary care in chronic disease

Neither the official [132] nor the evaluation report [133] identified any specific outcome measures for any party (patients, professionals, or health economy/system).

A mental health initiative from the south west of Scotland provided an example of horizontal and vertical integration within a single integrated health and social care pathway initiative. [134] The evaluation found a clear disconnect between what was expected and desired and what actually happened. In practice the pathway was seldom used and this was itself seen as a barrier to further integration. The focus of the evaluation shifted to identifying the barriers encountered when the pathway was implemented. These included those of an organisational nature (fragmentation, differing priorities, and distinct resources) and a general lack of resources for on-going support, team development, and change management.

A systematic review of integrated care pathways, using the European Pathways Association definition, [120] included only nine reports of seven randomised controlled trials from an initial sample of more than 4,000. [135] A narrative summary using a realist evaluation perspective was provided. Despite the small sample size, the review made a number of conclusions about when integrated care pathways were, and were not, effective. The review found that integrated care pathways were effective when care trajectories are predictable but the usefulness of care pathways in settings in which recovery is more variable was unclear. Integrated care pathways were most effective in achieving behavioural changes when there are known deficiencies and their value where inter-professional working is already well established was uncertain. None of the studies included an economic evaluation and therefore no conclusion could be made about the economic value of integrated care pathways and whether the benefits justified the implementation costs. [135]

2.6 Interventions specifically in IBD patient populations

With respect to IBD specifically, little evidence of new or redesigned vertically integrated models of healthcare was identified. No evidence was identified of an evaluation of an integrated care pathway in IBD, irrespective of the evaluation approach or technique. A brief summary to the associated evidence specific to IBD is provided.

2.6.1 Patient choice, shared care and shared decision-making

A key feature of the IBD Standards [1] which would later be incorporated into the IBD pathway evaluated in this thesis was the notion of patient choice, also described as shared care and shared decision-making. Specifically this relates to macro-level choices about the location and provision of healthcare (e.g. primary vs. secondary, GP vs. specialist, hospital vs. home) and micro-level choices about particular treatments. [1] These particular standards (box 3) reflected the general healthcare and governmental policy background which supported patient choice. [136] It was not clear whether this in turn reflected specific evidence for the benefits of increasing patient choice in decisions about different aspects of healthcare or whether it was politically motivated.

A theory-driven systematic review of patient choice in healthcare examined the evidence for the demand and impact of two aspects of choice; provider and treatment. [137] In terms of demand for patient provider-choice, the data did not reveal any conclusive evidence of preferences for primary vs. secondary care treatment. However patients were interested in choosing between different secondary care providers so long as there was a tangible benefit to themselves such as reduced waiting times or better quality care. The data did reveal that certain types of patient based on demographic and socioeconomic factors were more or less likely to exercise a right to choose and therefore the ability to obtain benefit from the provider-choice agenda was potentially inequitable. In terms of patient treatment-choice, the review found that there was a greater volume of evidence supporting this aspect of patient choice. Patients reported a relatively high demand for treatment-choice which wasn't always matched in practice even when the option to choose was available. The factors which influenced treatment-choice were highly complex and spanned social interactions and cultural beliefs as well as scientific interpretation. The authors concluded with an expression of caution regarding provider-choice but were more positive about treatment-choice, stating that patients 'want to be more involved in individual decisions about their own treatment and generally participate much less in these decisions than they would wish'. [137]

Box 3. IBD Standards which related to patient choice and related themes [1]

Standard B1. Arrangements for Shared Care

The arrangements and scope for shared care and the circumstances in which the patients should be referred back to hospital care must be clearly defined between the hospital staff and the GP. They must be explained verbally to the patient and written information on this provided to the patient, ideally as a care plan.

Arrangements should always be made in discussion with the patient.

Standard C. Maintaining a patient-centred service

Care for IBD patients that is patient-centred, responsive to individual needs and offers choice of clinical care and management where possible and appropriate.

No single model [of healthcare provision] is appropriate for all patients all the time, and choice between three approaches is appropriate: hospital care, shared-care with primary care and supported self-managed care.

Offering personalised and responsive healthcare means that any patient can migrate between models of care according to the activity and complexity of disease, local facilities and personal preference. They can also make different choices at different times in their illness.

Standard C3. Supporting patients to exercise choice between treatments

Where there are alternative treatment options then information and support should be offered to patients to enable them to participate in decisions about which treatment to select. ...

Standard C4. Supporting patients to exercise choice between care strategies for outpatient management

Patients may prefer continuing hospital management, shared care with their GP or supported self-management and they may wish to choose a different option at different stages in their illness. ...

Although no evidence was identified which specifically evaluated IBD patient choice, whether relating to the provider or treatment, a review of initiatives aimed at empowering IBD patients did include elements of patient choice as patients were educated to self-manage. [138] The self-management involved self-determination of specialist consultation and self-medication with prescription only medicines. However in these scenarios patients were operating according to specific protocols and it did not appear they were in a position to choose whether to consult a specialist or a GP, or select from amongst a number of specialists, or whether they were involved in the selection of drug treatments. In these respects, although patients were clearly empowered, this occurred in the context of constrained choice. The review still concluded that ‘the effects of guided self-management on compliance have not been evaluated, but early, qualitative data suggest that when patients feel more responsible for symptom control they are more likely to adhere to the treatment regimen especially if they have been involved in the choice of regimen’. [138]

One randomised controlled study incorporated elements of both provider and treatment choice within a patient empowerment programme, referred to as a self-guided management intervention [139] In this example the intervention involved discussion of treatment options with patients, presumably with a hospital-based specialist. A treatment regimen was then agreed which patients would use whenever symptoms of a relapse of ulcerative colitis occurred. In addition, if patients experienced symptoms of relapse they could consult their GP, or under specific circumstances consult specialist services, or commence self-medication with the agreed regimen. In the event, almost all intervention relapses were self-managed compared with just half of relapses in the control group. It was not clear what, if any, aspect of patient choice contributed to the positive outcomes in the intervention group as patient choice in this example was not isolated from patient and, to a lesser extent, primary-care physician empowerment. [139]

An epidemiological study of IBD in a primary care population in North East England found that GPs made a significant contribution to meeting the healthcare needs of IBD patients. Published in 2000, it reported that care was equally shared between GPs and gastroenterologists. The authors concluded that, given the large degree of care provided within primary health services, there was a need for GP training in the management of IBD and a redistribution of resources to primary care. [2]

2.6.2 Routine vs. ‘when required’ specialist care

One of the key reports available is of a UK-based project conducted in the mid-1990’s. Williams *et al* described a randomised controlled trial comparing ‘on-demand’ or open access with routine appointments for follow-up of patients with quiescent or mild, stable IBD. [140] Primary outcome measures utilised accepted quality of life indicators such as the SF36 and the disease-specific UK

quality-of-life IBD questionnaires as well as quantitative measures of healthcare utilisation. The study recruited 180 patients with similar numbers randomised to each type of care and high follow-up rates. The study ran for 12 months with patient-data collected for up to 24 months. The results demonstrated no significant differences in quality of life measurements. There was a clear patient preference for open access although a minority did express strong preferences for routine care. Open access patients used substantially and significantly fewer healthcare resources as measured by day visits and outpatient visits, with a corresponding reduction in the cost of total investigations. There were no significant differences in inpatient days or any specific individual investigation. However there were differences in use of drugs with open access patients demonstrating a greater level of use. No explanation for this observation was provided. The net effect on cost was small and not significant, with open access patients actually associated with slightly greater costs compared with those receiving routine care. Although total costs were similar the distribution did show clear differences with an apparent shift from secondary to primary care.[140] A separate report investigated the views of GPs (n = 69) whose patients were involved in the open access arm of the study. [141] The results, which included both face-to-face interviews and postal survey responses, found that 13% experienced a problem with the management of at least one open access patient, only 8% were aware of the IBD shared care guideline, 42% had experience of using the specific patient paper record, and 81% were in favour of providing written patient guidelines for open access. Ultimately 68% preferred open access for IBD patients in general, and 65% supported the establishment of a gastrointestinal specialist nurse to support open access. There was some discordance between preferences expressed by patients and their GP, with agreement for care model in only 60% of 122 cases. [141]

2.6.3 Routine vs. self-care in ulcerative colitis

High-quality evidence from randomised-controlled trials has been published relating either to specific sub-diagnoses of IBD or aspects of treatment such as patient empowerment and education. Robinson *et al* described a randomised-controlled trial conducted in the North West of England. [139] Patients with ulcerative colitis were randomised to either open-access follow-up aided by a 'personalised guided self-management regimen' (n = 101) or usual practice which relied upon regularly scheduled follow-up and referrals for specialist care (n = 102). After a median follow-up of 14 months (minimum 11 months) the results were striking; relapses were treated earlier in patients in the open access group compared with those in the usual care group (mean 14.8 vs. 49.6 hours, $p < 0.0001$). In addition, 97% of open access patients commenced treatment for relapse within two days compared with 63% in the control group and a non-significant trend towards a shorter duration of relapse was observed in patients who commenced treatment within 24 hours of the symptoms of a relapse (17.7 vs. 25.5 days, $p = 0.16$). Open access patients also demonstrated reduced healthcare utilisation as evidenced by a reduction in

the number of medical appointments (89 vs. 344) although this effect must be balanced against increased appointment duration in order to establish the patient management plan. Accordingly, there was a reduced impact for patients in terms of the time required to attend medical appointments and the direct costs of travelling to and from such appointments. The study identified strong and clear patient preferences for the self-management open access approach. The generalisability of this study was compromised because only patients with stable and uncomplicated ulcerative colitis were included, and it focused only on the management of relapses over a relatively short period of time.[139]

2.6.4 Randomised study of patient-centred care

Another randomised controlled trial conducted by the same researchers was published in 2003 under the auspices of the NHS Health Technology Assessment programme. [142, 143] This study was a cluster randomised trial of 19 secondary care centres within the English NHS. Selected patients had either ulcerative colitis or Crohn's disease. Nine sites were randomly selected to deliver an intervention that consisted of; training consultants to provide a patient-centred approach to care, provision of an information guidebook to patients, development of a written self-management plan, and patient self-referral to specialist services. Ten control sites continued to deliver care in the usual way which generally manifested as a disease-centred approach to care with regular follow-up appointments and medical referral for specialist care. After one year, patients in the intervention group recorded fewer hospital visits (1.9 vs. 3.0, $p < 0.001$) and reported they felt more able to cope with their condition ($p < 0.05$). The intervention group also had fewer relapses (1.8 vs. 2.2, $p < 0.01$), and a strong patient preference was indicated for the intervention. The primary outcome measure was a patient-reported disease-specific quality of life score, which showed no significant difference between groups after one year. A number of quantitative patient-derived outcomes were measured and none demonstrated a significant difference although they were all consistently in favour of the intervention group. The intervention was found to be associated with reduced costs of about 14%, although it was also associated with a small decrease in quality adjusted life-years. [142, 144] The net effect meant the intervention was considered to be highly cost-effective to the NHS and the evidence supported greater use of patient-centred care in IBD.[142, 144]

The project also explored qualitative aspects from the point of view of both patients and secondary care medical consultants. [142] With respect to patients, several attributes were identified which correlated with a patient's ability to manage and cope with self-care. With respect to medical consultants, they were generally supportive of greater self-management for their IBD patients although there were differences amongst them about which patients would be suitable for the intervention and concerns about the management and operation of the system [142].

2.6.5 Communicating clinical information to IBD patients

Other disease-specific evidence identified was referred to in a publication from the Royal College of General Practitioners in their 2008 publication 'Teams without walls'. This report described numerous examples of vertically integrated healthcare models within the UK. One project was described in which 'patients with IBD were educated and empowered to manage their condition with hospital attendance if they were stable. The results of blood test monitoring and advice were sent by email or text.' An evaluation of this project estimated that the freed outpatient slots alone saved an estimated £40,000 per annum and allowed rapid advice for patients suffering a relapse. More details were received from one of the lead clinicians involved in the project. Motivated by similar factors as the HTA study [142] it also appeared to focus on an apparent excess of routinely scheduled outpatient appointments. In particular, information was communicated to patients via novel methods concerning such details as the results of blood tests and other simple investigations which, if nothing untoward was identified and patients were otherwise stable, enabled a substantial reduction in outpatient appointments. The information was communicated via mobile telephone short message service, or 'text messaging', electronic mail, or both.[145] The service evaluation included 314 patients; 69% responded to the offer of the new service, 18% opted to remain with the existing service, 44% chose electronic mail, 31% chose text message, and 8% requested normal telephone communication. Thus, over half of all patients opted for at least one of the novel modes of communication offered. The proportion of out-patient appointments which were classified as 'unproductive' fell from 39% to 13% following implementation with estimated savings of about £30,000 per annum to payers. [146]

2.6.6 IBD-specific clinical information technology requirements

One of the specific requirements of the IBD Standards [1] was for an integrated or shared information system (box 4).

Box 4. IBD Standards which related to information sharing [1]

Standard B1. Arrangements for Shared Care

A system for sharing of information about test results or treatment changes should be in place through the use of IT, written communication between the GP and hospital or a patient-held record.

Standard E1. Register of patients under the care of the IBD Service

Every IBD Service should maintain a local Register of all diagnosed IBD patients in the catchment area (including those who have been diagnosed but are not currently being managed in secondary care) recorded on a searchable database and with adequate clerical support to maintain this.

Standard E2. Developing an IBD database.

IBD Services should develop towards keeping electronic records of patients' disease histories and treatments.

A National Health Service information technology programme called 'Do Once and Share' featured IBD as one of its core therapeutic areas. [147] The aim of the programme was to obtain feedback from specialist groups for NHS Connecting for Health, part of the NHS National Programme for Information Technology, in order to assist in the specification of new NHS information technology systems. The IBD component was led by a team from an acute hospital trust based in the South West of England. Following a national consultation the team submitted a set of requirements that were considered essential and desirable for an integrated IBD care record. The requirements were extensive and covered several aspects of care ranging from patient requirements, clinical standards, medication, in-patient specific care, surveillance, tests and diagnostic procedures, communications and others. [147] This aspect of the national programme did not appear to have been realised and there was no common NHS IBD-specific electronic patient record in existence.

Chapter 3: Methodology

3.1 Realist evaluation

The direct observation period of the evaluation ran from October 2009 to December 2011; 27 consecutive months. Some evidence was also gathered that pre-dated the direct observation period. Data relating to patient reviews, practice sign-up rates, and healthcare utilisation was collected up to 31st March 2012.

A diverse range of data sources was used within the realist evaluation of the IBD pathway. These were selected on the basis of their relevance to the project and evaluation, breadth of source type, availability and accessibility.

Data sources included in the evaluation:

- Official programme documents produced for, or otherwise supporting, the Department of Health integrated care pilots application including the IBD Standards (2009).
- Video recording of a presentation made by a project board member as part of the IBD Standards launch strategy.
- Official programme documents produced as outcomes of the pathway (e.g. patient information, clinician training aids).
- Presentations made as part of the pathway (e.g. for training or communication purposes).
- Official documents relating to project board meetings, such as agenda, minutes, action plans, and other associated documents.
- Evaluator notes of project board meetings.
- Evaluator notes of other associated meetings and events.
- Electronic communications (e-mails) which the evaluator was party to.
- Interviews with key actors and other relevant parties to the pathway.
- Focus group with local IBD patients.

This data, which was largely qualitative in nature, was supported by quantitative data.

- Descriptive measures of the IBD pathway relating to project management and implementation (e.g. number and frequency of project board meetings and other significant events, rate of sign-up from general medical practices).
- Routinely collected data from the annual review component of the pathway, including descriptive measures (e.g. number of reviews, completion rate per component, quality-of-life and symptom scores).
- Routinely collected NHS data from prescribing analysis and cost (PACT) data sets and health episodes statistics (HES) data sets.

3.1.1 Theories of change

A crucial step in conducting a realist evaluation is to identify the theories of change, whether explicit or implicit, within the programme being evaluated. [63] Within the IBD pathway any such theories were not explicitly stated within any of the data sources. Therefore the theories of change were elicited from the empirical data and observations.

3.1.2 Quantitative analysis

3.1.2.1 Pathway descriptive outcomes

A number of data sources were used to obtain descriptive outcomes relating to the pathway. Data was principally derived directly from the Primary Care Trust (PCT) project team and in particular the last update of the pathway audit template up to and including 31st March 2012. Data provided by the PCT project team was verified, where possible, against information provided during the course of the evaluation, for example during project board meetings and e-mail communications. Data has been presented in the most appropriate and easy to understand manner with particular reference to temporal parameters.

3.1.2.2 Annual review audit data

A comprehensive description of data relating to the delivery of primary care annual IBD patient reviews according to the IMAGE template (appendix 1) was planned. The source of data was the audit master sheets collated by the PCT commissioning team which collated separate audit data from individual practices using identical templates.

Reviews of patients in secondary care were also planned and would be collated and reported to enable comparison between primary and specialist care managed patients. Both primary and secondary care clinicians planned to use identical templates for conducting reviews and the hospital IBD team was encouraged to record reviews using the same template used in primary care to facilitate comparison.

3.1.2.3 Other pathway quantitative outcomes, e.g. relating to healthcare utilisation

A range of data sources was utilised to obtain quantitative data pertinent to the IBD pathway.

Prescription data

Data relating to prescription drug use was obtained from data collected by the NHS Business Services Authority – Prescription Pricing Division (PPD). This data is known as Prescribing and Cost Analysis (PACT) data [148] and has been widely used in studies of healthcare utilisation. Data was obtained for the whole of the target PCT and for the whole of the NHS North East Strategic Health Authority combined, consisting of 12 PCTs ('the SHA'). This data was provided by a sub-contracted NHS organisation on the basis that individual patients, clinicians, or primary care medical practices could not be identified, and the organisation had received the necessary permissions from the data owners (the PCTs) for this use. Compliance with the Caldicott principles was assured.

The PCT dataset was then subtracted from the SHA dataset which provided two datasets, one for the PCT and the other of the SHA-excluding the target PCT. The data was then analysed using a differences-in-differences approach, the same as that envisaged within certain quantitative aspects of the integrated care pilots programme evaluation. [149] A differences-in-differences (DiD) approach would account for, either partially or wholly, the effect of contemporary changes to the pattern of prescribing regardless of whether these changes were associated with the IBD pathway or any other intervention. [150] An implicit assumption within the DiD technique was that the only way in which the prescribing of the IBD drugs would differ between the target PCT and the rest of the SHA would be because the target PCT was subject to a specific integrated care pathway for IBD which might in turn have had an impact on prescribing of IBD drugs, i.e. it was assumed that the underlying trend in all data sets would be the same over time and other external factors were not included.

PACT data is not linked to individual patients and therefore cannot be linked to specific therapeutic indications. The data is therefore relatively crude and limited in its applications. [151] However, some medicines are licensed and used only for IBD and related diagnoses, and other medicines are used predominantly for IBD and related diagnoses such that they can be considered essentially specific to IBD. A list of licensed medicinal products commonly used to manage IBD was derived objectively from searching the electronic medicines compendium [152] and the British National Formulary (BNF) [28] to create a list of drugs known as the IBD basket and this formed the basis of prescription IBD-drug analysis.

Table 2. The IBD basket of drugs

Therapeutic class	Drug	Presentations or route of administration	Proprietary name or manufacturer
Amino-salicylates	Balsalazide	All	All
	Mesalazine	All	All
	Olsalazine	All	All
	Sulfasalazine	Enema / suppositories / rectal	All
		250 mg in 5 ml oral suspension	Rosemont
		500 mg tablets (excluding enteric coated)	All
Steroid preparations	Beclometasone	5 mg modified-release tablets	All
	Budesonide	Enema / rectal	All
		3 mg modified-release capsules	Entocort®
		9 mg modified-release capsules	All
	Hydrocortisone	Enema (foam)	Colifoam®
	Prednisolone	Enema / suppositories / rectal	All

The initial IBD basket of drugs was then refined by expert consensus through consultation with the academic adviser and consultant gastroenterologist members of the project board. Consensus was reached in entirety and only one change was made to the original list (table 2): Oral sulfasalazine was considered to lack sensitivity for IBD as it is used extensively in other inflammatory conditions, notably rheumatoid arthritis. [153] All available aminosalicylate drugs with the exception of oral sulfasalazine were considered to be highly sensitive to IBD.

Expert opinion was that sulfasalazine, even when differentiated by the nature of the tablet formulation, would not be sufficiently sensitive to IBD. PACT data was then extracted relating to the refined list of medicines and provided in Microsoft™ Excel™ format. The prescription data which was requested and provided covered 36 consecutive months from April 2009 to March 2012. This permitted concatenation of data into twelve fiscal quarters (three-month tranches) or three fiscal years (each April to March) as required.

Given that the prescription data spanned two distinct classes of drugs commonly used in the management of IBD, and included two administration routes (oral and rectal), a combined data analysis by volume alone was not appropriate. Therefore a single and consistent measure of use was required to enable a combined analysis of the whole data set. Such measures are included within PACT data sets, specifically the Average Daily Quantity (ADQ) [154] where such a value exists, or otherwise the 'defined daily dose' (DDD). [155] Both ADQ [156] and DDD values are specific to a drug plus route combination. Not all drug-route combinations have an ADQ [156] or DDD [155] value determined and this was true for only one of the drugs in the IBD basket. In this particular case a typical daily dose was identified with reference to the relevant summary of product characteristics (SPC) [157] and the BNF [28] and was substituted in place of an ADQ or DDD.

As can be seen in table 3, all but one of the drug-route combinations in the IBD basket of drugs had an ADQ defined and in four out of 10 cases this matched the corresponding DDD value. In only two cases, both of which were mesalazine-route combinations, did the DDD value vary compared with the ADQ and in both cases the variation was small (1.5 g vs. 1.6 g, respectively).

ADQ and DDD values are periodically reassessed and may therefore change over time. However, over the period for which the data was obtained no changes to the relevant ADQ or DDD values were identified.

The total quantity of each drug-route combination was calculated from each data set per unit of time (month, quarter, year) and then divided by the daily dose values in table 3 to yield a figure for each drug which described the total number of daily doses prescribed in the respective time frame. The number of daily doses was then summed across all drugs to yield a single figure per unit of time and this was the primary figure used in analyses.

Table 3. Measures of daily dose consumption for the IBD basket of drugs

Drug	Route of administration	Daily dose	Source
Balsalazide	Oral	6.75 g	ADQ*
Mesalazine	Oral	1.6 g	ADQ
	Rectal	1.6 g	ADQ
Olsalazine	Oral	1 g	ADQ*
Sulfasalazine	Rectal	2 g	ADQ*
Beclometasone	Oral	5 mg	SPC/BNF
Budesonide	Rectal	2 mg	ADQ
	Oral	9 mg	ADQ*
Hydrocortisone	Rectal	250 mg	ADQ
Prednisolone	Rectal	20 mg	ADQ

* : Same as DDD

Hospital and specialist healthcare utilisation metrics

Data relating to healthcare utilisation in hospital and specialist settings is routinely collected by the English NHS in the Health Episodes Statistics (HES) data set. [158] HES data is a valuable and rich source of data relating to diagnostic and procedural activities within the English NHS. Activity can even be tracked by individual patients and contains individual demographic details. [159] However, access to the full data set is restricted and can be costly to secure. For the purposes of this exploratory work, only the freely available HES data was utilised. This data consisted of current and historical data sets which could be aggregated at several administrative provider and purchaser levels. This analysis focused on the target PCT as a purchaser and the target NHS hospital trust as a provider. It was not possible to refine the provider by individual hospital site within the same trust, so that data relating to the actual hospital site in the target locality could not be distinguished from a secondary hospital site at the same trust in a neighbouring town not subject to the IBD pathway.

HES data consists of a series of codes relating to diagnoses and procedures. The diagnosis codes used in HES were those defined by the International Classification of Diseases (tenth revision), known as ICD-10.[160] The relevant diagnostic codes for IBD are listed in appendix 2.

The procedure codes used within the HES data set were the Office of Population, Censuses and Surveys: Classification of Interventions and Procedures (fourth revision), known as OPCS-4.

At the greatest level of detail, the OPCS-4 contains 341 separate codes in the 'lower digestive tract' chapter. The description of each code was screened to eliminate those which were clearly unrelated or lacked sensitivity to IBD. The screening process reduced the procedure code list to 158 codes. These codes were then subjected to independent expert consideration by the project academic adviser and consultant gastroenterologist, and a gastroenterological surgeon based at a local hospital trust. All three specialists were of the opinion that few of the codes were specific to IBD with the exception of those which related to the creation of a colonic pouch, total colectomy and panproctocolectomy.

The final screening process resulted in the identification of only ten IBD-specific procedure codes, the descriptions for which are listed:

- Panproctocolectomy and ileostomy
- Panproctocolectomy and anastomosis of ileum to anus and creation of pouch (however further qualified)
- Panproctocolectomy and anastomosis of ileum to anus (not elsewhere classified)
- Total colectomy and anastomosis of ileum to rectum
- Total colectomy and ileostomy and creation of rectal fistula (however further qualified)
- Total colectomy and ileostomy (not elsewhere classified)
- Subtotal excision of colon and rectum and creation of colonic pouch and anastomosis of colon to anus
- Subtotal excision of colon and rectum and creation of colonic pouch (not elsewhere classified)
- Subtotal excision of colon and creation of colonic pouch and anastomosis of colon to rectum
- Subtotal excision of colon and creation of colonic pouch (not elsewhere classified)

These codes formed the 'IBD procedure basket' used in analyses. Analysis was preferentially performed on a purchaser basis, i.e. using the target PCT as the defining data source commonality. A DiD analysis was performed with comparison against the SHA excepting the target PCT in a similar fashion to that performed with the prescribing data. Other analyses were performed as were considered suitable and appropriate due to any data or access constraints.

3.1.3 Ethical considerations – IBD pathway

Ethical approval for the evaluation of the pathway was first approved by the Durham University Research Ethics Committee in April 2011 after which a submission was made to an NHS research ethics committee via the proportionate review process, a constrained ethical approval process for non-interventional studies. The NHS ethics application was made via the electronic web-based Integrated Research Application System (IRAS) and the study was approved by the NHS National Research Ethics Service committee 'East Midlands – Derby 2' in May 2011. Final approval to actually conduct the study was provided by the relevant PCTs research and governance unit in August 2011.

During the ethical approval process specific concerns were highlighted regarding participant, especially patient, confidentiality both during the collection of data and in any publication thereof, retention and storage of data, and possible harm to patients. Advice was received from other researchers who had conducted patient-focused research with IBD patients. The participant information sheet used in this study (appendix 3) was based on one from an earlier study conducted by the same academic department. Concerns were raised in the event that a participant was not fully aware of the implications of a diagnosis of IBD, for example an increased risk of cancer. Therefore if any information was revealed which would cause alarm, distress, anxiety or any other emotional change a process would be needed to respond. The solution adopted was to ensure that any patients so affected would be encouraged to discuss concerns with the researchers present who could direct them to an appropriate service including consultation with an experienced medically trained and registered doctor.

In addition to consultation with other researchers guidance was also sought from a local NHS research governance adviser. These discussions did not identify any further issues from those identified by the University ethics committee or departmental colleagues.

An issue did arise concerning my dual role as both a researcher collecting data from the NHS and its staff, agents, and patients, and my concurrent NHS employment. Advice from the University ethics committee was that the NHS employee role, which could potentially facilitate a more flexible ethics approval approach due to the research being treated as an 'internal (i.e. within NHS) process' was irrelevant in the context of the research project being conducted. Consequently a full ethics committee submission as would be expected for research of the nature proposed was still required.

3.2 Pharmacy exploratory study

An exploratory study relating to the potential role of community pharmacy and pharmacists in the management of adult IBD patients was embedded within the over-arching pathway evaluation. This exploratory study was conducted in two parts to reflect two distinct types of data collection in which the first would partially inform the second. The first part consisted of a postal survey of adult IBD patients and the second consisted of a series of semi-structured focus groups with adult IBD patients drawn from the same survey population.

3.2.1 Survey

A postal survey was sent to all adult members of a local branch of Crohn's and Colitis UK, formerly the National Association for Colitis and Crohn's disease. The survey was designed according to standard recommendations regarding the design of postal surveys and questionnaires. For example, questions relating to baseline demographic details such as age, gender, area of residence etc. were positioned at the end of the survey. Questions were designed to be as unambiguous as possible. For that purpose, published examples of community pharmacy-orientated surveys were obtained and suitable questions were extracted or modified for inclusion.

The survey was designed so that the majority of the questions could be answered with a simple 'tick-box' response. There were two questions which could require a written response, although the survey was designed to keep any text to a minimum. Some single questions consisted of multiple separate assessments; some question responses were binary and mutually exclusive (i.e. 'yes' or 'no' type responses) whereas other questions permitted single or multiple responses. Other questions essentially served as a filter to a subsequent question which may not have been appropriate to answer depending on the response to the preceding filter question. Survey questions were designed to flow in a logical fashion from one to the next with occasional step changes in specific topics. An experienced pharmacy practice researcher from a neighbouring university assisted in the overall design of the survey, and the composition and modification of some questions.

The survey was composed in three distinct parts: The first was a series of eight questions designed to elicit baseline data relating to the opportunities that may exist for community pharmacy involvement in the management of IBD. The second section consisted of two questions, each itself consisting of multiple statements assessed on Likert scales. The second of these was a series of questions adapted from published examples. The third and final section consisted of five questions designed to elicit baseline demographic and disease characteristics. The final survey consisted of 15 questions (appendix 4).

The first of the multi-component Likert-scale questions in part 2 (question 9) was a modified version of a tested and validated patient satisfaction tool for community pharmacy services. [161] This consisted of 20 short statements about the provision of pharmaceutical care from a community pharmacy. The pharmaceutical tool was reviewed with an experienced pharmacy practice academic from a neighbouring university and it was determined that it would be suitable for a UK-based audience despite having been developed in the USA. The tool consisted of 20 items, or statements, each assessed on a Likert scale ranging from 1 (low score, negative responses) to 5 (high score, positive responses). One relatively small but important amendment was made with the addition of a 'no opinion' option alongside the five standard responses. This was added because it was felt that respondents might not have experienced the level of pharmaceutical care which some of the items referred to. The 'no opinion' option would count as 'zero' and would be recorded distinctly from an absent response. The 20 items were themselves split into two dimensions of pharmaceutical care; friendly explanation (FE) with 11 items and managing therapy (MT) with nine items. The items for each dimension did not appear to be in any specific order although most of the FE items were in the first ten items listed and correspondingly most of the MT items were in the final ten: FE items were in survey positions 1-7, 12-14 and 16. The order of the published survey was retained in the postal survey used in this study (appendix 4). Overall FE and MT scores for each individual were calculated as the mean responses of each item within each dimension.

The second of the multi-component Likert-scale questions in part 2 (question 10) consisted of 12 statements assessed on a scale ranging from 'strongly disagree' to 'strongly agree'. The statements were constructed to succinctly and objectively demonstrate the feelings of respondents about their experiences of community pharmacy, the involvement of community pharmacy and pharmacists in the management of IBD, and about IBD medication. Some statements were deliberately designed to contradict others in order to provide a measure of intra-responder reliability, to validate responses provided, and to identify non-complementary or conflicting responses within the same survey. All statements were derived from published examples. The questions were not designed for scoring of responses.

The survey was first piloted amongst a small number of members of Crohn's and Colitis UK from the national membership list. Several responses were received which resulted in some relatively minor amendments to create the final version of the survey. [162]

The survey was presented as an eight-page A5 size booklet (appendix 4). Survey packs included an introductory letter on a single A4 sheet (appendix 5), a stamped addressed envelope for return of the survey, a small yellow card for patients to provide their contact details for further information

about participating in a patient focus group (appendix 6) and a separate small yellow stamped and addressed envelope for its return.

Survey packs were packaged and stamped at the University. The survey packs were delivered to the chair of the branch of Crohn's and Colitis UK to which the survey was to be distributed. Crohn's and Colitis UK head office had provided stick-on address labels with the addresses of all adult branch members. The branch chair then applied one address label to each pack and posted 397 packs. No one from the University had sight of or access to branch member names or addresses.

3.2.2 Focus groups

Three focus groups were planned and were prospectively stratified to consist of one group of patients with ulcerative colitis, one group with Crohn's disease, and one group of younger patients with any IBD aetiology, defined as aged 50 years or less. This stratification was based on expert opinion of the potentially differing views and experiences of community pharmacy of the different groups.

3.2.2.1 Recruitment

Participants were recruited by volunteer subscription from the same population which received the IBD postal survey. Included in each survey pack was a request for further information concerning participation in a focus group. Interested parties were required to complete a small yellow reply card with their preferred contact details to enable details concerning the focus groups to be sent to them (appendix 6). A stamped-addressed envelope was also provided for the cards to be returned in. Those who expressed an interest in participating in a focus group were sent a separate pack of information, either via post or e-mail as requested.

The follow-up focus group information consisted of an introductory letter (appendix 7), a participant information sheet (appendix 3), consent forms (appendix 8) and, for those sent via post, a postage-paid envelope for return.

3.2.2.2 Conduct

Each focus group was scheduled to continue for up to two hours. All focus groups were conducted in a large seminar room on the ground floor of the Wolfson Research Institute in Stockton-on-Tees. Light refreshments were provided including the availability of lactose-free milk and gluten-free biscuits. I served as the focus group facilitator for all focus groups. An experienced pharmacy practice researcher from a neighbouring institution was present and assisted on several aspects including observational note taking and sound recording.

Consent forms were available for participants at each focus group in case some had not provided them previously, for example those who had corresponded via e-mail.

Both the facilitator and assistant were registered and practising pharmacists, although neither was working substantially within the community pharmacy field at the time. This information was declared to participants before the recording of each focus group commenced.

The room was arranged so that the facilitator was seated at the head of the tables with participants down either side in a 'boardroom' style. A single unobtrusive microphone in the centre of the tables was connected to a laptop to make a digital sound recording of each focus group.

3.2.2.3 Content

The first part of each focus group involved a number of non-specific questions regarding the manner in which patients currently interacted with their community pharmacies and pharmacists, and their general impressions of those interactions and of the professionalism and clinical knowledge of pharmacists. More specific questions included topics such as the use of non-prescription medicines and similar such as herbal, vitamin, and health-food products.

The second part of each focus group was more structured and introduced six different types of service or intervention which could, in theory, be delivered by a community pharmacist or within a community pharmacy (see preceding section and appendix 9). Five of the six scenarios were based on components of the IBD Standards [1] and the other was developed *de novo* using prior knowledge of community pharmacy practice and some common problems with medication use in long term conditions such as IBD. Each scenario itself consisted of between three and five steps with each subsequent step often representing a greater level of management or involvement from the community pharmacy or pharmacist. Each step within a scenario was presented in this order with subsequent steps only presented if the group was generally positive about the preceding step. The scenario schedule was adapted by the facilitator (myself) depending on the nature and content of preceding dialogue.

The focus groups were semi-structured in nature although the structured element, a series of headings and topics which had been derived from survey responses was not proscriptive nor strictly adhered to.

Development of scenarios for focus groups

Several hypothetical scenarios relating to clinical services which could be provided by community pharmacies were developed for presentation to each focus group (appendix 9). The scenarios were developed primarily relative to the IBD Standards [1] but also with reference to knowledge

of existing community pharmacy best and experimental practice, both in the UK and in other healthcare systems, and the general profile of IBD management.

A. Medication adherence

This scenario was identified as being a common problem in the management of long term conditions [163] and specifically within IBD. [37, 164] It was developed using knowledge of interventions and developments in community pharmacy relating to other long-term conditions. It is the only scenario which did not relate directly to the IBD standards. [1]

B. Medication monitoring

This scenario suggested that community pharmacists could be involved in monitoring of oral immunosuppressant drugs. Different degrees of involvement were postulated with each step ranging from simple reminders given to patients that they were due, for example, a blood or liver function test, to extraction of a sample on the pharmacy premises with the pharmacist then receiving the results and making dose adjustments as required. This scenario related to IBD standard A6: Arrangements for use of immunosuppressive and biological therapies. [1]

C. Supplemental and enteral feeds

This scenario related to non-medicinal products sometimes used to manage poor nutritional status and were reflected in the IBD Standards (A5: Access to nutritional support and therapy). [1] Community pharmacies regularly dispense such items, potentially for IBD patients. The scenario consisted of five steps ranging from, at the most basic level, providing information about the available products through more targeted advice, on-site sampling, at-home sampling and assuming responsibility for ordering of products.

D. Choice of medication

This scenario suggested that community pharmacists could be involved in helping patients select a particular treatment modality, starting with choosing between medical or dietary control, on selecting between the most suitable type of medication, or selecting on a type of medication formulation or route of administration. It was made clear to participants that the decision to prescribe would remain with a medical prescriber in all steps within the scenario. This scenario linked to the IBD standards (C3: Supporting patients to exercise choice between treatments). [1]

E. Managing a relapse

This scenario suggested that pharmacists could be involved in helping patients to manage an IBD relapse if one occurred. At its most simple it consisted of providing information or counselling about how to prevent, cope with, and manage a relapse. At a greater level of involvement it suggested the provision of medication either with or without prior medical approval. This scenario

did not relate to a specific standard within the IBD Standards, however the standards did refer to 'rapid access to specialist care' including that within the context of a relapse of disease. [1]

F. Associated healthcare needs

This scenario described the provision of other healthcare services where a specific need had been identified in IBD. It was derived jointly from the IBD Standards (A11: Outpatient care) [1] and components of the IMAGE project which related to IBD. [40] The elements derived from the IMAGE project specifically related to depressive illness, weight or body mass monitoring, and smoking cessation.

3.2.3 Focus group analysis

Digital sound recordings of each focus group were copied onto compact disc media and transcribed into electronic Microsoft™ Word™ documents by an external transcription service. Each transcript was checked for accuracy against the relevant sound recording and all transcripts were deemed accurate with no changes or editing following the first transcription. Analysis then commenced through reading and re-reading of each transcript to familiarise with the text.

Transcripts were then formally analysed according to a framework analysis. A framework analysis permits certain prior assumptions and provided a starting point for the analysis of the focus groups. In view of the extensive survey results from the same participant group, and extensive background knowledge of pharmacy practice research, a framework analytical approach was considered to be an efficient and appropriate technique. It provided a more efficient analytical process compared with alternative analytical techniques, permitted the incorporation of prior knowledge of quantitative findings, and facilitated external scrutiny of the analysis. [165, 166] The framework analysis was expected to yield of specific themes. Key words which were unusual, unexpected, or recurrent would be sought to guide the text analysis.

3.2.4 Ethical considerations – Pharmacy component

The pharmacy pilot project, both the survey and the subsequent focus groups, presented a number of ethical points which had to be considered. The survey was approved by the Durham University Research Ethics Committee (School of Medicine & Health) in December 2010 after initial submission in October 2010. The local NHS Research Ethics Committee confirmed in October 2010 that an NHS ethics approval was not required for this particular project.

With respect to the surveys, although these would be distributed by a third party thus maintaining participant confidentiality, recipients were provided with an opportunity to engage with researchers. It was therefore important that any such engagement was kept separate from the patient's survey responses. An additional consideration of the survey was to ensure that it did

not request information which could directly or indirectly compromise patient confidentiality. This was best reflected in the final section of the survey where patient demographic details were requested. The upper age category, for example, was left open-ended as it was felt that few participants would fall into that age group (older than 89 years). Another example was with the final question which requested the participant's post code, but which only requested the first half of each post code as the full post code would likely be unique to individual participants. The survey was also piloted amongst a small number of known members of the same patient charity to which the survey would be distributed. Part of this pilot testing was also to identify any potential ethical issues which the survey might present, although in the event none were identified during the pilot testing process. A specific concern of the ethics committee was maintaining survey participant confidentiality with respect to participants requesting further information regarding focus groups. The initial plan had been for any such requests to be returned in the same envelope as completed surveys. However by separating the two, although at increased cost, participant confidentiality could be ensured as well as providing an opportunity for participants to opt out of the survey whilst still requesting information about the focus groups.

Prior to conducting and during planning for the focus groups specific training in the conduct and interpretation of focus groups was undertaken by me and potential issues were discussed with other researchers who had conducted focus groups with IBD patients. These consultations elicited useful information which was reflected in the ethics committee submission and patient-related material. The patient information sheet used in this project (appendix 10) was based on one which had been used in another research project in the same department which utilised focus groups with adult IBD patients.

Other changes which were made to the project through consideration of ethical aspects, and following feedback from the University ethics committee, included:

- Providing information about possible non-selection for focus group participation
- Requesting participants to respect the confidentiality of other focus group participants
- Actions which would be taken by researchers in the event of participant withdrawal
- Providing participants with information that transcripts would be produced by an external service, and that there was an appropriate confidentiality agreement with the provider
- Providing consent forms for information in advance of each focus group in addition to obtaining signed copies at each focus group

Chapter 4: Results

4.1 IBD integrated care pathway

The pathway underwent three distinct phases with only limited temporal overlap between them. The three phases occurred, out of necessity, in the order of *design*, leading to *implementation* leading to *operation*. Due to limitations relating to temporal parameters the evaluation observed predominantly the design and implementation phases with only a short part of the evaluation coinciding with the operational phase.

4.1.1 Theories of change

The first step to identifying the theories of change is to identify the change or changes which were sought, desired or aimed for. However the aims of the IBD pathway were not explicitly stated either within any official documentation or during any project board meetings or any other source made available. Implicitly, the aim of the pathway was identified singularly through direct associations with other initiatives, such as the IBD Standards [1] and project documents as ‘increasing the quality of care of IBD patients’.

The aims and objectives of the IBD pathway when set within the context of the integrated care pilots were stated in documents dating from November 2008:

‘... This proposal is based on the recommendations of the national IBD Standards Working Group, prepared for NHS Managers and Commissioning Organisations in order to improve services for patients (2006). ...’

The crucial element herein is that of ‘quality’, a subjective and potentially abstract concept, which itself may consist of multiple dimensions. However, for the purpose of this evaluation and due to the clear link between the pathway and the IBD Standards, quality of care for IBD patients is considered in the context of, and defined by the criteria laid out in, the IBD Standards.[1]

4.1.1.1 The IBD Standards as the aims of the pathway

The IBD Standards were intrinsically linked to the genesis of the IBD pathway project. The aim of the IBD standards was singularly described as: [1]

‘... to ensure that IBD patients receive consistent, high-quality care and that IBD Services throughout the UK are knowledge-based, engaged in local and national networking, based on modern IT and that they meet specific minimum standards.’

4.1.1.2 Pathway mechanisms to deliver change

After much deliberation and discussion, particularly during project board meetings but also through other mediums such as electronic mail, a final iteration of the pathway was arrived at. It was clear that several methods, or mechanisms, in the pathway redesign would be employed to deliver the aims through multiple changes to the existing model of care. The mechanisms identified were:

1. Patient education, delivered with support from a leading IBD patient charity
2. A subtle but important element of patient choice for a limited, clinically appropriate and objectively identifiable cohort of patients
3. Improved quality and consistency of primary care management through clinician (GP and nurse) education, itself incentivised through financial payments
4. Greater consistency of care within primary care, and between primary and secondary care, for non-acute patients in remission through use of a standardised and tested annual review template
5. Identification of IBD patients through accurate and comprehensive coding of IBD diagnoses on primary care medical practice records
6. Bilateral sharing of information across the primary and secondary care interface
7. Expanded and increased patient access and communication with the hospital IBD team
8. Identification and consistent application of evidence-based strategies for managing IBD patients within primary care

In addition, the pathway would provide opportunities for primary and secondary care clinicians, both doctors and nurses, to meet and converse, i.e. 'networking' opportunities would be generated.

The mechanisms as described, some of which would operate through the same processes, were driven by two theories of change which I had identified:

1. Patient empowerment
2. Clinician empowerment

I identified these through a reflexive and iterative process and discussed them with my lead supervisor. I had sought to identify firstly how any change was to be delivered by the pathway. Following identification of several specific mechanisms which were either explicitly or implicitly

identified as a direct outcome of the pathway, these were refined and categorised at less granular and more abstract levels. The pathway would not be utilising any new hardware, structural facilities or labour resources but would instead be utilising existing care providers supported with new information flows and the consistent application of credible patient processes. To support this, the principal agents, i.e. the healthcare providers and patients, would be informed, educated and trained generally regarding IBD and specifically regarding agreed local processes. This led to the realisation that all change which the pathway sought to deliver would be achieved through the actions of either patients or clinicians and to enable each party to achieve this they were to be empowered both intellectually (through education and training) and through new 'rights'. This led to the identification of two theories of change within the pathway, as distinct from the pathway development process, being patient and clinician empowerment. Each is considered separately.

4.1.1.3 Patient empowerment

The theory of patient empowerment has two main themes. The first, direct, and most obvious is that patients become empowered and enabled through various mechanisms to better manage their own health both preventatively and reactively. [167] The second theme to the theory of patient empowerment is that patients become better informed and more demanding health consumers with an attendant impact on the quality of healthcare with which they are provided. [168] Within the pathway both aspects of patient empowerment were present although that relating to patient self-management was more obvious.

4.1.1.4 Clinician empowerment

The term *clinician-* or *clinical empowerment* is not new, having featured in Department of Health publications, [169] however its association with an underlying theory of change does appear to be novel. No specific references to the theoretical concept or related terminologies have been identified in the relevant literature.

In the context of the IBD pathway design which was eventually arrived at, and in project processes, there were several themes to the theory of clinician empowerment:

- Ownership of, and meaningful involvement in, pathway design and project oversight.
- Empowerment, principally through externally validated education, targeted at primary care clinicians to assist in the management of a condition which previously was seen largely as needing specialist care. Not only would this directly empower the clinicians who undertook the training, but it would give confidence to specialists to discharge patients into the care of primary care clinicians. Specialists were further empowered through a substantive role in delivering and validating the education provided for primary care clinicians.

- Sign-posting of clinicians to a single evidence-based, accessible, credible and in many cases familiar source of information regarding disease management.
- Ensuring that quality of care with respect to providing an annual review was of the same evidence-based standard as that provided within secondary care.
- Enabling primary and secondary care clinicians to meet and converse directly and establish on-going methods of communication.
- Shared-informational structures and increased volume of bilateral data sharing between primary and secondary care.

4.1.1.5 Project management to deliver the pathway

Although two theories, patient and clinician empowerment, were identified as the driving mechanisms to deliver change from the implementation and operation of the pathway which was eventually designed, the overarching project processes themselves existed within their own context and mechanism paradigm to realise those changes, and thus were also linked to a theory, or theories, of change. There was explicit evidence that this complex process would be delivered by project management. Therefore a third theory of change was evident within the pathway project, that of project management. The theory of project management was identified as the theory underlying the process being utilised to design, implement and operate the IBD pathway project.

The original project application for the Department of Health integrated care pilot scheme was the most explicit and specific of all project documents with respect to project management theory by identifying a specific methodology.

Even though the project was not ultimately included within the Department of Health pilots scheme, correspondence between key actors and the sponsoring PCT confirmed that the project would still continue and that the PCT would 'absorb' the project management arrangements. The actual method of project management to be employed under the new ex-pilots arrangement was not stated. Under the care pilots scheme the project was to be managed according to the PRINCE2 methodology but this would not necessarily mean it should be assumed that the same methodology would also be utilised in the ex-pilots project where there would not be a dedicated project manager.

Box 5. Evidence of project management theory

Excerpt from integrated care pilots stage one application form (November 2008)

Describe the project management and governance arrangements for the pilot programme.

...

The utilisation of PRINCE2 methodology in the management and control of this project will provide structure, planned implementation and appropriate monitoring and evaluation.

...

A project manager will be appointed who has the authority to run the project on a day to day basis on behalf of the Project Board.

The Roles and Responsibilities for the Project Board, Project Steering Group and Project Team will be clearly outlined within the Project Initiation Document.

...

Excerpt from subsequent information in 'further questions regarding the integrated care pilots application' (February 2009)

... outline in detail your programme management processes and governance structures and explain why you are confident these are robust (including your approach to supporting clinical leadership of the programme). ...

The Programme Board will be jointly accountable to the joint PCT and Foundation Trust Momentum Board. The programme will have a dedicated project manager who will manage the pilot using PRINCE 2 methodology. ...

A rational assumption was that the PCT would continue to manage the project according to PRINCE2 methodology as this methodology was described as 'the UK's *de facto* standard for project management'. [170] In addition, the individual initially given responsibility for managing the project by the PCT was already trained to PRINCE2 practitioner level.

Therefore it was the project management organisations' (i.e. the PCT) desire to manage the project in a structured way and the PCT appointed an experienced NHS project manager trained in PRINCE2 to manage the project. However it would appear that the culture within the organisation was not conducive to enabling and ensuring that PRINCE2 methodology was applied in practice.

The 1st project manager (actor 'H', p84-5) reported in e-mail correspondence that the adoption of PRINCE2 methodology was somewhat tokenistic and did not reflect the realities of actually being a project manager within the NHS.

In addition, the first project manager (H) was involved with other projects at the same time, claimed to be eight, including projects of a larger scale and much greater local interest and impact

H: '... I don't think I needed any more support from any of the board members. I mean, like any project, you can always argue that the project should have had more dedicated time but I think that would have been very difficult to justify when I had all manner of other, you know, bigger, larger scale, you know, higher profile projects to work on at the same time. You know, I was working on the closure of A&E in [locality]. You know, at the time ...'

Interviewer: 'At the same time you were doing ... ?'

H: 'Oh, I was doing all manner of projects, I had, you know, something like eight Momentum work scheme projects on the go at the same time so it was just ... this was a really small part of my day-to-day job.'

This mode of working within the PCT, whereby a project manager was assigned to several projects at potentially different stages simultaneously, was also true for the replacement project management team. The recruitment of all members of the project team appeared to have been undertaken on a convenience basis and did not appear to have been done purposefully by selecting members with particular skills, experience, or networks, as the following excerpt from project team member 'L' (p84-5) demonstrates:

L: '... the rest of my team were going so I was kind of the only person in the office at the time when they were saying, you know, "we need somebody to be the contact".'

L: '... . So then it was more formal that I would keep working on it but with [I] because [I]'s more senior than me, so he would be the lead for it. ... '

Both actors I and L (see p84-5) also reported being involved with numerous other projects at the same time, as H had reported. Members of the new project team (I and L), with no apparent prior involvement with the project, expressed concern about the longer-term viability or success-likelihood of the project from the outset, as described succinctly by L in the following interview excerpts:

L: 'Because there are so many bits of work, I'm sure you know what the NHS is like, it's the pathway changes and things like that, that just don't happen for one reason or another and, you know, the genuine reasons they don't happen. ... '

L: ' But there's always that nagging doubt that "Will it actually ...". Because it's obviously not just me that's going to make the project work, there was a number of key people that will make it work. Specifically, the practices as well. And I know how difficult it is getting practices signed up to something that's different where they think they might need to do, maybe, a bit more work or change their processes for certain things.'

The extent and nature of senior management involvement with the project from within the project management organisation (the PCT) did not appear to be structured with absent automatic feedback or update mechanisms and only incidental and informal checks.

Interviewer: ' Would either [of your managers], would they ask you about [the IBD pathway]? Would they say "What's going on with the IBD pathway?" '

I: '[line manager] probably would more because she's the ... she will ask me outside of the one-to-ones, I don't actually have a one-to-one [with line manager], because she's more closely linked to [the IBD pathway] really so' [trails off]

An explicit statement of project aims and objectives is part of the key stage of 'project start-up' within PRINCE2 project management and reflected in documents such as the project initiation document and mandate. The existence of an explicit mandate or project initiation document was not demonstrated within the IBD pathway project. In the first stage application for the integrated care pilots the aims and objectives were described as 'based on the recommendations of the national IBD Standards Working Group'. This provided an explicit link between the project and the IBD Standards. Neither of the senior clinical representatives on the project board (actors B and G, p84-5) or any members of the project team made this link when interviewed about the aims and objectives of the project. In fact only two individuals did refer to the IBD Standards in this respect during interviews and they were both members of the Standards working group. However the project aims and objectives which were stated by interviewees were generally concordant and complementary to at least significant components of the IBD Standards.

An aim or objective which was mentioned by both the first and second project managers (actors H and I, respectively, p84-5) was the effect of the pathway on the primary care health budget. For example both stated that the overall cost or budget impact of the pathway were important aims of the project or a crucial argument for ensuring continuing funding of the project:

Interviewer: 'Were you aware of any explicit aims and objectives of the project, of the pathway?'

H: 'Yeah, I mean there were very some generic ones about improving the care of patients with IBD but there were some, at the time we were all about value for money and we'd

moved into, now we call that QIPP - you know, invest-to-save, so there were some clear aims and objectives around saving admissions. I like to think of that as, if you improve the quality then they're going to go into hospital less, so that's the way I like to look at it. So they're one and the same aim, really.

Interviewer: 'So a potential cost saving aspect was quite important?'

H: 'Yeah, definitely.'

Interviewer: 'To you or to your organisation?'

H: 'To the organisation. I think basically if we didn't have that invest-to-save value-for-money element we wouldn't have got any funding.'

And,

I: ' [The pathway] has to be able to show that it's either offering the same value for money and with increased quality or potentially has some cost savings attached to it and, yeah, I certainly think that was something, as well as the quality aspects and being able to manage patients with the GP, nurse, that they're familiar with and within their own, closer setting to their own home. I do certainly think that the cost elements were taken into consideration, were quite important for the [practice-based commissioning] board.'

The motivations of the PCT were not entirely hidden from the consultant gastroenterologist member of the project board (B). He expressed scepticism about the motivation of the PCT and felt that it was too concerned with reducing costs:

B: ' ... it's fairly clear from meetings that primary care really wants to take all of these patients back into primary care. So that's, I guess, been a slight concern from my point of view that we don't move away from this being patient-centred, that obviously there are financial drivers and political drivers to move patients back into primary care, and that's good provided the patient wants that.'

The primary care medical lead (G) also had a concurrent although not obvious cost-saving agenda:

G: ' The one thing that I eternally think is a waste of money are follow-up [outpatient] appointments. Eternally! ... '

Later during the same interview this point was reinforced:

G: ' Well part of the success for me would be less patients coming into secondary care one way or another.'

And,

G: 'I think if you genuinely say, you know "We would like to shift more of the management of IBD into primary care and therefore have less of it in secondary care" I actually think that secondary care would immediately step back a little bit ...'

Another aspect of the aims and objectives of the project was the apparent disconnect between the strategic aims of the pathway, as illustrated by the local 'Momentum' initiative, and the project team. This was apparent in the behaviour of the project team who appeared to view the project as a day-to-day functional task with occasional milestones and significant events to arrange, such as training events and project board meetings. Individually and collectively they did not appear to assent to the longer-term and strategic aims of the project or the Momentum initiative. The reasons for this were not further explored and this observation is presented as a untested theory. If true this would serve as a negative attribute with the main link between the project management organisation (the PCT, one of the key project partners) and the project board unaligned.

4.1.2 Context: Healthcare policy

Underpinning the pathway was a realisation from all parties involved in the provision, procurement and consumption of healthcare for IBD that demand would outstrip current provision and the gap between demand and provision would likely increase without intervention. [49] Ultimately this translated to a desire to constrain the relative costs of current and future healthcare. [171] The realisation that there was an increasing burden on healthcare through a longer-living, more chronically morbid and growing population has translated to several NHS policies over the past decade. None better encapsulates this than the 2006 White Paper 'Our health, our care, our say'. [50] One of the four main goals of the White Paper was stated as providing 'more support for people with long-term conditions'. Although not specifically identified as a long-term condition within the paper, IBD and its sub-diagnoses are recognised as long-term conditions. [1] The IBD standards, [1] the implementation of which has been interpreted as the aim of the IBD pathway, did not refer to the 2006 White Paper, instead referring to the 2008 NHS Next Stage Review, 'High Quality Care For All'. [172] The next stage review also identified long-term conditions as an important focus for the NHS however it only recommended the use of 'personal care plans' with no underlying rationale for their use other than as a goal already set out in the 2006 White Paper.[50]

Specifically, the 2006 White Paper stated: [50]

'... , everyone who requires and wants one has a personal health and social care plan as part of an integrated health and social care record. Initially we will focus on offering integrated

care plans to those individuals who have complex health and social care needs. By 2008 we would expect everyone with both long-term health and social care needs to have an integrated care plan if they want one. By 2010 we would expect everyone with a long-term condition to be offered a care plan.’

The IBD standards made only limited reference to use of personal care plans with a greater emphasis on community-based care in preference to specialist care in general. [1]

The general policy of the Department of Health and many other healthcare systems towards long-term conditions over the preceding 10 years has been a shift from specialist to non-specialist care such as primary and community-based care. [43] This directly influenced the policy landscape surrounding the IBD pathway project.

Firstly, the patient charity which had been heavily involved in the design and implementation of the pathway was the same charity which published the IBD Standards. [1] Thus, they were explicitly aligned to promoting community-based management of IBD in preference to specialist-led care for specific types of IBD patient, consistent with general healthcare policy.

Secondly, healthcare providers and commissioners, and the academic advisor working within the project board were likely to have had at least a working knowledge, if not greater, of the general policy direction from the Department of Health with respect to long-term conditions. [173] This may have manifested itself overtly or more subtly. For example, the rationale or evidence for the following aspects of the pathway were not questioned within the project board and may have represented a fatalist approach to, or inevitability about, centrally driven policies of the nature described:

- Permitting patients to choose between secondary and primary care for annual review
- Patient education elements of the pathway such as provision of specific educational material and provision of time-limited free membership of a leading IBD patient charity
- Provision of patients with a copy of their annual review and the ultimately abandoned idea for patients to own a personal written care plan and record

Transferring care of patients with long-term conditions from specialist to community settings is not entirely motivated by a desire to reduce healthcare costs. Other advantages which might be expected, or which are at least alluded to, with a transfer of care from specialist to community include improved health and wellbeing for patients and greater patient satisfaction. The evidence for these benefits, including cost reductions, is limited at best. [130]

4.1.3 Design phase

4.1.3.1 The origins of the integrated care pathway for IBD

The IBD integrated care pathway emerged in the local health economy due primarily to historical professional relationships between leading protagonists; the locality did not appear to have been otherwise purposively selected. The IBD integrated care pathway project was initially submitted for inclusion within a Department of Health project but despite the significant setback of not being accepted into that project there was sufficient local interest and desire to ensure the IBD pathway project was still progressed locally. This may have been facilitated by the local context in which the project was complementary to a large cross-sector healthcare project. [59]

4.1.3.2 Aims and objectives

One of the first and crucial outcomes required was a pathway design that could realistically achieve the relevant aims and objectives of the project and which would be acceptable to all parties. The first problem encountered in this respect was that the project aims and objectives had not been explicitly stated or agreed. Without such it would prove difficult to gain consensus amongst the project board.

Interviews with members of the project board (p84-5) revealed little consideration and a somewhat confused picture regarding the aims and objectives of the pathway.

H: '... there were some very generic [aims] about improving the care of patients with IBD but there were some ... at the time we were all about value for money, and we'd moved into – now we call that QIPP - you know, that's to save. So there were some clear aims and objectives around saving commissions. ...'

G: '... what were the aims and objectives? If the aims and objectives are to deliver the IBD standards of care I still think the jury is out whether it will deliver that. I think if the aims and objectives are to deliver us to a point where there is a disease register for IBD and practices are doing something a little bit more structured and organised to proactively manage IBD, I think that we've got a better chance of delivering that. The other one for me is, have we raised the profile of IBD as a long term condition among local GPs? ...'

B: '... I guess over a course of a number of meetings the aims were made fairly clear.'

Although others, particularly the two individuals who had also been members of the IBD Standards Group (A and D), had a clearer and better formed idea about what the pathway was trying to achieve:

(Following a lengthy explanation from 'D of the aims and objectives of the IBD Standards [1])

Interviewer: 'So if I was to suggest that [the project aim] was, in a nutshell, to operationalize the IBD standards, would you agree with that?'

D: 'Yes. Yeah, exactly, and it's to pilot the fact that you could do it.'

And from a separate interview:

A: 'At the outset [the aims] were to see if you could implement the IBD standards through a kind of more integrated approach from primary and secondary care. I think that there's a subsidiary aim in that; which is the role of [the patient charity] and whether they can have a more structured input into service delivery. ...'

Regardless of the aims and objectives which members of the *de facto* project board believed they were working to, the specific aims and objectives laid out in the original care pilots application were seldom referred to at any point during the design or any other phase and the generic aim of implementing the IBD Standards was only occasionally referred to whether in one-to-one interviews or within project communications and during project board meetings.

A notable omission from the design of the IBD integrated care pathway was an attempt to map the existing provision of IBD services and referral pathways. This task was not formally undertaken although a presentation delivered by the project manager (H) at the 6th project board meeting in September 2010 did include a brief outline of the current and proposed 'model of care' (box 6).

Despite the existing provision of IBD care not being mapped out previously there was general agreement within the project board that current care was almost exclusively delivered by specialists, that primary care clinicians tended to refer IBD patients for most if not all IBD-related issues, and that primary care clinicians had little confidence to manage IBD patients. [174]

For an extended period during the evaluation, between its commencement in October 2009 and leading up to the pathway 'launch' in November 2010, discussion about the integrated pathway lacked any significant specific detail. [174]

Box 6. Content from a presentation at the Project board meeting of 6th September 2010

Model of Care:

Maintain current outpatient arrangements including IBD nurse helpline and perhaps telephone clinic.

Any IBD patient who has attended the hospital previously can contact the IBD Nurse direct who will decide if the patient needs to be seen in clinic.

Depending on situation (e.g. how long since patient last seen/complexity of problem) nurse books patient as a 'new' or a 'follow-up' without needing a new GP referral

Annual reviews:

If active disease/associated on-going problems patient will be being seen in clinic.

If not, patients can discuss & agree with the IBD Team what follow-up system they should be on:

- Attend hospital for annual review
- IBD Nurse telephone review
- GP Annual Review
- Each will use same structured annual review

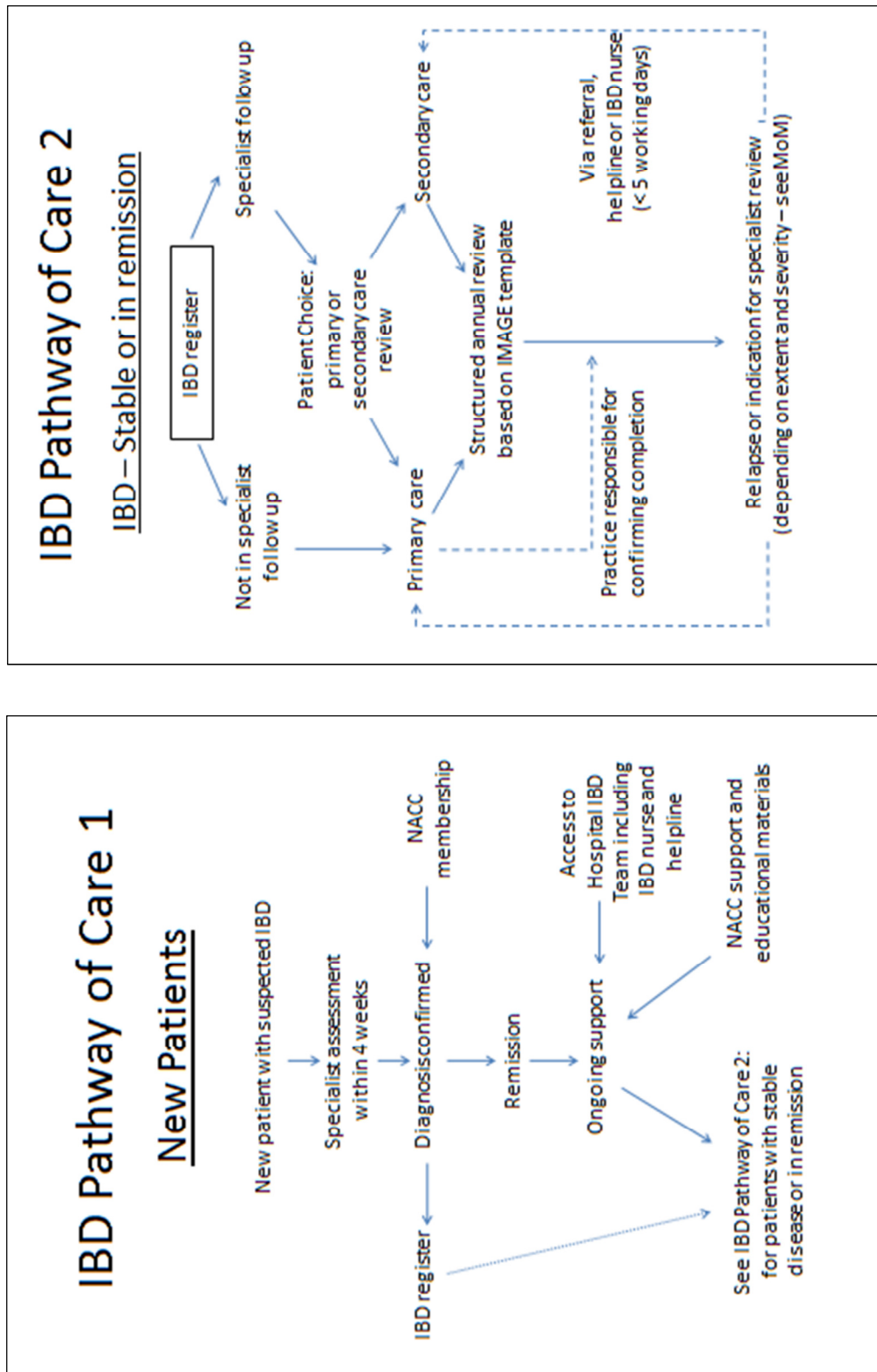
From about July 2010 shared efforts from two project board members (A and B, p84-5) were made to develop an 'Integrated care model'.

At the project board meeting on the 6th September 2010 the board was introduced to two previously unknown individuals employed by the PCT in senior project management roles, identified as actors 'J' and 'K' (p84-5). They were brought into the project as part of the project management team under the then project manager's (H) direction. At the September 2010 project board meeting they focused on identifying the existing tasks that needed to be performed and both individuals discussed creating a 'project plan' and 'communication plan' for the project. This was the first time planning of this nature had been explicitly discussed despite such plans being key components of PRINCE2 project management methodology. [175] Following the meeting an attempt was made to diagrammatically represent the proposed integrated care pathway for IBD using a flow-chart design. Despite some uncertainties regarding the process for GP registration or 'sign-up' to the pathway, the 'process map for the model of care for IBD' was e-mailed to the project board on 20th September 2010. This was commented on by two members of

the project board, the academic adviser (A) and the consultant gastroenterologist (B) with neither in agreement with the model of care presented. Consequently the pathway model was further refined, primarily by the academic adviser, until the final version (figure 1) was arrived at.

In October 2010, a pathway design was presented by the academic adviser and this was accepted by the project board as an acceptable pathway for implementation. This two-part pathway distinguished between newly diagnosed and established IBD patients. The pathway continued to undergo several small but cumulatively substantive refinements after this point and some additional details were added to certain aspects. The final version agreed by the project board is reproduced in figure 1. The pathway design did not undergo any further changes after September 2011.

Figure 1. Final version of the integrated care pathway for IBD



Key: MoM – Map of Medicine™; NACC – National Association for Colitis and Crohn’s Disease.

4.1.3.3 Project board

One of the first steps in structured project management protocols is to establish a project board. [175] This task was not formally conducted within the IBD pathway project although a leadership group did emerge early on which performed this role throughout. The *de facto* project board also required a chair-person and again no formal appointment was evident. However an earlier iteration of a diagram included within the care pilots application outlined the 'project management and governance framework' for the project which included an 'IBD Programme Board', later referred to as the 'IBD Steering Group'. These documents identified the primary care medical lead (G) as chairman and the consultant gastroenterologist (B) as vice-chairman. However neither individual formally took on such roles at any project board meeting during the evaluation although the primary care medical lead frequently conducted himself in a manner which could be interpreted as the chairman of the meeting. This behaviour received the tacit and, on at least one occasion, the explicit approval of other group members. Regardless of the name of the group, the role assumed and functions performed by it were most similar to that of a project board.

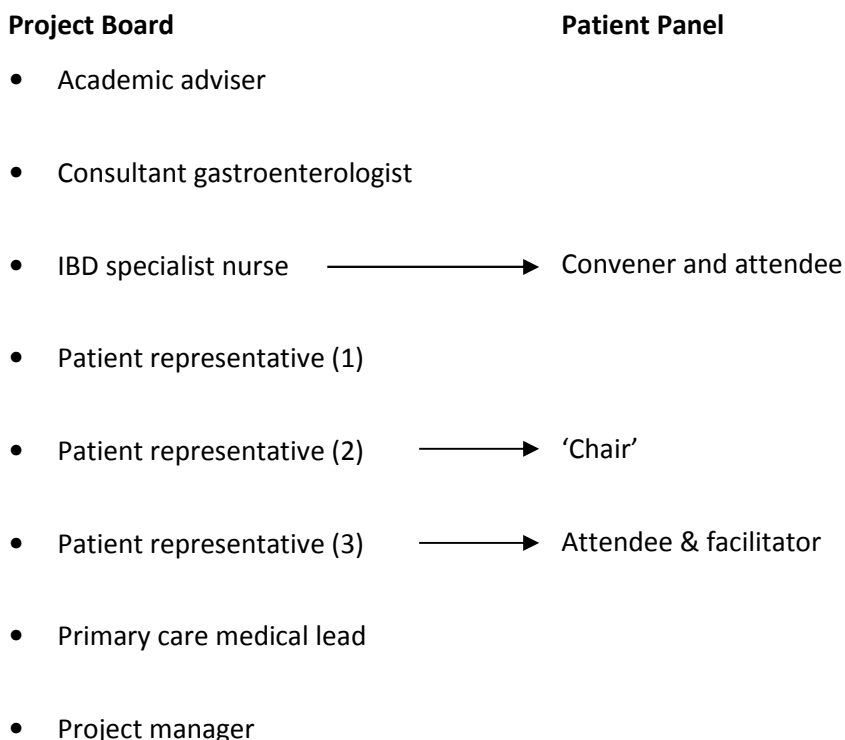
Four agencies were represented on the project board by multiple individuals:

1. Primary care, represented from a clinical (medical) perspective and a budgetary/commissioning perspective.
2. Secondary care, represented from a dual clinical perspective (medical and nursing) and from an operational or managerial perspective.
3. Users or patients, represented principally through non-patient representatives but also indirectly through a local patient panel.
4. Academia, represented by a single academic adviser.

Some individuals brought more than one perspective to the table. For example, the primary care medical representative (G) for the majority of the evaluation period was also the practice-based commissioning (PBC) lead employed on a part-time basis by the PCT. Therefore he also brought a commissioning perspective as well as a clinical perspective to the board. Another example was the academic adviser (A), a practicing GP within the locality who therefore brought primary care medical experience as well as an academic perspective to the project board.

For the majority of the time over which the evaluation operated the project board consisted of eight core individuals or representative roles. Figure 2 shows the make-up of the core project board and its links to an external 'patient panel'.

Figure 2. Constitution of core project board and relationship to patient panel



From the commencement of the evaluation in October 2009 to the end of the evaluation in December 2011 the project board met on eleven occasions. A review of project documents also revealed two earlier project board meetings therefore for the purpose of the evaluation there were 13 project board meetings and these are, henceforth, identified numerically in chronological order. The total number of different individuals who attended or otherwise participated in each meeting, excluding myself as an independent observer, was fifteen.

Individuals who attended project board meetings at various stages of the evaluation are listed, with core project board members listed first, but otherwise in no particular order:

- A. Academic adviser, Professor of primary care, formerly a part-time GP within the locality, and a member of the IBD Standards Working Group.
- B. Consultant gastroenterologist based at the main hospital site within the project locality and later honorary lecturer at the same institution as the academic adviser.
- C. IBD specialist nurse based at the main hospital site within the project locality.
- D. Patient representative 1 was the chief executive of a leading IBD patient charity and a member of the IBD Standards Working Group.
- E. Patient representative 2 was a national patient involvement advisor employed on a contractual basis by the same leading IBD patient charity.
- F. Patient representative 3 was the chair of the local branch of the same IBD patient charity and which included the project locality.

- G. Primary care medical lead, also a practising GP and partner in a general medical practice in the project locality employed on a sessional basis by the locality PCT as its Lead for practice-based commissioning (PBC lead) until about December 2010.
- H. Project manager-1 (March 2009 until about December 2010) was the 'Commissioning manager for health systems development' at the locality PCT and also PCT project manager for the Digestion & Bowel (planned) component of the local joint pathways project.
- I. Project manager-2 (from about January 2011 until the evaluation close) was the 'Commissioning manager' for the PCT cluster with specific responsibility for the project locality.
- J. Project management team member 1 was a project support officer at the locality PCT until about January 2011.
- K. Project management team member 2 was a project support officer at the locality PCT until about December 2010.
- L. Project management team member 3 was a Commissioning support officer at the locality PCT.
- M. Clinical champion, also a local GP and partner at a medical practice within the project locality.
- N. In attendance at one board meeting was the 'Assistant director for commissioning and systems development' at the locality PCT cluster.
- O. In attendance at three later project board meetings was the 'Strategic development manager' at the main hospital trust within the locality.

Table 4 shows the dates, locations and participation metrics of the 13 project board meetings which fell within the scope of the evaluation. Note that these project board meetings span the phases of design, implementation and operation.

Table 4. Dates and attendees of the IBD pathway project board meetings up to December 2011.

	Attendee initials	N	A	H	G	D	B	C	E	F	J	K	I	L	O	M	Total meeting attendance
1	18/05/2009**	1	1	1	1	1*											5
2	01/09/2009**		1														Unclear
3	16/11/2009		1	1	1	1*	1										5
4	15/03/2010		1	1	1	1	1		1								6
5	08/06/2010		1	1		1	1	1	1	1							7
6	06/09/2010			1	1	1	1		1		1	1					7
7	26/10/2010			1		1			1	1	1						5
8	09/11/2010		1	1	1				1	1							5
9	09/02/2011		1		1		1			1			1				5
10	12/05/2011						1		1	1			1	1			5
11	18/07/2011				1	1		1	1	1			1		1		7
12	15/09/2011		1*		1					1			1		1		5
13	08/12/2011		1		1		1							1	1	1	6
Total meetings attended		1	9	7	9	7	7	2	7	7	2	1	4	2	3	1	

* : Participation via teleconferencing facilities. ** : Only partial meeting information available as both meetings preceded the commencement of the evaluation. Attendance was usually for the entire duration of a meeting although on several occasions an attendee was present for only part of a meeting. Greyed-out segments indicate that individual had departed the organisation or project by these meetings, or was not involved with the project during these meetings.

4.1.3.4 Board members, roles and meetings

Some members of the project board were not always clear about their role:

E: ' ... I feel I'm representing [the charity] who have invested money into the project. So it's about making, you know, my role is to try and ensure that the project works because [the charity] want value for money. ... , when you're at a meeting, you try and look at things from the patient perspective rather than from a professional perspective and try and think "Well, what, how will that work for a patient, what will it be like for a patient?" '

F: ' I'm chairman of the local [charity] group. I just thought it would be interesting to come along and see what was happening but I've always felt I'd be more of an observer even if I had put my penny's worth in occasionally.'

Others had a much clearer idea of their role on the project board even if these did not meet the necessary roles for project members to fulfil:

B: ' ... And within this project I'm the secondary care lead so I'm, the idea of that is I, again, provide some sort of coordination from a secondary care point of view to give the voice of the [hospital] trust and the other consultants when we meet, and to convey any sort of information from our [project board] meetings back to the secondary care service.

A theme that emerged from several members of the project board was that they were part of the project team in a more passive and observational role as opposed to taking a more involved or even a leading role. This perhaps reflected a general failing in the project management process with a lack of leadership both at project board meetings and strategically. Despite earlier project documents which were produced for the integrated care pilots application identifying the primary care medical lead as chair and the consultant gastroenterologist as vice-chair of the 'steering group' the role of chair at board meetings was often assumed and shared in a rather *ad hoc* fashion between the primary care medical lead and the project manager at the time. At later meetings the project manager, when present, did enquire about who would chair the meeting with the implied options being either the project manager or the primary care medical lead (e.g. meetings 11 and 12).

A possible choice for project leadership and possibly also to serve as chair of project board meetings would have been the clinical champion. However no one was recruited to this role until about November 2011 and the first meeting the clinical champion was able to attend was the December 2011 meeting which was also the last meeting covered by the evaluation.

Meetings tended to be arranged from one to the next with relatively short notice. The short notice for meetings presented particular problems for the secondary care clinical representatives

(project board members 'B' and 'C'), both of whom were key individuals to the project and both of whom were the only full-time practicing clinicians on the board. For example, on many occasions notice of a project board meeting was given at less than six weeks which was the minimum notice required to provide patients to change or cancel clinical appointments. Both secondary care clinicians in particular reported problems in attending project board meetings for this reason as their record from meeting number 7 onwards demonstrates (table 4). Table 5 highlights details concerning the organisation and administration of project board meetings.

Table 5. Administration of project board meetings

Meeting number	Date	Days since previous meeting	Venue	Meeting notice (weeks, approx.)	Agenda provided	Agenda provided in advance	Minutes or actions from previous meeting (advance)	Other pre-meeting documents	Other documents during meeting	Other documents post-meeting
1	18/05/2009		NK	NK	NK		Yes	NK	NK	NK
2	01/09/2009	106	NK	NK	Yes	NK	NK	NK	NK	NK
3	16/11/2009	76	DU	NK	No	No	No	No	No	No
4	15/03/2010	119	H	6	No	No	No		Actions, also provided post-meeting	
5	08/06/2010	85	PCT	4½	No	No	Yes	No	No	No
6	06/09/2010	90	PCT	9	No	No			Presentation hand-out	
7	26/10/2010	50	PCT	6	No	No	No	Project plan, also handed-out during meeting		
8	09/11/2010	14	PCT	8	No	No	In e-mail			Actions in e-mail text
9	09/02/2011	92	PCT	2	No	No	No			
10	12/05/2011	92	PCT	2	No	No				Actions
11	18/07/2011	67	PCT	> 2	Yes	5 days	5 days	3		Actions & document review
12	15/09/2011	59	PCT	3	Yes	1 day	1 day	3		Actions
13	08/12/2011	84	PCT	15	Yes	1 day	No	No		Actions

Key:
 DU: Durham University
 H: Hospital
 NK: Not known
 PCT: PCT head office
 Shading: Change in project manager

4.1.4 Implementation phase

A pivotal event in the IBD pathway project was the 'launch' of the pathway in November 2010. Other events described as belonging clearly within the implementation phase of the project would be the education and training meetings. All of these events served as examples of clinician empowerment operating within the pathway, as well as, to a lesser degree, patient empowerment.

Launch of the pathway

The audience for the launch event itself consisted of general practitioners and practice managers, being the locality 'GP commissioning forum'. Membership of the forum consisted of one GP from each of the 26 registered medical practices within the locality, although not all practices had a nominated representative and not all practices will have been represented at all forum meetings. [176] The actual attendance list was not available.

The individual who took the lead at the launch event was the project primary care medical lead (G), who was also a local GP. He was supported by patient representatives 2 (E) and 3 (F) as well as other members of the project board although a complete list was not available. Although I was not present at this event information was obtained from subsequent meeting minutes, email correspondence and direct conversations.

The primary care medical lead's precise role in the local health economy appears to have been somewhat fluid during the IBD project but he did appear to have been a well-known and at times controversial individual within the local health system. He was also naturally gregarious and animated and was well suited to, and comfortable with, undertaking the lead role at an important project event such as the launch. However, he was conscious that his involvement could be viewed negatively by the audience, who may have been somewhat ambivalent towards another clinical initiative being promoted by the same individual:

G: ' ... [the pathway] was on an agenda with multiple other things. Many of which I was involved in, so this was another weakness of having somebody that's doing ten different things.'

Education and training

Following the pathway launch in November 2010 the first clinician educational event was delivered in March 2011. The reason for the delay between launch and first training event was not clear but it would at least have enabled practices to decide whether to partake in the pathway project and undertake preparatory work. A second educational event was delivered in November 2011. The educational events also provide further examples of clinician empowerment operating within the pathway as well as providing networking opportunities for the locality clinical

community, both intra-primary care (i.e. practice to practice) and inter-professional (i.e. nursing and medical professionals) and inter-sectoral (i.e. hospital and primary care).

The pathway design required primary care clinicians, both GPs and practice nurses, to undertake specific training and this was mandated in the practice agreement (appendix 11). At least one GP and one nurse from each participating practice were required to undertake verifiable education or training in relation to IBD and the mechanisms of the IBD pathway. Requirements differed for GPs and nurses; GPs had to undertake an online training package already provided by a third-party (BMJ Learning™). This relied upon an assumption that any GP who wished to undertake the training would be a member of an organisation for medical professionals which would permit free access to the package. An equivalent online training package was not identified for non-medical (i.e. nurse) clinicians. Additionally, it was assumed that the majority of the annual reviews which would be performed in primary care would actually be performed by practice nurses. Therefore the project board felt that practice nurses would benefit from a more practical educational package which could also focus on the technicalities of conducting a patient review. Nurses were therefore required to attend a bespoke training event organised and delivered by members of the project board.

Box 7. The pathway education and training meetings

A personal experience and interpretation of the IBD Pathway education and training meetings

The project, within the timespan of the evaluation, delivered two training meetings, each scheduled to last two hours on a Thursday afternoon at the head office of the PCT near the town centre. Thursday afternoons had been identified by the project board as convenient for all those required to deliver the sessions, especially those members of the Hospital IBD Team (the consultant gastroenterologist and the IBD specialist nurse). The first meeting was held in a large space on the top floor of the office block where there was ample room and light. The second meeting was held in a small meeting room on the ground floor which was too small for the number present and which created a cramped and dark atmosphere. The format and agenda for each meeting was similar, consisting of five separate sessions linked in an intuitive progression from one to the next. In the second meeting the fourth and fifth sessions were delivered in reverse order (i.e. session 5 preceded the final session, number 4).

Session 1 was delivered by the primary care medical lead and consisted of a relatively brief introduction and was less than 10 minutes in duration at both meetings. The presenter essentially chaired both meetings, introduced each session, and fielded, and often answered, any questions. Despite having a relatively short session at the start of each meeting the presenter had a dominant role at each meeting.

Session 2 was delivered by the consultant gastroenterologist and was about 30 minutes in duration. The session covered the disease, therapeutic and other treatment options for IBD patients. The session was delivered without the use of any presentation materials in a relaxed and informal manner. It also included audience participation with a number of questions presented to the audience and suitable pauses made for them to consider a response and reflect on the information. However, the audience was not entirely receptive and active in this aspect of the presentation. It was not clear what level of preparation was made for the session; overall it had the impression of being somewhat *ad lib*. However due to the presenter's style, confidence and knowledge this was not detrimental and indeed could be viewed as a positive attribute.

Session 3 was delivered by the academic adviser. This session was the first to introduce the use of presentation materials at each meeting, specifically a Microsoft PowerPoint™ presentation and, at the first meeting only, a paper hand-out. The session was about 30 minutes in duration at the first meeting and about 15 minutes at the second meeting. At the first meeting the initial part of this session focused primarily on the background to the project and the wider theory and evidence base, such as the IMAGE project and the IBD Standards. This was largely omitted from this session at the second meeting and explains the discrepancy in duration between both meetings. The omission of the background material from the second meeting did not appear to be detrimental to the session and indeed the background material in the first session seemed out of place amongst the other material. The presenter's style and delivery was confident and relaxed, and he did not get flustered.

Session 4 was delivered by the project board patient representative 2 (E). He also used a PowerPoint™ presentation and described the activities of the patient organisation both locally and nationally. The presentation consisted of 25 slides although many were not displayed for any significant amount of time, in particular at the second meeting. The presentation appeared to lack confidence in delivery with a hesitant and hurried style. Patient panels were described confidently, a topic the presenter was most familiar with. Overall, the session appeared to generate limited interest with each audience. At the first meeting the session was of about 20 minutes duration and less than 10 minutes at the second meeting.

Session 5 was delivered by the IBD specialist nurse. The description of the session had changed from 'The interface between primary and secondary care' to 'Annual reviews' in the meeting agenda from the 1st to the 2nd meeting, although the content differed little. During the second meeting a significant part of the session was taken over by the academic adviser and the primary care medical lead, and to a lesser extent the consultant gastroenterologist, who interjected and fielded multiple questions from the audience. The presenter appeared content with this as these questions related principally to some of the finer details of conducting annual reviews in primary

care, including some technical questions relating to coding systems. Despite, or perhaps because of, these interjections the presenter appeared more comfortable at the second meeting than at the first. The presenter also used a PowerPoint™ presentation with just ten slides. The presenter made an explicit appeal to fellow nursing colleagues and displayed empathy with them, with a slide providing contact details. The overall impression of this session was positive and it appeared to be well received by the audience. Many of the audience were observed to note down the contact details provided. The session was about 30 minutes duration at each meeting with a slightly longer duration at the second meeting largely due to questions from the audience.

The overall delivery of the second meeting was noticeably better in style and content than the first meeting despite the facilities being worse. The presenters appeared more confident in delivering their presentations. Most presenters had subtly refined their presentations following the first meeting. The exception to this generalisation is with the final presentation at the second meeting from the patient representative. As the second meeting had overrun and the facilities were dark, cramped and becoming 'stuffy', the presentation was delivered in a hurried and disorganised style and it appeared to generate minimal interest from the audience.

A particularly embarrassing incident occurred at the end of the first meeting when it became apparent that none of the presenters had actually shown a diagram of the 'new' pathway model. There was an implicit expectation that this might have been included within the final session delivered by the IBD specialist nurse. A frantic search for a digital copy of the pathway diagram ensued and one was found on a memory stick and duly presented by the academic adviser. The academic adviser stepped in to lead this closing part of the first meeting and duly made good of what was becoming a deteriorating scenario. No such mistake was made at the second meeting and the diagram was included in the academic adviser's presentation.

This experience suggests that a trial run of the education and training meeting would have been useful and might have negated some of the clumsiness which was evident at the first meeting. However, this would also have required additional commitment from the presenters which may not have been easy or considered an effective use of resources for all parties. The project management team could also have provided a better brief for each of the presenters. It appeared that, in preparing for the first session, each presenter was provided with only a brief title for their session and only a short period of time, about two weeks, to prepare for the first meeting. As well as the first meeting serving as a trial run for the second, presenters were provided with a more detailed presentation brief for the second meeting.

As well as providing the necessary educational content the training events served as networking opportunities for practice nurses to form a peer-support network. At the close of the evaluation the clinical champion and project support officer from the PCT indicated their intention to arrange some specific networking meetings for practice nurses, and at least one edition of a newsletter aimed primarily at practice nurses had been produced with a second edition planned. Both these separate aspects of clinician education could be expected to lead to some degree of clinician empowerment, both in the specific therapeutic field of IBD and more generally. A number of GPs also attended the training events which were organised primarily for practice nurses.

Table 6. Details of the two IBD pathway project training meetings

	1 st training meeting	2 nd training meeting
Day, date and time	Thursday, 31 st March 2011, 2 to 4 pm	Thursday, 17 th November 2011, 2 to 4 pm
Number of nurses in attendance	Seven; all female	Seven; all female
Number of GPs in attendance	Six; one female	Two; one female
Total number in attendance	Thirteen*	Nine*
Number of different practices represented	Eight	Six
Also present if not primary care clinician or presenting	Patient representative 3 (project board member 'F')	Strategic development manager at the main hospital trust within the locality (project board member 'O')

* : Included one member of the project board; primary care medical lead and clinical champion, respectively.

4.1.4.1 Clinical Champion

From the outset a 'clinical champion' was to be incorporated as a key element of the project for all phases including the pathway design. For example, the appointment of an individual to the role of clinical champion and discussion as to whether the primary care medical lead would take on that role was discussed in the preamble at the March 2010 board meeting. The scope of this discussion indicated that some relatively detailed discussions had preceded this point.

The clinical champion role was first formally defined in a document described as a draft job description. This was presented to the project board on the 17th September 2010 by electronic mail by the newly appointed project management team. Up until that point discussions had remained at a relatively abstract level with the role being frequently referred to but not properly defined. The draft job description appeared to lack detail and was based on a generic template. The 'Job purpose' was described as:

To work with PCT, GP Community and Specialist Care teams to assist the successful implementation of the new Inflammatory Bowel Disease integrated pathway in [the locality].

The 'Key result areas' were listed as:

- Work with PCT, GP Community and Specialist Services colleagues in developing and implementing the new IBD integrated pathway
- Commissioning/developing, with the IBD multi-disciplinary team, appropriate programmes of professional development regarding the care of patients with IBD
- Promote the new pathway and accompanying audit via launch events and via other marketing opportunities.
- Engage and influence others individually and collectively to achieve successful implementation, particularly within the GP community, to help to build the capacity structure, culture and framework that delivers effectively the new pathway.
- Provide leadership regarding the IBD Integrated pathway in the GP Community.

Both the draft 'job purpose' and 'key result areas' were unchanged in the final version of the clinical champion job description.

A project plan distributed by electronic mail on the 25th October 2010 defined the appointment of a clinical champion as a separate task with several components such as confirmation of funding, completion of the job description, identification of potential candidates, advertisement, interviews and candidate selection. The plan at this point was to advertise the post to local primary care medical practices between the 15th and 29th November, with interviews and candidate selection to be conducted between the 6th and 13th December 2010. This was a change in position from that stated at the previous project board meeting where an explicit desire had been made to have the clinical champion appointed in time to participate in the launch event scheduled for the 17th November 2010. This position was reflected in the first iteration of the project plan, which was never circulated outside of the project team. In that version of the plan the post was to be advertised between the 27th September and the 18th October 2010, with

interviews and selection to be conducted between the 25th October and 1st November 2010 thus ensuring that the clinical champion role would be filled in time for the launch event.

At the project board meeting in November 2010 the first point raised by the project manager was that the appointment of a clinical champion was delayed. The reason for this was given as issues existing within the PCT finance department on the mechanisms and ethics of accepting and handling funds from a commercial party which sells healthcare products to the NHS (i.e. a pharmaceutical company). The project manager and the primary care medical lead were open about expressing their frustrations with this apparent bureaucratic hurdle and this view appeared to be shared by the project board as a whole. At the same meeting the project manager informed the board that the primary care medical lead would fulfil the role of 'clinical champion' for the purposes of the launch event.

The next (9th) project board meeting was in February 2011 by which time a new project manager was in place. At this meeting the primary care medical lead assumed the role of chair. One of the key reasons for the meeting having been arranged was given as a discussion of 'finding a GP lead' (i.e. recruiting a clinical champion). At the end of discussion of the clinical champion the project manager was directed by the primary care medical lead to advertise for the role.

At the following project board meeting (10th) in May 2011 the project manager reported that the clinical champion job had been advertised twice but no applications had been received. The risk of not receiving any applications for the clinical champion job had been highlighted in the draft project plan of October 2010. The contingency for this risk was: '[primary care medical lead] picks up the role'. It was not clear how long this contingency plan was intended to remain in place. Despite much prior discussion of active recruitment strategies such as enlisting the hospital IBD team to identify primary care medical professionals with an interest in IBD, and reports from the primary care medical lead about actively canvassing colleagues concerning the role, the advertisement and recruitment strategy employed by the new project team appears to have been relatively passive. The strategy was reported as consisting of notices in routine paper and electronic communications which were distributed to primary care medical practices in the locality. It was not clear whether these communications were sent to the practices generally or directly to medical practitioners.

The clinical champion job was discussed again at the next (11th) project board meeting in July 2011. A potential candidate was discussed who later did not go on to fill the role. The key point that arose during this meeting was that the post had to be filled by the 30th September 2011 to fulfil the conditions attached to the funding. It was not clear whether this condition was imposed by the funder (the pharmaceutical company) or whether it was stipulated by the PCT or NHS.

At the 12th project board meeting in September 2011 the project manager and primary care medical lead reported a high level of optimism concerning recruitment of a named individual. This was the individual who was eventually recruited to the clinical champion role and it is assumed that the individual was officially appointed at about this time (late September 2011).

Role of the clinical champion in the IBD pathway

The roles that the clinical champion would fulfil had been alluded to or explicitly stated during several project board meetings. These included:

- To lead, or chair, project board meetings
- To promote the pathway to medical practices and practitioners, ensuring that practices sign-up to the pathway and fulfil the obligations that accompany it
- To lead education and training events, including delivery of specific aspects or components
- To act as a focal point for practice enquiries concerning audit completion
- To provide clinical support for medical practitioners and nurses in primary care

It was not possible to evaluate whether these or any other roles were realised as the clinical champion was recruited at the end of the evaluation period and there was no opportunity to assess whether the clinical champion fulfilled these roles.

Recruitment of clinical champion

The individual appointed as clinical champion learnt about the post by word of mouth from a practice colleague, who in turn had been informed about it by the primary care medical lead (G). The clinical champion (M) then followed this up with enquiries to the primary care medical lead and later conversed directly with the project team. The clinical champion indicated a particular interest in gastroenterology as a therapeutic speciality which led to her initial interest in the post. The following excerpts from a research interview highlight the recruitment process and motivation:

M: '... when I was a medical SHO I did a gastro job, gastroenterology job, over at [local hospital] and really enjoyed it and I think if I hadn't gone down the GP line I'd have become a gastro consultant.'

Another appealing feature of the job may have been that it would help distinguish her amongst her peers and signal potential leadership qualities:

Interviewer: 'And what appealed about the job, what in particular? What interested you?'

M (joking expression): 'The job title of course'

Interviewer: 'Is it clinical champion?'

M: 'Clinical champion! You're on to a winner really if you've got that sort of title under your belt.'

Although this was by no means the only motivation:

M: ' But also, I think I'm interested in that sort of thing. I see, I've recently seen a lot of patients with new diagnoses of inflammatory bowel disease and I think just the variety of patients there have led me to have a bit of an interest in the condition and I just felt it would be a good bit of a challenge really.'

Interestingly, there appears to have been no direct financial motivation although the individual would not have been able to take up the post without financial recompense to her practice.

At the point the individual took up the post she reported having been a general medical practitioner for five years and a partner in her practice for most of that time (4½ years). She also reported not having had a similar role in the past and appeared to be somewhat naïve with respect to the primary care commissioning landscape, processes and potential motivations:

M: ' The PCT is somewhat an unknown force to me. I don't know, and I couldn't even start to guess, whether it's something to do with, I don't know, patient care and, you know, qualities and standards and all that sort of business. But I don't know particularly what [the PCT] do gain from it. ... '

This relative inexperience, in terms of working with commissioning organisations and involvement in service redesign initiatives, did cause some concern:

M: 'Why aren't more people interested in this? Why hasn't somebody picked it up beforehand, you know, that sort of thing. But then again, though, thinking about it, where do GPs hear about this sort of thing coming up? And it is typically word of mouth.'

Especially when goaded by more senior peers:

M: ' ... at the first meeting I did get asked by two other doctors there "So, why have you signed up to this then?".'

4.1.5 Operational phase

Results obtained relating to the operational phase of the pathway were substantially curtailed against expectations, due primarily to delays in the design phase which provided a reduced period for the evaluation to observe the operation phase.

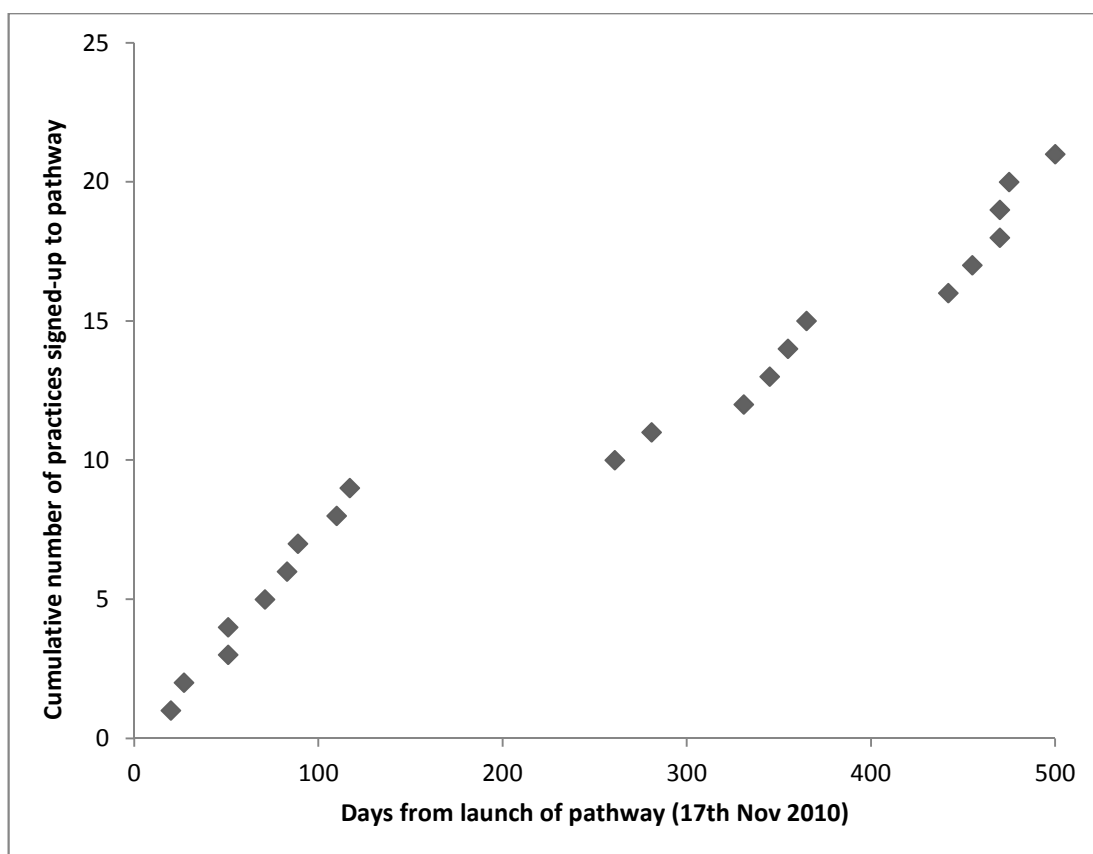
4.1.5.1 Pathway descriptive outcomes

The first outcome of primary importance was the proportion of general medical practices within the locality which participated with the pathway. There were 26 general medical practices within the PCT with a registered primary care population of about 190,000 as of 2011. [20] However one of these practices, with less than 1,000 registered patients, was essentially a drug addiction treatment centre and due to the nature of the patients it served was considered unlikely to participate with, or benefit from, an initiative such as the IBD pathway. The remaining 25 practices therefore constituted the target general medical practice population. However one of these practices, and the smallest in terms of patient numbers with just over 1,000 registered patients, indicated that it was going to close on the imminent retirement of its only GP. For this purpose the project team ceased to actively pursue participation from that practice after October 2011. Therefore for the purpose of the evaluation the effective target practice population consisted of 24 practices with a combined registered population of just fewer than 190,000, ranging in size from just over 1,000 patients to nearly 21,000 patients.

The sources of data for practice outcomes were the records maintained by the PCT project team and provided in February and May 2012. Additional information was extracted separately from e-mail correspondence with missing values imputed to the end of the calendar month in question.

By 31st March 2012, 21 practices had agreed to participate with the pathway yielding an effective participation rate of 88%. These practices also accounted for 88% of the available registered patient population. The three practices which had not participated consisted of about 1,400; 4,000 and nearly 17,000 patients each. All three non-participant practices were reported by the project team as having shown interest in the project and one, the smallest, had 'agreed to take part' in October 2011 although the necessary steps for participation had not been fulfilled by the evaluation close. Further information revealed that specific self-reported practice issues for non-participation related to not having sufficient nursing staff available to enable participation and not having anyone available to participate in a scheduled training meeting. One practice which was not indicated as participating on the February project team record was subsequently stated to be participating by March 31st 2012. Therefore the participant date for this practice has been imputed as the 31st March 2012 although the actual date will have been between 27th February and 31st March 2012. Figure 3 demonstrates the temporal pattern of practice participation following the launch of the pathway on the 17th November 2010.

Figure 3. Cumulative practice recruitment to the IBD pathway (days)



As can be seen in figure 3, the recruitment of practices appears to have occurred in three distinct phases. The first cohort consisted of nine practices which all commenced participation with the pathway within the first four months and before the end of the first fiscal year in which the pathway was launched (i.e. by 31st March 2011). There was an interval of nearly five months between commencement of the ninth and tenth participating practice. Subsequently, between August and November 2011, which coincided with renewed activity from the project team, a further six practices commenced participation. A less distinct third phase is also evident which consisted of the final six practices to participate and this occurred in February and March 2012. The final phase coincided with a concerted effort from the project team which had by now been bolstered with a clinical champion who specifically undertook practice-recruitment tasks. This pattern of innovation diffusion, led by ‘early adopters’ and tailed by ‘laggards’, is a recognised feature of healthcare and non-healthcare innovations. [177] It has been extensively analysed and described by others and could have been predicted. [178]

Data relating to completion of the educational package for GPs is available for 12 out of the 21 practices; 7 out of 9 in the early adopters cohort; 5 out of 6 in the medial cohort; and none of the laggard cohort. The educational package was completed at a mean of 82 days from the date of practice sign-up (range -3 to 273 days). The mean number of days between commencement of participation and training completion was 124 days in the early adopter cohort and 23 days in the

medial cohort. Training completion by practices was, naturally, constrained by the availability of the training events organised by the project team.

All nine early-adopter practices had at least one clinician staff member present at the first training event on the 31st March 2011, with between one and three staff present per practice. Smaller practices tended to be represented by only one attendee. A small discrepancy existed between the official attendance record provided by the project team, my notes, and a later attendance record provided by the PCT to track payments. Further scrutiny indicated that the official record was more likely to have been a list of those who had indicated they would attend as opposed to a list of those who actually attended. The majority of attendees were female (about 8 out of 12) and nurses; the majority of GP attendees were male (table 6).

All six medial cohort practices had at least one clinician staff member present at the second training event on the 17th November 2011. The meeting was attended by nine individuals; eight female, seven of whom were practice nurses, and one male GP. The other attendee was a female GP (table 6).

No staff members from the laggard cohort had attended a training event as this group was defined from a sign-up date of February 2012 and the last training event was in November 2011.

Data relating to the 'number of patients to review' was also available. The submission by a practice of a 'number of patients to review' indicated that a practice had performed one of the first steps in the audit process and identified the number of patients with IBD registered at the practice. This data was available for 18 practices with the three missing data all from the final cohort of practices to have signed-up. The number of patients to review ranged from 5 to 135 per practice and correlated closely with the number of registered patients, i.e. the practice size. The mean crude prevalence of adult IBD as a proportion of the practice population was 0.58% (range 0.21% to 0.95%) which was similar to that obtained by Rubin *et al* in an epidemiological report on IBD in the same locality which observed an adjusted IBD prevalence of 0.39%. [2]

The mean crude prevalence of adult IBD did not appear to correlate with the practice size. The mean practice size of those with prevalence less than the mean ($n = 11$) was about 7,800 and the mean practice size of those with prevalence greater than the mean ($n = 7$) was about 8,400. However, the mean crude prevalence did demonstrate greater variation depending on the innovation classification; early adopters and the medial cohort were similar at 0.55% and 0.45% respectively. However the three practices in the laggard cohort for which data was available yielded prevalence rates of 0.91% to 0.95%.

Information concerning practice payments and the number of patients who were offered and accepted free membership of the patient charity was not made available to me and it was unclear if this information had been recorded.

4.1.5.2 Annual review audit data

Only limited data was available from the collection of annual review audit data by the project team. As of 31st March 2012, 44 submissions of audit data, and by direct association claims for payment, had been made due to a primary care annual review of an adult IBD patient. Review data had been submitted by 8 practices; 5 out of 9 early adopters, 2 out of the 6 medial cohort and, unexpectedly, one from the laggard group. That a practice from the laggard group had submitted review data indicated that the link between training and reviews was not fully implemented as nurses at that practice did not have an opportunity to undertake the necessary training to conduct reviews. The number of reviews per practice ranged from 2 to 12. The proportion of the adult IBD practice population for which a review had been conducted ranged from 3% to 92% (mean 14%). The highest rate of review completion was associated with a single practice which had conducted 12 reviews from an indicated IBD patient population of 13 adult IBD patients. The top six practices ranked according to proportion of reviews performed were all early adopter practices and the bottom ranked practice was the laggard cohort practice. Table 7 describes the data.

Table 7. Primary care adult IBD patient annual reviews

Practice innovation classification	Number of declared adult IBD patients	Number of reviews completed as of 31 st March 2012	Completion rate
Early adopter	37	4	11%
	40	3	8%
	20	12	60%
	11	3	18%
	13	12	92%
Medial	99	7	7%
	26	2	8%
Laggard	76	2	3%

Submission of audit data, whilst technically correctly completed, was less descriptive than had been anticipated. For example, where practices were required to indicate whether they had performed assessments of quality-of-life and symptom scores it had been expected that the actual scores would be provided as evidence that the task had been carried out. However, in the event, only one practice with seven reviews actually provided scores with all other practices simply indicating 'yes' or 'no' in response to the columns headed 'Has symptom control been assessed?' and 'Has quality of life been assessed?'. There were other examples of audit data where similar binary responses had been provided when a more detailed response had been expected. Each component of the audit is considered in turn:

Diagnosis

Thirty-two review submissions provided a diagnosis; 17 (53%) identified Crohn's disease, 13 (41%) identified ulcerative colitis, and two identified indeterminate colitis. Both of the indeterminate colitis diagnoses originated from the same practice which had only recorded four reviews with the other two diagnoses being Crohn's disease. This raises concerns about the veracity of the audit data, for example 'indeterminate colitis' could have been selected in error in place of 'ulcerative colitis'. Nonetheless, the overall figures were broadly similar to those that would be expected from epidemiological reports. [2]

Aminosalicylate medication

All 44 submissions provided a response to the question 'Is the patient on 5-ASA medication?' Twenty-two (50%) were affirmative, of which 15 were linked to a diagnosis; 9 (60%) for Crohn's disease and 6 (40%) for ulcerative colitis.

Medication adherence

Thirty-nine submissions provide a response to the question 'Has adherence to medication been assessed?' All five missing responses had been answered 'not medicated' to the previous question concerning 5-ASA medication and therefore represented a logical response to this question. Of the 39 responses, three were 'no' and 36 were 'yes'.

Symptom and quality-of-life assessments

Only one practice with seven review submissions, three Crohn's disease and four ulcerative colitis, provided the actual results (scores) of the symptom [179, 180] and quality-of-life assessment tools. [14] Symptom scores for Crohn's disease varied from 25 to 47 points and from 0 to 8 points for ulcerative colitis. The range of each score indicated that the correct assessment had been performed for each type of diagnosis although it would appear that the Crohn's disease scores represented a single day's score and a weekly summed score, as required, had not been generated. Symptom scores generally correlated in rankings with quality of life scores, for which the overall range was 11 to 32 points with the three lowest scores all being in Crohn's disease

patients. Two reviews associated with a diagnosis of 'indeterminate colitis' were identified with a symptom assessment even though a suitable symptom assessment tool was not available for that diagnosis (the two symptom tools provided were for Crohn's disease and ulcerative colitis). [179, 180] This indicated an inappropriate symptom assessment may have been carried out with these patients. Of the 37 reviews for which a quality-of-life score was not provided, 36 responses were 'yes' and one was 'no'. Similarly, for the 37 reviews for which a symptom score was not provided all responses were 'yes'.

Depression

In response to 'Have you screened for depression?' all 32 responses from 7 practices were 'yes'. A single practice with 12 review submissions had indicated 'not depressed' for 11 reviews and 'depressed' for one. Further information indicated that this patient had been referred for follow-up with a GP following the identification of depression.

Biochemical and other monitoring

All 44 review submission responses were 'yes' to the question 'Has an annual review been carried out?' and this was expected given the nature of task. The intention of this component of the annual review, which had undergone some local revision compared with the component which had been developed within the IMAGE project, was to ensure that a minimum range of biochemical and other monitoring tests were carried out annually. It was not clear to what extent the range of ten listed interventions had been completed for each patient. In addition, the review template required that dates were recorded for planned or previous assessment of 'bone health' and colonoscopy however the audit template on which the review data was recorded did not specifically request this data. It was therefore unclear whether the intended comprehensive biochemical, physical and health screening components were completed for all patients within the scope of a primary care nurse-led review appointment. The veracity of the data in this respect was undetermined.

Access to specialist care

One component of the review specifically enquired as to whether patients knew how to access specialist care: 'Does the patient know how to access hospital / IBD nurse for flare ups?' for which there were 44 positive responses.

Patient information and support

Two components of the review prompted questions about patient information and support and were explicitly linked in the pathway to the patient charity through provision of their information and local branch support group details. Again, all responses were of the binary 'yes' / 'no' type. With respect to provision of patient information 43 responses were positive and one was negative. With respect to provision of details of support groups, 42 were positive and two were negative.

The single negative response to the information question was also matched with a negative response to support group details. Both were further qualified with additional information indicating that the patient actively declined the information although no further explanations were provided.

Smoking

The question 'Has advice been provided on smoking?' elicited 43 responses, of which 31 were positive, one was negative and eleven stated 'not applicable'. Of the 31 positive responses, eight were further qualified with information concerning the patient's smoking history such as whether they had never smoked or were an ex-smoker.

Dietician

The question 'Does the patient have access to a dietician?' elicited 42 responses of which 25 were positive, nine were negative, and eight stated 'not required'. Of the nine negative responses six originated from the same practice which had only seven submissions and for which the remaining response was 'not required'. This could indicate a particular issue with access to or provision of dietetic services at that practice. Another practice with only two submissions also provided two negative responses. One positive response provided further information concerning an onward referral to a dietician, presumably as a consequence of the review.

Complementary and alternative medicines

'Have complementary and alternative therapies been discussed?' elicited 43 responses of which 31 were negative and 12 were positive. None of the responses, whether positive or negative, were further qualified with additional information concerning the nature of the discussions or reasons why complementary and alternative medicines were not discussed.

Secondary care reviews

Annual IBD patient reviews in secondary care were intended to be delivered to the same template as those in primary care. However secondary care patient reviews conducted during the operational phase of the pathway were not systematically or collectively recorded by the hospital IBD team and therefore were unavailable for analysis. It was subsequently reported anecdotally that by the time of the evaluation close few secondary care reviews had been conducted within the context of the integrated care pathway and none had utilised the agreed template.

4.1.5.3 Prescription data

Over the course of the 36 months from April 2009 to March 2012 there was 591,690 days' worth of IBD medication prescribed from the PCT. The corresponding figure for the SHA (excluding the locality PCT) was 7,285,566 (table 8). The summed DDD values for the PCT and the SHA (excluding the PCT) were slightly greater than the corresponding ADQ values at 600,130 and 7,380,972 respectively. Appendices 12 and 13 provide monthly breakdowns of summed ADQ and DDD prescribing data, respectively.

The difference between summed ADQ and DDD values is attributable to the difference between the mesalazine ADQ and DDD values. Mesalazine constituted the overwhelming majority of all prescribing by ADQ from within the IBD basket at more than 80% in each year for both the PCT and the SHA. There was a trend for mesalazine to constitute an increasing proportion of prescribing within the IBD drugs basket over time (table 9). The rate of increase of mesalazine prescribing for IBD is slightly greater for the PCT compared with the SHA (excluding the PCT) although the absolute difference was small at less than 4%.

Table 8. Summary of IBD prescribing by summed ADQ for the PCT and the rest of the SHA

		2009-10	2010-11	2011-12
PCT	Total daily doses	183,901	198,453	209,336
	Mean doses per day	504	544	572
	Year-on-year increase*		8%	5%
	Cumulative increase*		8%	14%
SHA (excl PCT)	Total daily doses	2,292,656	2,441,432	2,551,477
	Mean doses per day	6,281	6,689	6,971
	Year-on-year increase*		6.5%	4%
	Cumulative increase*		6.5%	11%

* : From 2009-10 baseline year.

The IBD basket consisted of only two types, or therapeutic classes, of drug; aminosaliclates and steroid preparations (table 2). All aminosaliclate drugs in the basket were considered to be highly sensitive to IBD. Both drug classes included both oral and rectal preparations however the ratio of oral to rectal preparations within each therapeutic class within the IBD basket varied substantially (tables 10 and 11).

Within the PCT the overall ratio of oral to rectal prescribing, by ADQ, was 15:1 however this disguised opposing situations within each class, with an aminosalicylate ratio of 47:1 and a steroid ratio of nearly 1:5 (table 10). A notable omission from the steroid class was oral prednisolone which expert opinion had indicated would constitute the great majority of oral steroid prescribing in IBD.

A reasonable assumption would be that the inclusion of oral prednisolone within the IBD basket would make the proportion of oral preparations exceed rectal preparations within the steroid class as with the aminosalicylate class. The steroid oral to rectal ratio would then be in the opposite direction. However, prednisolone, and in particular oral prednisolone, is a corticosteroid drug which is used for a multitude of acute and chronic inflammatory conditions. Therefore data relating to oral prednisolone alone without linked data relating to the therapeutic indication would lack specificity for IBD. Data for the SHA (excluding the PCT) is provided in table 11 for comparison.

Table 9. Proportion of mesalazine within the IBD basket (ADQ)

Period	PCT	SHA (excluding PCT)	Difference-in- difference
2009-10	153,457 (83.4%)	1,885,500 (82.2%)	
2010-11	169,276 (85.3%)	2,034,308 (83.3%)	
Annual increase	1.8%	1.1%	0.8%
2011-12	184,139 (88.0%)	2,153,129 (84.4%)	
Annual increase	2.7%	1.1%	1.6%
Three-year total	506,872 (85.7%)	6,072,937 (83.4%)	

A comparison between the PCT and the SHA (excluding the PCT) demonstrated a similar pattern with aminosalicylates. The majority of prescribing by ADQ consisted of oral preparations and remained relatively stable over each of the three years in the data set. However, with respect to steroid preparations, although both data sets demonstrated that rectal preparations constituted

the majority of items within the IBD basket in each year, and both showed the proportion decreasing over time, the absolute levels and the attendant ratios were quite different (e.g. 83% vs. 72% rectal preparations over the whole period for the PCT vs. the SHA (excluding the PCT), respectively. Caution must be expressed against any further interpretation of this data as the data set for steroid use in IBD was incomplete, due primarily to the omission of oral prednisolone. Relatively subtle and clinically appropriate differences in prescribing could have resulted in the observed differences between the two groups however it can only be concluded, on current evidence, that the pathway had no clear or important impact on prescribing.

Table 10. PCT prescribing for IBD by therapeutic class (ADQ units)

Therapeutic class	Period	All prescribing	Oral	Rectal	Oral:Rectal ratio
Aminosalicylate	2009-10	173,583	170,449 (98.2%)	3,135 (1.8%)	54:1
	2010-11	187,066	182,863 (97.8%)	4,203 (2.2%)	44:1
	2011-12	200,382	195,955 (97.8%)	4,427 (2.2%)	44:1
	Total	561,031	549,267 (97.9%)	11,765 (2.1%)	47:1
Steroid	2009-10	10,318	1,281 (12.4%)	9,036 (87.6%)	1:7
	2010-11	11,319	1,818 (16.1%)	9,501 (83.9%)	1:5
	2011-12	8,936	2,244 (25.1%)	6,692 (74.9%)	1:3
	Total	30,573	5,343 (17.5%)	25,229 (82.5%)	10:47

Table 11. SHA (excluding PCT) prescribing in IBD by therapeutic class (ADQ units)

Therapeutic class	Period	All prescribing	Oral	Rectal	Oral:Rectal ratio
Aminosalicylate	2009-10	2,159,071	2,093,947 (97.0%)	65,123 (3.0%)	32:1
	2010-11	2,299,891	2,234,456 (97.2%)	65,435 (2.8%)	34:1
	2011-12	2,417,609	2,346,197 (97.0%)	71,411 (3.0%)	33:1
	Total	6,876,570	6,674,600 (97.1%)	201,970 (2.9%)	33:1
Steroid	2009-10	133,448	33,244 (24.9%)	100,205 (75.1%)	1:3
	2010-11	141,388	36,168 (25.6%)	105,220 (74.4%)	1:3
	2011-12	113,806	44,133 (33.0%)	89,674 (67.0%)	1:2
	Total	408,642	113,544 (27.8%)	295,098 (72.2%)	5:13

Note: Some totals do not sum to expected or previously quoted values due to individual and accumulated rounding errors.

4.1.5.4 Health episode statistics data analysis

Following extensive probing of the HES online interface it was impossible to obtain diagnostic- or procedure-code specific data for a specific entity, whether that unit was a PCT or hospital trust or hospital site. The data that was freely available from the NHS Information Centre, which managed the HES online database, only provided national (England) data at grouped diagnosis and procedure codes, or therapeutic classification. This data was unsuitable for determining local IBD activity.

However the integrated care pilots stage 2 application (March 2011) did include data relating to local IBD healthcare utilisation. This data was obtained by the PCT project team from their MIDAS system (see box 8). A detailed financial plan was included in the stage 2 application which utilised actual population, morbidity, acute and planned care utilisation and expenditure data.

The project team used MIDAS to identify all admissions linked to an IBD diagnosis. Admissions were stratified into two groups; non-elective activity and out-patient activity. Non-elective activity was further distinguished between higher cost and lower cost patients with the former including all patients aged 70 years or older or patients with 'complications or co-morbidities' (annotated 'cc'). The lower cost group included all patients aged 69 years or younger and without 'cc'. Out-patient admissions were distinguished between 'new' and 'review' appointments with new appointments attracting a slightly higher value per episode than review appointments (see box 9).

The data provided in the application consisted of three time periods for each type of activity (non-elective and outpatient). The time periods used were fiscal years and included April 2006 to March 2007, April 2007 to March 2008, and the partial year April to November 2008 (eight months) which was assumed to be the most up-to-date volume of data available when the application was prepared. The data provided was for all of the PCT patients and indicated that care was delivered by one of three NHS hospital foundation trusts including two large teaching and tertiary referral centres. Each hospital trust itself consisted of multiple hospital and other sites. The data did not provide detail at the site level only at trust (provider organisation) level. The data demonstrated no discernible trend with respect to IBD healthcare activity. Total non-elective admissions were 293, 273 and 205 respectively with the latter figure representing only eight months of data; the equivalent expected annual rate was estimated at 308 admissions. Total out-patient admissions were 1,055, 1,342 and 837 (1,256 annualised equivalent) respectively.

This data is provided to permit any future analysis which is able to utilise MIDAS data or similar sufficient to enable a meaningful comparison against these pre-pathway or baseline values.

As discussed in chapter 3, the application also included a number of assumptions of cost savings which the pathway was expected to generate based on these levels of admissions.

Box 8. MIDAS [32]

MIDAS is an acronym for [Locality] PCT Information, Data and Statistics.

MIDAS was a web-based software package used by a PCT conglomeration ('cluster') which included the locality PCT and three other neighbouring PCTs. MIDAS was an in-house information system that served as a reporting tool for the collective organisation's data warehouse. It was initially designed to support Practice Based Commissioning and was claimed to empower both general medical practitioners and their staff and commissioning (i.e. PCT) staff to monitor and audit patient information relating to the clinical outcomes of patients and progress of their service against targets.

The system enabled data interrogation down to the individual patient level and adjustment of data boundaries (e.g. PCT, practice, patient, hospital trust, political boundaries). MIDAS was a secure system which could only be accessed by authorised users.

The data contained within MIDAS has its origins in the HES data generated by any hospital trust which has provided care or had contact with patients from the PCT cluster and this is combined with locally generated referral data. The majority of care was therefore provided by local hospitals. Standard and bespoke data reports could be generated based on diagnosis and procedure codes or combinations thereof. The data could be manipulated in numerous ways to ensure that it was useful and relevant to users and could be exported in familiar formats such as Microsoft Excel™.

I was not an authorised MIDAS user and the system or data extracts from it were not made available to me.

Box 9. NHS definition of outpatient appointment classifications [181]

'New' and 'review' outpatient appointments are officially referred to as 'first attendance' or 'follow-up attendance' respectively in the NHS payment by results tariff. The distinction between the two appointment types is made as *'This indicates whether a patient is making a first or follow-up attendance.'*

Outpatient appointments are defined in the NHS Data Model and Dictionary as:

A first attendance is the first in a series of attendances, with subsequent attendances in the Consultant Out-Patient Episode recorded as follow-up attendances. Follow-up attendances within a Consultant Out-Patient Episode are all subsequent attendances to see the same Consultant following a First Attendance. A Consultant Out-Patient Episode ends when the Patient is not given a further Out-Patient Appointment by the Consultant.

In practical terms, a first-attendance will attract a higher charge than a follow-up attendance, presumably to reflect the additional resources required for the first consultation compared with follow-up consultations for the same episode.

4.1.5.5 Combined IBD Healthcare Utilisation Metric

The development of a single combined IBD healthcare utilisation metric was not pursued as there was no suitable non-drug healthcare utilisation data available to combine with the primary care drug data.

4.2 Community Pharmacy and IBD

4.2.1 Survey

Of the 393 surveys which were posted, 197 completed surveys were returned before the cut-off date. One of these was later excluded as although the registered member was an adult they were serving as a proxy member on behalf of their child with IBD. The responses provided in this case were a mixture of proxy child-patient responses and direct responses from the non-patient parent.

In addition, a small number of uncompleted surveys were returned by adult members of the branch who were not IBD patients or patients who lived outside of the locality and felt that they were not eligible to complete the survey. A small number of completed surveys were returned after the cut-off date and were not included in the final analysis set. Thus the actual response rate was in excess of 50%, however the effective response rate was 196 out of 393 (49.9%).

Response rates for individual questions, or parts thereof, ranged from 23% to 99%. Question 8 was unusual in that it was preceded by a filter question and therefore only respondents who provided a specific response to question 7 were required to then complete question 8. With question 8 excluded the response rate ranged from 72% to 99%. Individual responses to each question are described in turn.

Questions 1 to 8 were used to elicit baseline data concerning the extent and nature of the respondents' use of various types of medication and interaction with community pharmacies.

Questions 9 and 10 elicited information concerning patient-pharmacy interactions.

Questions 11 to 15 elicited patient demographic details.

4.2.1.1 Baseline drug-related healthcare utilisation and services

Question 1

The results from question 1 demonstrated a high rate of prescription medication use amongst respondents.

Do you currently use medicines prescribed for you for IBD?		
Response	n	%
Yes	168	86.6%
No	26	13.4%
Not answered	2	
Multiple responses	0	

Question 2

Results from question 2 demonstrated that GPs were the most common source of IBD medication prescriptions although prescriptions from hospital doctors were also high. Other prescribers accounted for much smaller proportions. The two responses received and listed as 'other' were 'Initially hospital consultant' and 'health care at home', the latter being a recognised medication home delivery service provider.

Who currently prescribes your IBD medication? (tick all that apply)		
Response	n	%
Hospital doctor	102	52.0
General practitioner (GP)	122	62.2
Hospital nurse	28	14.3
Other nurse (e.g. working in practice or district nurse)	4	2.0
Hospital pharmacist	2	1.0
Community pharmacist	3	1.5
Other (please indicate)	2	1.0
Response descriptions	n	%
Not answered	30	15.3
One response	90	45.9
Two responses	58	29.6
Three responses	16	8.2
Four responses	2	1.0

Question 3

A supermarket in-store pharmacy is also a type of community pharmacy therefore the true response rate for community pharmacy required additional calculation to account for this duplication. It was not possible to calculate this simply by adding the two response counts together as some respondents provided positive responses to both categories. Seven surveys answered positively to both community pharmacy and supermarket pharmacy, thus the adjusted, or true, number of responses for 'community pharmacy (including supermarket pharmacies)' was 139 (71%). The results demonstrated that more than two-thirds of respondents received their IBD medication via a community pharmacy.

Where are your IBD medicines dispensed? (tick all that apply)		
Response	n	%
Community pharmacy	133	67.9
Supermarket in-store pharmacy	13	6.6
Hospital pharmacy	33	16.8
General practice surgery (e.g. if your doctor also dispenses medicines)	22	11.2
Internet pharmacy	0	0
Other (please indicate)	12	6.1
Response descriptions	n	%
Not answered	32	16.3
One response	124	63.3
Two responses	31	15.8
Three responses	9	4.6

Question 4

Question 4 was effectively screened by the preceding question. In question 3, 146 responses from 139 surveys indicated that their medication was dispensed by a community pharmacy or an in-store supermarket pharmacy and only these respondents would be expected to answer question 4. Therefore question 4 should have been answered by these same 139 respondents. In the event, 149 surveys provided a response and 47 did not provide a response to question 4. 133 had responded to question 3 with community or supermarket pharmacy or both therefore 13 surveys provided a response to question 4 which was unexpected. Six surveys that responded with community pharmacy or supermarket pharmacy to question 3 did not provide a response to question 4. Analysis is independent of question 3. A number of respondents indicated that they did not understand question 4 in addition to answering 'not sure' or in lieu of any response. No multiple responses were received for question 4. The results demonstrated that about half of patients always use the same pharmacy, and nearly a third usually use the same pharmacy, with a minority demonstrating less commitment.

If your IBD medication is dispensed by a community pharmacy or an in-store supermarket pharmacy, is that at the same pharmacy? (tick only one)		
	n	% (as a proportion of all responses)
Always	77	51.7
Usually	42	28.2
Sometimes	13	8.7
Rarely	1	0.7
Never	10	6.7
Not sure	6	4.0

Question 5

Question 5 was an open question which requested up to three written responses. The intention was for this question only to be answered depending on the answer provided for the preceding question. 149 respondents answered question four and 142 provided at least one response to question five. However 29 respondents (20%) who either didn't provide a response for question four (n = 11) or who didn't respond with either 'usually' or 'always' (n = 18) did provide at least one response for question five. Irrespective of response to question four, all responses for question five were analysed collectively.

331 responses were received from 142 surveys, a mean of 2.35 responses per responding survey, or a mean of 1.70 responses from all 196 returned surveys in the analysis set. 80 surveys provided three responses, 30 surveys provided two responses, 31 surveys provided one response and 54 surveys did not provide any response.

Responses were not requested to be, nor were they necessarily, ranked although the construct of the question could have led to an assumption of this nature by respondents. The actual responses received did not indicate any obvious or apparent ranking by respondents and analysis has not therefore considered any ranking.

A thematic analysis of responses using text-based analysis was undertaken using a framework analysis approach. [182] Themes were identified based on prior knowledge of community pharmacy and relevant published research. These themes were refined and validated by an experienced pharmacy practice academic from a neighbouring institution with a small number of relatively minor amendments. Each theme was classified into one of five induced categories which were further defined as either external to the influence of the pharmacy, or internally influenced attributes.

Twenty-two distinct themes were identified which were subsequently classified into five main categories. Details of the themes, categories and frequency counts are provided in the table 12.

Table 12. Thematic analysis of responses to question 5

If your prescription is usually or always dispensed at the same pharmacy, what are the factors that influence that decision? List the three most important.				
Category	Theme	n		Influence
Geographical	Proximity to GP	40	159	External
	Convenient	104		
	Restricted choice	7		
	Proximity to parking	8		
Business and Staff attributes	Familiarity with staff	3	96	Internal
	Internet (online) prescription service	3		
	Service quality	14		
	Staff attributes	44		
	Waiting time	11		
	Information	10		
	Loyalty not otherwise specified	10		
	Opening hours	1		
Pharmaceutical services	Prescription collection and delivery service	23	42	Internal
	Repeat prescription service	14		
	Provision of monitored dose system	1		
	Provision of medicines use review, or other medication review	2		
	Emergency supply	2		
Drug specific	Provision of preferred medicine brand(s)	1	22	Internal
	Stock-holding	21		
Pharmacist attributes	Helpful	5	11	Internal
	Confident	2		
	Pharmaceutical/medical knowledge	1		
	Professionalism not otherwise specified	2		
	Dispensing accuracy	1		
Other	Recommended by GP	1	1	External

Question 6

Question six was expected to return one response per respondent who reported receiving prescription IBD medication (question 1) and the results correlated accordingly.

'Other' responses included 'wife' for which the respondent had already indicated 'family member', 'infiximab infusion at hospital every eight weeks', 'military nurse', and 'delivered by chemist if not well' for which the respondent had only indicated 'you'. These results were all counted separately.

Who usually collects your prescription once it has been dispensed? (tick only one)		
	n	%
You	129	65.8
Family member	28	14.3
Friend or neighbour	1	< 1
Social services carer	0	0
A health care professional (e.g. district nurse)	1	< 1
It is delivered	18	9.2
Other (please indicate)	4	2.0
	n	%
Not answered	30	15.3
One response	154	78.6
Two responses	9	4.6
Three responses	3	1.5

Question 7

This question was potentially independent of question 1 as it related to non-prescription medication and similar items. This meant it was the first question which respondents would encounter which would not be related to prescription medication. The results demonstrated that a significant minority of respondents did report taking non-prescription IBD medication.

Do you take other medicines for IBD which are not prescribed for you? This might include medicines that you buy from a pharmacy, supermarket or grocery store, or herbal or vitamin preparations.		
	n	%
Yes	45	23.0
No	145	74.0
Not answered	6	3.1

Question 8

Question 7 was explicitly intended to serve as a filtering question for question 8, therefore only respondents who had answered 'yes' to question 7 were expected to provide a response to question 8. Forty-five surveys responded 'yes' to question 7 and 46 surveys provided at least one response to question 8. All 45 surveys which responded 'yes' to question 7 provided a response to question 8. The additional response to question 8 was from a survey which had not provided a response to question 7. The 'other' response indicated direct supply to the patient from a clinical trial centre.

If you answered 'yes' to question 7, where do you obtain these medicines? (tick all that apply)			
	n	%	%
Community pharmacy	9	19.6	4.6
Supermarket (including the in-store pharmacy)	15	32.6	7.7
General store (e.g. local convenience store)	3	6.5	1.5
Health food, herbal or vitamin store (e.g. Holland & Barrett)	22	47.8	11.2
Internet / online	7	15.2	3.6
Mail order, or from a magazine or television advert	6	13.0	3.1
Given to you by family or friends	0	0	0
Other (please indicate)	1	2.2	< 1
	n	%	%
No response	150		76.5
One response	32	69.6	
Two responses	11	23.9	
Three responses	3	6.5	

4.2.1.2 Patient satisfaction with pharmaceutical care and pharmacy

Question 9

Respondents were required to recall experiences relating to the pharmacy that they usually use or otherwise their most recent visit to a community pharmacy. Fifteen respondents did not recall visiting a community pharmacy, 14 of whom did not provide any response to the 20 statements which constituted this question. The question was preceded by a filter statement to eliminate respondents who could not recall visiting a community pharmacy. One respondent who indicated that they could not recall visiting a community pharmacy still provided a response to each of the 20 statements. The reporting and analysis of responses has been conducted irrespective of response to the filter question and other questions.

The response rate for individual statements varied from between 81% to 88%. The response matrix is provided in table 13. The question order presented in the results is not that which was used in the survey (see appendix 4) as items for each constituent scale incorporated into the question have been grouped together in the results. The 'no opinion' response was extensively used, ranging from 0 to 24% within FE items and 18 to 43% within MT items.

Calculation of FE and MT scores required a complete set of responses excluding 'no opinion' within each scale. A complete set of required responses for FE was available from 89 surveys and for MT from 61 surveys.

The range of individual FE and MT scores was 1.0 to 5.0, corresponding to the mean score over all items within each scale. The overall mean FE score was 3.80 (standard deviation 0.96; 95% confidence interval 3.61 to 4.00). The overall mean MT score was 3.31 (SD 1.25, 95%CI 2.99 to 3.62). The difference between mean FE and MT scale scores was significant using a two-sided test and an alpha value of 0.025 to give an overall significance level of 5%; difference in mean scores was 0.49 points ($p = 0.01$).

There were some limited examples which indicated that responses had not been properly considered with responses presented in an obvious pattern. This was most commonly demonstrated by responses inserted into the same vertical column for all 20 items. Analyses have not been adjusted to account for seemingly irrational or non-properly considered responses.

Responses corresponding to 'no opinion' were the third most common response overall, accounting for one-fifth of all responses. However there was a striking difference between scales, with 'no opinion' accounting for 9.8% of all FE responses and 33.9% of all MT responses. The most common response for eight out of nine MT items was 'no opinion'.

Table 13. Response matrix for survey question 9

Scale	Item	Poor	Fair	Good	Very good	Excellent	No opinion	Total
Friendly explanation	The professional appearance of the pharmacy	3	7	44	67	51	1	173
	The availability of the pharmacist to answer your questions	2	14	34	52	52	15	169
	The pharmacist's professional relationship with you	6	16	31	51	43	19	166
	The pharmacist's ability to advise you about problems that you might have with your medications	5	7	34	41	39	36	162
	The promptness of prescription drug service	6	19	42	46	58	0	171
	The professionalism of the pharmacy staff	4	12	43	53	57	1	170
	How well the pharmacist explains what your medications do	11	13	30	37	35	40	166
	How well the pharmacist instructs you about how to take your medications	11	18	37	30	35	34	165
	Your pharmacy services overall	3	17	48	48	56	1	173
	How well the pharmacist answers your questions	5	11	38	32	43	35	164
	The courtesy and respect shown to you by the pharmacy staff	5	13	48	41	65	0	172
Total		61	147	429	498	534	182	1851
Managing therapy	The pharmacist's interest in your health	18	23	29	22	23	50	165
	How well the pharmacist helps you manage your medications	15	16	27	22	20	61	161
	The pharmacist's efforts to solve problems that you have with your medications	8	14	29	25	25	63	164
	The responsibility that the pharmacist assumes for your drug therapy	16	14	17	26	19	67	159
	The pharmacist's efforts to help improve your health or stay healthy	17	14	22	23	16	69	161
	The privacy of your conversations with the pharmacist	26	34	22	26	30	30	168
	The pharmacist's efforts to assure you that your medications do what they are supposed to	14	13	24	26	17	64	158
	How well the pharmacist explains possible side effects	27	16	31	22	22	45	163
	The amount of time the pharmacist offers to spend with you	27	17	27	24	21	47	163
	Total		168	161	228	216	193	496
Grand total		229	308	657	714	727	678	3313

Question 10

This question consisted of 12 statements, each assessed on a Likert scale. The responses matrix is provided in table 14. Some statements were deliberately designed to contradict other statements to provide a measure of intra-responder reliability.

No response was received from 13 surveys and a full response (i.e. a response for each of the twelve statements) was received from 158 surveys (81%). Twenty-five surveys (13%) provided between one and 11 responses each.

Responses were not scored but ranged from negative to positive agreement. The skew of responses was informally assessed by visual inspection of the data. The highest level of positive agreement was statement 4, with 128 respondents indicating agreement (73%). The highest level of disagreement was with statement 9, with 139 respondents indicating disagreement (79%). Some statements demonstrated bimodal levels of agreement due to relatively few mid-range responses of 'neither agree nor disagree'. Specifically, these were the 2nd, 7th, 11th and 12th statements, with mid-range responses ranging from 25 to 43 against an overall range of 19 to 70. Statements for which the mid-range response was the most common were the 3rd, 6th, 8th and 10th statements although some of these still demonstrated an overall skew in the spread of responses.

The results can be interpreted as cautiously positive for community pharmacy with more respondents agreeing to statements which support a role for pharmacy and disagreeing to negative statements. However, there is a considerable degree of heterogeneity in responses and nearly one-quarter of responses were ambivalent. Of particular note was that relatively few patients reported problems with managing their medication although those who did agree with the statement that they struggled with their medication still accounted for over 10%.

Table 14. Response matrix for survey question 10

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Total
When I visit a community pharmacy I feel that I can discuss medication issues with the pharmacist	7	23	29	88	29	176
My community pharmacy lacks privacy for me to discuss issues with the pharmacist or other staff	25	41	30	56	22	174
I would like my community pharmacist to be more involved in the overall management of my condition	20	48	70	27	9	174
If I have a question about my medicines the pharmacist is always available	1	15	32	104	24	176
There is no need for a pharmacist to be involved with the management of my condition	14	34	37	65	27	177
My community pharmacist does not have the time to discuss medication related issues with me	28	52	60	23	8	171
I would be happy to have my medication monitored in a community pharmacy	19	47	43	58	12	179
Pharmacists are suitably qualified to take on a bigger role in the management of my condition	19	40	67	35	14	175
At times I struggle to manage my medication	62	77	19	14	5	177
I would not feel comfortable with a community pharmacist being more involved in the management of my condition	14	40	54	49	22	179
If I have a question about one of my medicines I ask my pharmacist first	27	69	25	44	12	177
My community pharmacy has a suitable place for me to discuss confidential issues if I need to	26	33	26	65	26	176
Total	262	519	492	628	210	2111

4.2.1.3 Baseline disease and demographic data

Questions 11 to 15 constituted the final section of the survey and consisted of five questions designed to collect baseline demographic and disease characteristics.

Question 11

Question 11 obtained information concerning the gender of respondents. The overall response rate was very high, with only three survey respondents omitting a response to this question. The results demonstrated that almost two-thirds of respondents were female.

Are you	N	%
Male	70	36.3
Female	123	63.7
Not answered	3	

Question 12

Question 12 obtained information concerning respondent age. The overall response rate was high with only two survey respondents omitting a response to this question. The results demonstrated that the majority of respondents were 'middle aged', in the range 40 to 69 years, however significant numbers of responses were received from younger and older patients.

One returned survey indicated that the respondent was aged under 18 years. This contravened ethical approval for the study and the survey and all associated data was removed from the analysis set. The survey respondent indicated that they were a proxy adult member for their child with IBD.

Which age group are you?	n	%
Under 18 years	0	0
18 to 29 years	16	8.2
30 to 39 years	22	11.3
40 to 49 years	36	18.6
50 to 59 years	45	23.2
60 to 69 years	40	20.6
70 to 79 years	26	13.4
80 to 89 years	9	4.6
Older than 89 years	0	0
Not answered	2	

Question 13

This question sought to obtain a self-declared diagnosis. 185 surveys provided one response, two did not provide any response, and nine provided two responses. Of those which provided two responses, two stated that they had Crohn’s disease and ulcerative colitis, two that they had Crohn’s disease and another IBD diagnosis other than ulcerative colitis, and five stated that they had ulcerative colitis and another IBD diagnosis other than Crohn’s disease.

What form of inflammatory bowel disease do you have?	n	%
Crohn’s disease	104	51.2
Ulcerative colitis	86	42.4
Other IBD diagnosis	13	6.4
Not answered	2	

Question 14

This question sought to obtain a self-declared assessment of disease severity. 191 respondents provided one response, one respondent provided two responses (indicating moderate and severe), and four respondents did not answer this question.

Most patients stated that their disease was mild or moderate although a significant minority, almost 1 in 4, stated that their disease was ‘severe’.

Regardless of your official diagnosis, how would you personally describe the severity of your IBD	n	%
Mild	60	31.4
Moderate	89	46.6
Severe	42	22.0
Not answered	4	

Question 15

This question required a text (written) response from respondents relating to their residential location.

What is the first part of your postcode? e.g. TS17, DL3

Nine respondents did not answer this question. 186 respondents provided a single answer consisting of the first three or four characters of their postcode, i.e. the postcode district. 181 of the postcode districts were immediately local and 5 were near-local. One postcode was from a remote location and this respondent indicated that they used a relative's address within the group locality for their membership and registration with the patient charity, hence they were assigned to that particular branch.

Further analysis of postcode data was compromised by misjudged data collection. A full post code or any further information than requested, for example the next numerical characters denoting post code sector, was not obtained so as to maintain respondent confidentiality. However postcode data is correlated with, for example deprivation scores or other socioeconomic characteristics, at the postcode sector level of granularity which is one level further than the district level collected. Consequently further analyses were terminated. The post code district data was not entirely redundant as it did confirm the geographical spread of respondents which corresponded closely to that expected with the sample derived from a geographically-defined branch of a national patient charity.

4.2.2 Summary of survey responses

The overall findings from the survey data of adult IBD patients were that:

- The condition was managed extensively with prescription medication
- The condition relied upon a significant element of primary care management
- Patients regularly visited community pharmacies themselves
- Patients chose their community pharmacy due equally to external and internal factors
- Use of non-prescription medicines was relatively high and these were purchased from a diverse number of sources including community pharmacies
- Satisfaction with current levels of pharmaceutical care was generally good, with satisfaction with care relating to 'friendly explanation' being greater than that relating to 'managing therapy'
- Adult IBD patients valued pharmacists for information-providing roles but were less welcoming of pharmacists becoming more involved in the management of their condition
- Few patients reported current problems in managing their medication

4.2.3 Focus groups

By 12th January 2011, 76 recipients of survey packs had returned a completed focus group enquiry (appendix 6). Two of these were participants declining to participate. Of the 74 respondents who indicated they were willing and able to potentially participate, focus group information packs were sent by post to 49 individuals and via e-mail to 25.

From the 74 packs distributed, 25 replies were received either by return of consent form or through other correspondence, most often e-mail. One individual was ineligible for participation as she was not an IBD patient although she was an adult member of the local branch of the patient charity as a proxy member for her child who did have IBD. Three respondents subsequently withdrew consent or were unavailable for the proposed focus group dates. Confirmed invites were sent to 21 individuals for one of three focus groups as indicated in table 15.

Table 15. Focus group stratification, invites, and attendance

	Focus group 1	Focus group 2	Focus group 3
Planned patient type	Younger (age ≤ 50 years) ulcerative colitis patients	Older (age > 50 years) ulcerative colitis patients	Crohn's disease patients
Date and time	Wednesday 23rd February 2011. 7 to 9pm	Sunday 27th February 2011. 1 to 3pm	Sunday 27th February 2011. 4 to 6pm
Invited	6	7	8
Attended	2	5	2

In order to accommodate the specific requirements of some participants, and in reflection of the confirmed participant response rate, the proposed stratification was not strictly adhered to. In particular, two patients with Crohn's disease attended the second focus group and both attendees of the first focus group were aged over 50 years.

The focus groups were semi-structured although the structured element was not proscriptive or strictly adhered to. Questions were generally presented in an open manner and as facilitator I was conscious of permitting participants to discuss amongst themselves rather than interjecting with too many questions. During the focus groups several of the scenarios (appendix 9) arose incidentally at various times. In these situations the scenarios, or the specific steps within them, were not re-interrogated although they were taken as a starting point for interrogation of a particular scenario. In the event each focus group endured for most of the allotted two hours.

Table 16. Focus group attendees

Participant code	Focus group	Details
11	1	Female, UC
12	1	Male, UC
21	2	Female, UC
22	2	Male, CD
23	2	Male, CD
24	2	Male, UC
25	2	Female, UC
31	3	Male, CD
32	3	Male, CD

CD: Crohn's disease UC: Ulcerative colitis

Ultimately, for each theme, a single document was generated which would contain text relating to a single specific theme. Some sections of text featured within multiple different themes if it was deemed that more than one theme was clearly included within that section. Thematic iterations underwent some revisions to yield the themes identified in table 17. Each is considered in turn.

Table 17. Themes identified from community pharmacy-IBD focus groups

Theme	Notes
Pharmacists*	As individuals, professionals and healthcare providers
Pharmacies	The environment and facilities (including staff)
IBD	The condition, being a patient, social impact
Medication	Importance in the management of IBD condition, use of non-prescription medicines
Boundaries of care	Relationship with key providers, relationships between providers
Medication adherence*	Identifying the boundaries of care with respect to community pharmacy, willingness to accept specific care from community pharmacies
Medication monitoring*	
Choice of medication*	
Nutritional support*	
Managing a relapse*	
Associated healthcare needs and services*	

* : Theme identified *a priori* and specifically queried.

4.2.3.1 Pharmacists

This particular theme was specifically investigated and served as the opening topic within each focus group. Participants typically described their interactions with community pharmacists and, by extension, the pharmacies and other staff. The majority of comments were positive. In general, participants recognised community pharmacists as healthcare professionals, with expert knowledge about medicines, but perceived their current level of healthcare provision as limited and constrained. Participants were concerned that pharmacist's knowledge would not extend to non-drug aspects of IBD.

Participants expressed concerns about how well integrated community pharmacy was with their overall healthcare management, and were particularly concerned that if pharmacists were making disease management decisions this would be difficult to communicate to GPs and specialists. The existing role of community pharmacists was perceived as largely technical as opposed to clinical. Some participants were clearly aware of actual or perceived clinical hierarchies and felt that pharmacists were less important than GPs in such hierarchies, and that shifting some elements of care to community pharmacists was tantamount to deskilling of healthcare provision.

Pharmacists were perceived as being busy; participants were not inclined to consult a pharmacist particularly as the pharmacist was removed from the patient interface (e.g. pharmacists were located away from the pharmacy counter) and participants were reluctant to interrupt a busy professional.

4.2.3.2 Pharmacies

The community pharmacy environment and experience, i.e. the 'shop', emerged as a theme in the focus groups. Community pharmacies were perceived as convenient and accessible places. Participants reported community pharmacies as busy environments where the pharmacist was often occupied. Some participants expressed feelings of guilt if they wished to speak to the pharmacist as they were distracting the pharmacist from the task of dispensing. Concerns were expressed about confidentiality as the patient interface (the pharmacy counter) was public. This was a particular concern given the embarrassing nature of the condition. Several participants were aware of private consultation rooms within pharmacies but were not sure about how to access them or the pharmacist. Some participants were unaware of private consultation facilities. None reported actually using a pharmacy consulting room with respect to IBD. Waiting times in pharmacies could prove problematic given the nature of the condition and a potential need for frequent and urgent toilet visits. The pharmacy counter was perceived as a physical barrier inhibiting interaction with pharmacy staff and pharmacists. Pharmacy staff were generally considered to be helpful.

Overall, despite some issues, participants appeared to be satisfied with their community pharmacy experiences.

4.2.3.3 IBD

Another theme that emerged consistently in focus groups was the perception and handling of the diagnosis. Participants reported being embarrassed about having IBD and keeping the diagnosis secret from family and friends. Concerns were expressed about public misunderstanding of the condition and not wanting to be thought of as 'sick'. This seemed to be more common amongst male participants. This in turn imposed some constraints on interacting with community pharmacists as these interactions were at least initiated or even wholly conducted in public.

24 '... it's [IBD] not something that I talk about '

25 '... one of the problems with IBD, it's not a talked about illness is it?'

11 'Not if there's somebody in the queue behind you!'

The need to visit a toilet frequently and promptly was a restriction for some participants, particularly with respect to, for example, prescription waiting times. There seemed to be a great fear of experiencing another relapse and a feeling of being lucky that their own condition was not as bad as others of which they had knowledge. During a relapse some patients reported a loss of self-confidence particularly with respect to social interactions.

A few participants referred to the actual or perceived impact of the condition on their employment, which was consistently negative. One participant explicitly stated that he kept his diagnosis secret for as long as possible due to the macho working environment he operated in and the potential effect on his employment.

4.2.3.4 Medication

A general theme concerning medication also emerged beyond those issues which were specifically raised within the scenarios. Participants reported extensive experience of medication rotation over time i.e. having tried a number of different types of drug for their IBD. There appeared to be a common 'trial and error' approach to medication prescribing for IBD with patients directly associating symptom relief or recovery with the drug that they happened to be taking at that time. Participants also reported that after taking their medication for a period of time the efficacy waned or was in some way diminished. Some participants reported hoarding prescribed medication to self-manage their condition in the event of a relapse and one participant undertook this activity with the co-operation of their GP.

A number of participants reported concerns about the adverse effects of drugs, that this information had only been presented in print, e.g. the patient information leaflet accompanying dispensed medication, and that it was not presented in a balanced or risk-appreciated manner.

25 'I wasn't warned of the side effects that could go with it, I mean, I was really quite spaced out on them so, you know, stopped driving myself 'cos I was, I felt as though I wasn't safe to be driving but nobody warned that I could feel like that.'

All groups reported a degree of intentional non-adherence and this appeared to be common for all participants. This finding agrees with a contemporary postal survey conducted with nearly 1,900 members of a national (UK) patient charity. [37] One-third of those respondents reported intentional non-adherence with IBD maintenance therapy. Participants also reported considerable experience of having tried several medications over long periods of time before settling on a combination that 'works'. For example there was a consistent desire to reduce or eliminate need for medication.

25 'I think I got to the stage you see, a few years ago when I was in remission, like you, I was taking the six a day and I thought "no, I'm going to try and get off these".'

This appeared to be implicitly associated with dissatisfaction with the efficacy of conventional medicines. A significant amount of interest in and some direct experiences of use of non-prescription 'alternative' medicines (e.g. herbal, vitamin, health food-type products) was reported although direct experience of such preparations was limited.

Information about medicines was obtained from a variety of sources particularly the IBD nurse, Crohn's and Colitis UK (formerly the National Association for Colitis and Crohn's disease), and the internet. Although a community pharmacist was recognised as an accessible expert on medicines few participants reported actually consulting, or initiating a discussion with, a pharmacist for information about their medicines.

4.2.3.5 Boundaries of care

A more subtle theme that emerged was that relating to the boundaries or responsibilities for care, specifically where it was suggested or posited that a community pharmacist could provide a particular service and with respect to the boundary between specialist and generalist provision of medical care. With respect to the latter, there was a difference in experiential view expressed between participants. A few participants reported they had confidence in their general medical practitioner for the management of their IBD and they would seek to consult their GP when a problem arose. However, a more common experience reported was of the opposing stance, whereby there was a lack of confidence in generalist care and a heavy reliance on specialist care,

whether provided by an IBD specialist nurse or a consultant. This reliance on specialist care was often fostered by the specialists themselves.

25 'No, well I can just go straight, direct to my specialist at [hospital name]. You can just ring straight up.'

32 'Because I have like a, there's a consultant that's always at the end of the phone. It's hard getting through to him sometimes but I tend to find, if I'm poorly and steroids take days and days to work, don't they? Weeks in fact, so I want to speak like, to the main person, type thing. I want to cut out ..., I don't want any middle man.'

24 '... but if I need to see them before then I can usually ring and speak to the consultant's secretary and they can usually squeeze you in.'

25 'We hold those consultants in high regard, don't we?'

25 'I've never had particular faith in just going off to any GP to talk about it; you end up back with the consultant. You always do.'

32 'I'd go straight to me consultant; because consultants, I don't know if yours do, sort of like, encourage you to contact them.'

32 '[The consultant] sort of like, he took me to one side and he said "there's me number, any problems, phone me direct". So I used to phone him, direct. I remember I was going on holiday or something, I went "oh, should I take me tablets with me?" He phoned me back, like, within half an hour so I've always, I've always, I don't know, it always seems to be consultants saying "there's me number, I will get back to you" and, by and large, I've only ever had a couple of queries, they've always got back to me, probably within the hour.'

22 'I've found that my GP is, you know, she's more a..., I mean I've actually been in to, when they've had junior doctors in, to talk about my problems, to go through things like that and she's very good. When I am ill ... "straight across the road to the hospital".'

Although some participants felt that expansion of IBD care into community pharmacies might be more convenient in terms of access concerns remained about information integration and the limited authority and autonomy of pharmacists. The boundaries and level of care that participants were comfortable with did not reach consensus within or across groups and was highly individualised

4.2.3.6 Scenarios

The latter part of each focus group, typically the second of two hours, involved the presentation of scenarios (appendix 9) relating to pharmaceutical care services which could, in theory, be

delivered by community pharmacists for adult IBD patients. These were sometimes explicitly revealed to participants, and other times subtly woven into each discussion. On several occasions elements of the scenarios arose spontaneously without any specific propagation from the facilitator. The following syntheses were derived irrespective of the manner in which the scenarios were presented.

A. Medication adherence

Participants were generally positive about community pharmacists taking an active role in improving medication adherence including active monitoring of actual compared with expected prescription volumes. There was general acceptance of this role to a relatively high level through passive provision of information, targeted delivery of specific information to active monitoring and provision of specific devices to aid adherence. Some participants reported that they felt these tasks were already performed by community pharmacists although in an *ad hoc* fashion as opposed to a systematic and integrated model.

22 'That's what I've been picked up on about because I've gone in for some medication and it's obvious that I haven't been taking it because it's the length of time between, since I had them and I've ordered the next one. It's obvious that I'm not taking the correct dosage. They pick it up.'

Interviewer 'Who picked you up on that?'

22 'Well the doctor did initially, but as I say, this pharmacist who's retired, he used to pick it up all the time, because he used to say "well, I haven't seen you for a while, what's happened? Have you been taken off them" and then I'd give him the prescription and he'd look at it and say "it's a while since you've had these".'

And from the same focus group:

25 'It's a very up and down illness, so you do learn to adjust your own.'

24 'It is really, because it's a self medicating illness really, that's what the GPs say, 'you can manage it better than we can' because, I mean, you know what to do better than the GPs.'

Although the extent or nature of non-adherence to prescribed medication regimens was not specifically investigated either in the patient survey or focus groups, it was referred to, often indirectly, by participants in each focus group. Findings regarding non-adherence were in common with published evidence. A systematic review of 17 studies of medication adherence in IBD (n = 4,322) found that non-adherence was reported at up to 72% of patients with most studies reporting a rate between 30 and 45%. [29] The authors reported that none of the commonly reported demographic and clinical characteristics were consistently associated with non-

adherence. A trend was identified for more complex treatment regimens to be associated with greater rates of non-adherence as was psychological distress and doctor-patient discordance. [29]

B. Medication monitoring

Only a small number of participants had direct experience of being prescribed a medicine which required regular monitoring. In general participants were in favour of a role for community pharmacists in the monitoring of medication to a relatively advanced degree, for example in taking test samples and making dose adjustments. Some participants felt that their current process with significant patient responsibility functioned adequately and they could see little need for a community pharmacist to be involved.

Some reported that the regular contact with their general medical practice due to monitoring visits was reassuring and provided an opportunity for them to engage with primary medical providers concerning their IBD and that this could be missed. A more common concern was with regard to information sharing and the mechanisms by which a community pharmacist would communicate test results both to the hospital IBD team and general practice. Concerns were expressed that the existing two-way communication between secondary and primary care was often imperfect and adding a third party into this system could complicate the situation. Concerns about the ability of a pharmacist to extract, for example, a blood sample were expressed by some participants. The suitability of the pharmacy premises for such services was not explicitly expressed.

This excerpt from the second focus group highlights some of these issues:

25 '... but at the minute it's between the consultant and the GP, if you start with the pharmacy as well you're not going to know which direction you're going in, it might be a bit confusing.'

Interviewer 'And what about, you know, thinking if this [medication monitoring] got a bit more involved now. What about if the actual sample itself could be taken in the pharmacy and sent off to be measured?'

24 'Well, that's what I was thinking would be quite convenient, or could be convenient, as long as those results were going to the hospital and to the ...' [interrupted by 22]

22 'They'd have to go back to your GP. I've just had mine done'

24 '... go to the GP and go to the hospital, you know.'

21 'It would be handy for other people, like, wouldn't it? But as you say, for us, as you said, we get ours checked.'

And from a different focus group:

Interviewer 'With the monthly blood tests that you have [name], at the GPs' surgery, is that an inconvenience when you have to go to the GPs for that?'

32 'Oh no, it, to tell you the truth it makes me feel quite well in meself, do you know, that I'm doing something about it. I go to get me bloods done. 'Cos I'd probably even say the blood tests sometimes are not a waste of time, ...'

Concerns were also expressed about the patient impact of being informed of a problem with a test result by someone who was potentially unable to do anything about the problem as might occur within a partial pharmacy-based monitoring system, or if bad news was delivered to a patient in a community pharmacy. This was a particular concern expressed at the first focus group:

12 'I think if it was going to be something like a liver function and there was a problem with your liver, then if, if you've got the pharmacist saying "you've got a problem with your liver" then you'd rather be there at the doctors to say, "ok, so how do we approach, you know, how do we deal with it?" Where psychologically you get told by the pharmacist "oh, you've got a liver problem" then it's "oh I'll have to get in to the doctor's" and then it's "oh God what's wrong?"'

11 'No, I would say no, I agree with you [participant 12]. You're there and you get a test result back, and "yes, you have cancer", well, or you have a question, even if it's not clear, you know this is not "we think you should see your doctor" you know, and immediately anxiety level goes straight up because we are just human and we immediately think all the wrong things and I think, I would actually say that's the wrong setting [community pharmacy].'

Overall, with respect to the monitoring medication scenario, consensus across and within focus groups was not achieved. Although participants were generally positive, there were disparities concerning the level of community pharmacy involvement, and perceived need. Many barriers were identified by participants and any advanced level of involvement would likely require suitable information technology infrastructure before it was acceptable to IBD patients.

C. Supplemental and enteral feeds

Participants reported little direct experience of use of such products. Some reported experience of friends who had used them, or having personally used such products only during in-patient stays, or having read about them. One aspect that was considered useful by most participants would be for community pharmacists to provide samples for patients to try before they committed to ordering larger quantities on prescription.

Interviewer 'And what about if the pharmacist was to provide samples of products? Because there's quite a large range available.'

24 'Yeah, that would be a good idea.'

21 'Yes, it would, wouldn't it?'

Interviewer 'So if a pharmacist, say, would provide samples of products for you to take away and try and then come back and say "yes, these I liked, I would like some of these".'

All (focus group 2) 'Yeah.'

From the third focus group:

32 '... 'cos like I was saying, when I was in hospital, I didn't get that. I was getting "have this, it's going to build you up" and I'm thinking "I haven't had a solid stool in six weeks" do you know what I mean? So that would be much more welcome, have a sample, take 'em home, see how you get on with them, come back and then, like I say, ... yeah ... definitely to that.'

Participants were generally positive about the involvement of community pharmacists in the management of supplemental and enteral feeds although an obvious need was not clear and there appeared to be little interest in this aspect of treatment.

D. Choice of medication

There was general acceptance among participants for community pharmacists to have a limited level of involvement in medication choice. For example, provision of information about different dose formulations or different drugs within the same class and the types of medicines which are available. Involvement beyond a limited level was generally unenthusiastically or negatively received by participants, as the following excerpt demonstrates:

11 'I mean your doctor, yeah, has to look up what to give you and the pharmacist, perhaps, would have maybe a better understanding of what's available out there, better than the doctor, ... but I don't know.'

In particular, it was felt that community pharmacists would be encroaching too far into the role of a medical prescriber:

31 'Yeah, I mean, my thought is that here we've got pharmacists treading on the toes of GPs and consultants and I think it's got the makings of problems. In my opinion, if they go down the track, in our condition, or with our condition, that they would say "well, I think you should change from whatever you're on, to this that *might* be better" because who then carries the can if it all goes pear shaped?'

32 'I personally, would rather have just one person to hold responsible for the medication.'

However participants did not recollect having had discussions with their doctors regarding medication choices. Many participants reported having tried a number of preparations and types of drug over time. Some participants did report specific preferences for types of formulation:

12 'I'd been prescribed with suppositories and when I saw the consultant for a colonoscopy he said "oh, we'll put you on these suppositories" and then when I went and saw the [GP], and I'm not quite sure what happened, but she prescribed a different type of suppository and the other ones were easier to administer given the shape and I keep thinking I must get, ... when I hand these in, ... I might go "oh, by the way, could I go on to the ones that were prescribed from the hospital?" So, ... and it was actually when I handed in the prescription at the pharmacist I saw the ones I was on and then I got these new ones and I thought "oh, are they the same type of things?" but they're still, ... so something like that would [be good].'

Although patients reported little or no involvement in decisions about choice of medication in the past, few reported this was a problem despite having tried many different medications over time.

E. Managing a relapse

Participants were generally positive about the involvement of pharmacists in helping to manage a relapse particularly where it could result in the expedient access to appropriate medication. Concerns were consistently raised regarding information sharing between the pharmacist, hospital and GP. Some participants reported holding their own supply of oral steroids for relapse management, sometimes with the agreement of their GP:

25 'Because what I have, what I actually do is, I've got a good GP and if I'm going on holiday, I do quite a bit of holidays, and I'm going away for three weeks, I have said to him in the past "would you be able to let me have some prednisolone to take with me?" So I usually have a little supply tucked away.'

Interviewer 'Ok. And is that something that many of you have?'

25 'But if I thought I could just have access to it, at the pharmacy over the road, I wouldn't be so concerned about having my little pot at home.'

Other concerns raised were whether a pharmacist could be expected to have the knowledge and ability to contribute appropriately:

12 'In theory yes, but as [participant 11] said, has mentioned before, have they got time to do this? Because pharmacies are very busy places and would, ... I mean, I've got the IBD but

there's all the other, you know, chronic illnesses that are going about. If it, I mean, ... I'm all for it, yes if there was somebody'

Other concerns were that relapse medication was not always provided in isolation, for example a blood sample might be taken:

24 'Well usually, if I start a flare up I phone the IBD nurse and she prescribes some prednisolone but she always wants a blood test first to see, you know, the extent of the inflammation. Although she does give me the prescription, you know she takes a blood test at the same time so the pharmacies probably wouldn't have that facility would they? Or they wouldn't do that, they'd just ...'

F. Associated healthcare needs

Many participants were not aware of the associated healthcare needs of IBD such as increased risk of depression and osteoporosis. There were few smokers were present and discussion of smoking cessation services targeted at IBD patients received little comment. One participant was particularly interested in the association between smoking and IBD symptoms which made him question his past actions and disease history. Generally, participants were receptive to the idea of pharmacists providing targeted advice and additional services for IBD patients. Some concerns were expressed about whether pharmacists would have the time and the facilities to deliver such services, but the overall response was positive. Participants were, in the main, commenting speculatively as they had no personal experience or in many cases knowledge of the associated health needs with IBD.

For example, many participants reported that they were non-smokers:

11 '... these are all additional things that, yeah, perhaps a pharmacy could get into. Again, I wouldn't be too pleased about having all that with a queue of people behind me, you know?'

Interviewer 'Right, so it's about whether the pharmacies have, a, the facilities but, b, also the time?'

11 'The time, facilities, the privacy, you know, that's quite a lot to ask of a pharmacist, I think, personally, but ...'

12 'Well that, I mean, yes, it's more convenient if you can go along rather than sit going to your doctor and trying to get an appointment ...'

Privacy was consistently raised:

32 'I'd have no objection to that [bone densitometry, being delivered in a community pharmacy], definitely not.'

31 'Once again, I think it would have to be done [in private].'

32 'Yeah, definitely.'

A degree of confidence was also expressed in discussing associated healthcare needs with community pharmacists:

Interviewer 'But you feel you could speak to a pharmacist [about feeling depressed] then?'

21 'Yeah, I'd speak to a pharmacist if I really felt down and I wanted any problems ... or I was really worried about anything, ... I would, yeah.'

4.2.4 Focus groups summary

The focus groups provided useful information, particularly on the boundaries of care which adult IBD patients would find acceptable to receive from a community pharmacy. Due to the small number of groups conducted and overall low numbers of participants no single point is claimed to have reached saturation in terms of thematic analysis. [182] Therefore data from the focus groups by itself is formative only.

Chapter 5: Discussion

5.1 Integrated care pathway

5.1.1 Integration of care and related processes

The pathway was described as an 'integrated care pathway' although the nature of the integration was never explicitly defined.

A number of real and non-physical IBD-care-related boundaries existed within the locality which patients, clinicians, information and funds had to cross. These are broadly categorised and described.

Geographical

Healthcare related to IBD was provided at different sites, locations and buildings. For example, primary care medical practices, hospital outpatient clinics, gastroenterology wards, accident and emergency departments, patient's own homes.

Environmental

There were different facilities available in different locations. In general, more facilities were available in secondary care settings than in primary care settings, for example diagnostic and imaging apparatus was only available within hospital sites. Overnight nursing care was only available to patients who were willing to stay in hospital.

Personnel

Due largely to other factors, specific care locations defined geographically and environmentally, were associated with their own distinct care providers. For example, consultant gastroenterologists and specialist IBD nurses who were employed by the hospital trust were not known to have delivered care within a primary care medical practice.

Informatics

Within the locality there was no shared information source or database that could contribute to the care of IBD patients. The principal information sources relating to IBD patients were distinct between primary and secondary care. Primary care medical records were generally electronic and inaccessible to secondary healthcare personnel. Secondary care medical records were typically paper-based. Information transfer between primary and secondary care was usually by hard copy and clinical information was often transferred only from secondary to primary care and less often in the other direction.

Financial

Primary and specialist healthcare budgets were separately held by distinct statutory organisations. Specialist healthcare providers were essentially customers of primary care-based budget holders.

5.1.1.1 Extent of integration in the IBD pathway

The pathway that was eventually designed for implementation (figure 1) would not result in any change to the locations of where care was delivered (i.e. geographical integration) even though the nature of the care being delivered in primary care in particular would change. Neither would the pathway result in any changes to the facilities or personnel which were available in care locations (i.e. environmental integration). For example, members of the hospital IBD team would not be required to deliver care outside of the hospital.

However, the pathway could, potentially, have had an impact on the financial and informatic boundaries and these are described in-turn.

5.1.1.2 The pathway's effect on the informatic boundary

The informatic boundary is a significant hurdle to integrating care within any healthcare system. Typically, within the NHS, primary care providers hold their own information concerning patients on a single electronic system whereas secondary care holds patient information across multiple providers and in multiple separate systems. A single paper-based file (the 'medical record') is held by the principal secondary care provider. Information generally flows from secondary care providers, often by hard copy, to the patient's nominated primary care provider with less information moving in the opposite direction. [183]

The pathway would help to diminish this boundary primarily through bilateral sharing of annual review information. The pathway was intended to provide for triplicate hard-copy summaries of the previously defined patient annual review. The final specification of the patient review summary is provided in appendix 1. The summary report had been agreed by the project board with significant contributions from all parties. The project management team undertook to arrange printing of triplicate forms with the annotated (top) copy being held by the review provider whether primary or secondary care, the middle copy being sent to the other care party (e.g. if the review was conducted in primary care then the middle copy would be sent to the hospital IBD team, and *vice versa*) and the bottom copy provided to the patient.

An unresolved issue arose which related to reviews carried out in primary care for patients who were not under the care of the participating hospital IBD team. It was not clear whether primary care providers were required to communicate the review to the hospital IBD team or to the patient's current specialist if they were so registered. This presented two issues:

1. The first issue concerned the communication of reviews to the hospital IBD team for patients who were not or never had been under the care of that team. This communication could breach patient confidentiality as well as being of minimal clinical value to the hospital team. The only benefit from the provision of this information to the hospital IBD team was that the patient could be recorded on the IBD database held by the team which could then be expanded to include all IBD patients in the locality regardless of the specialist care provider.
2. The second issue was essentially the reverse of the first and concerned the communication of reviews to a non-locality hospital consultant. Such an individual would not be expecting nor would they be familiar with the review and it could cause confusion to all parties. A partial solution to this particular issue was proposed; the consultant gastroenterologist member of the project board was requested to contact his colleagues at neighbouring hospitals and inform them about the project so that they would not be surprised or confused if they received a review summary from a patient's GP. However these issues, as with several others, were not properly resolved despite being queried again by the clinical champion at the project board meeting in December 2011. It was not confirmed whether the consultant gastroenterologist did contact his colleagues in neighbouring trusts.

In addition to these unresolved issues the project management team, which had undertaken to arrange the printing of triplicate review summaries, did not complete this task for reasons which were not explained by the team or queried by the project board. Instead it was known that at least one practice, and potentially others, had incorporated the summary into their electronic practice systems. The practice appeared to have undertaken this task without support from the project team. Electronic copies of the summary such as this could help practices with record keeping and in accessing the necessary paperwork for the reviews. It could also help with electronic communications where such arrangements were in place although it was not believed that appropriate arrangements were in place with respect to the IBD pathway project.

Due to the immature state of the pathway at the close of the evaluation, there was no opportunity to properly evaluate the information flow between primary and secondary care within the IBD pathway. Anecdotally, the hospital IBD team had reported they had not received any copies of review templates from primary care medical practices and the same team reported that it was not conducting patient reviews according to the agreed template and was not using the agreed summary. It therefore appeared that patient clinical information flow across the primary and secondary care interface was not actually changed by the pathway in its earliest operational phase. The pathway as designed did, however, have some limited potential to integrate informatics across the primary and secondary care interface.

Informatic integration within the IBD pathway project had generated discussion at some of the earlier project board meetings. The earliest idea was presented at the project board meeting of June 2010 and involved making use of the patient-held summary care record, a separate project which developed within the NHS National Programme for Information Technology (NPfIT). [184] However some members of the project board had reported negative experiences with other related components of NPfIT and ultimately the NPfIT summary care record was not delivered within timescales which would have been compatible with the IBD pathway project. The idea was therefore not developed within the IBD pathway project.

A later idea presented at the project board meeting of October 2010 was for the hospital gastroenterology department to serve as a pilot site for an imminent national IBD patient database project which was being supported and promoted by the patient charity. [185] However this idea was presented in the absence of anyone from the hospital and it was not known whether it was ever communicated to them. At the following project board meeting in November 2010 an action was noted for the chief executive of the patient charity (project board member D) to discuss the IBD patient database pilot with the consultant gastroenterologist (project board member B). However both individuals were absent from the meeting and it was not known whether this discussion did take place. It does appear that the hospital did participate in the database pilot to some degree. At the following project board meeting in February 2011 the consultant gastroenterologist (B) was present but did not refer to the database pilot at points in the meeting where this would have been relevant and appropriate. The chief executive of the patient charity (D) was not present at the project board meeting in February 2011. The last project board meeting at which both individuals were present was in September 2010 although there were a number of e-mail communications after this date.

Had these relatively ambitious plans relating to the informatic boundaries been realised within the IBD pathway project they would have been complementary to the IBD Standards. [1]

5.1.1.3 The IBD pathway's effect on the financial boundary

The financial boundary remained in place despite the pathway. A single, shared, IBD-specific budget, which would have represented full financial integration, was not created. Financial considerations were frequently referred to during project board meetings. Primary and secondary care parties were willing to discuss the impact of the pathway, or specific components thereof, on their respective financial positions. Even the chief executive of the patient charity (D), a patient representative and non-NHS party, appeared to have an in-depth understanding of how the pathway could affect an organisation's financial position. On occasion this led him to raise such issues in advance of other board members. One particular example related to the hospital IBD service discharging patients to primary care but being able to readmit patients to the service expediently as defined within the pathway. There was a concern that this would not be counted as a full discharge so that if a patient was readmitted the hospital would be funded at a lower 'follow-up' appointment rate whereas under existing arrangements the admission would often attract a higher 'new patient' appointment. This issue was negotiated relatively easily by all parties with a specific time-point defined after which any subsequent admission or appointment would be paid at the higher rate.

5.1.2 Relation to other integrated care initiatives

During the evaluation, from October 2009 to March 2012, there were some important healthcare policy changes within the English NHS. The most significant resulted from the Government White Paper 'Liberating the NHS' published in 2010 [186] which led to a fundamental change in the organisation of commissioning within the NHS in England. Although this resulted in substantial local upheaval and reorganisation, particularly with respect to primary care commissioning and support, [187] the general policy direction for integrated care, both locally and nationally, remained. [188, 189] One of the most important exponents of integrated care within the NHS, and whose report led directly to the Department of Health integrated care pilots programme, [190] commented that long-term commitment was still needed from the Department of Health to integrate care as well as more exploration of integration between primary care and hospitals (vertical integration). [191] The general healthcare policy direction, of which integrated care in its various guises was a key component, had already persisted for a number years through numerous political changes and health service reorganisations. It is likely that healthcare integration will remain a key policy. Therefore projects and evaluations such as the IBD pathway will continue to have immediate relevance to the English NHS and other health economies.

There is a growing body of evidence relating to the integration of healthcare, accepting the caveats concerning inconsistent and shifting terminology and foci, and crucially the different and often subtle contextual differences. [112, 192] A review of integrated care reported health economic benefits [193] although these depended upon the approach used, how well it was implemented and the environment in which it was introduced, including the financial environment. The conclusion of the Department of Health's integrated care pilots evaluation concurred, whilst also noting that few if any such effects had actually been demonstrated in the first two years of observation. [108] An important aim of the IBD pathway was to deliver cost savings to the local health economy, primarily from reduced hospital admissions and outpatient care. A review of an integrated care project by the Nuffield Trust observed that 'the importance of reducing avoidable hospital costs means it attracts a high degree of policy attention and profile' and '... a target of reducing admissions is often a prerequisite for funding and support [for integrated care projects]'. [194] This was also identified as a key objective in many of the projects included within the Department of Health integrated care pilots programme. [108] As the IBD pathway had only just entered the operational phase at the point of the evaluation close there was no realistic prospect of health economic effects observed over the course of the evaluation being attributed to the pathway. In addition, such outcomes as would impact on rates of healthcare utilisation are recognised to be more likely longer-term outcomes requiring at least two or three years from operation to become apparent. [194] However a rational and objective review of the IBD pathway designed within this project (figure 1) would lead to a reasonable

expectation that it could deliver the reductions in healthcare utilisation expected and the attendant savings.

Reports of integrated care have often identified a diverse range of enabling and disabling, i.e. barrier or inhibitory, attributes to the successful implementation and operation of an assorted range of integrated care models. [187, 192, 195, 196]

In place of specific enabling attributes some reports have instead identified the processes that need to be done or put in place to facilitate successful integrated care initiatives. An example of this was a joint report from the Nuffield Trust and the King’s Fund published in 2011 which identified several points to overcome barriers to integrated care including evaluation of the impact of integrated care. [43]

5.1.2.1 Comparison with the Department of Health integrated care pilots evaluation

The IBD pathway was originally planned for inclusion within the Department of Health integrated care pilots project which commenced in 2009. A comparison is therefore made between the methodology and outcomes of this evaluation with the Department of Health evaluation of the integrated care pilots. [108, 197]

Methodology

The evaluation plan for the IBD Pathway was formulated in isolation of the Department of Health evaluation. Despite this the two evaluation strategies bore more similarities than differences (table 18).

Table 18. Comparison of the evaluations of the Department of Health integrated care pilots and the IBD integrated care pathway

Attribute	IBD Pathway	Department of Health integrated care pilots
Theoretical framework	Realist	Not stated, but general and specific contextual elements were considered
Methodological strategy	Mixed methods	Mixed methods
Duration (planned)	Two years	Two years
Duration (actual)	2½ years	Two years
Focus	Single locality and disease target, health providers only	Sixteen individual integrated care projects across England each being distinct, several included social and community care providers

Even within the broad methodological strategy identified in table 18 there were similarities in the nature of the mixed methods employed. For example, with respect to isolating changes associated with the intervention from contemporaneous background changes both evaluations made use of a differences-in-differences approach. Both evaluations also utilised interviews with key actors and non-participant observation of meetings as components of the qualitative evaluation strategy.

Outcomes

The Department of Health integrated care pilots evaluation was an overarching evaluation of 16 distinct and diverse individual projects. The evaluation primarily reported overall findings as opposed to specific individual project outcomes. The quantitative component of the Department of Health evaluation was more detailed and was able to draw more robust conclusions relating to healthcare utilisation than this evaluation. Of the key outcomes reported in the Department of Health evaluation none could be identified as corresponding to any outcome identified in this evaluation. This may relate more to the differences in the scope of the evaluations (multiple diverse projects vs. single disease-specific project) than any underlying differences in methodology.

Enablers and Barriers

The Department of Health integrated care pilots evaluation team described the barriers and enablers to integrating care that were identified across the evaluation. [197] A summary of these is described in table 19 [108] and a full description is provided in appendix 14. [197]

Many of these enablers and barriers are common to the field of change management, some are specific to the healthcare field, some may be specific to the NHS structure and culture, but many are specific to the contemporaneous implementation of integrated healthcare in England. Those indicated with an asterisk (table 19) were also identified, either explicitly or indirectly, within this evaluation.

Of the barriers identified as common to the IBD Pathway project some were inherent in the design of the project (e.g. multiple partners), others were foreseen but unsuccessfully overcome (e.g. IT solutions and information sharing), others were unrecognised (e.g. organisational culture, sub-optimal training), and others had not been foreseen and arose incidentally (e.g. concurrent internal reorganisations). With respect to unforeseen incidental barriers the response of the project team was sub-optimal. Better project management, which was itself impaired by the organisational culture, may have meant that barriers could have been identified and successfully mitigated or managed. Sub-optimal project management was not identified as a barrier in the Department of Health evaluation although notably the included projects each received external project management support. [198]

The Department of Health evaluation identified many enablers and barriers across the overall evaluation (table 19 and appendix 14) although it did describe the manner in which individual projects sought to manage barriers either prospectively or reactively.

Table 19. Enablers and barriers to integrating care identified in the integrated care pilots [108]

Enablers	Barriers
Strong leadership	Large-scale, complex integrations
Pre-existing relationships at a personal level across organisations *	Roles or professional identity of staff under threat
Shared values; collective communicated vision *	Changes to staff employment involving TUPE (Transfer of Undertakings Protection of Employment) regulations
Investment of effort in widespread staff engagement; staff can see clear benefits	Unrelated organisational changes; unexpected budgetary changes *
Provision of education and training specific to service change *	National policies, processes and legislation; NHS and local government bureaucracy (e.g. pooling budgets)
	Poor IT connectivity between systems and organisations *

The Department of Health evaluation may have been expected to identify more enablers and barriers to integrated care than were identified in this evaluation as it was the sum of findings from 16 different and diverse integrated care projects.

5.1.2.2 The North West London Integrated Care Pilot

A widely reported contemporaneous project which had a number of similarities with the IBD Pathway project was the North West London Integrated Care Pilot. [199] Although similar in some respects a key difference was a broader remit, focusing not only on a single long-term condition (diabetes) but additionally and more broadly all patients aged 75 years or more. The project also included mental health, social and community care providers as well as primary and acute (secondary) care. Nonetheless, there were more similarities between them as the London project also focused on a single locality and the evaluation utilised a similar methodological approach. For example, it was a mixed-methods evaluation albeit initially over just the first 12 months with a less intensive longer-term evaluation. The evaluation included quantitative analyses of healthcare utilisation across a specific and identifiable patient cohort, as well as qualitative analyses which included observations and interviews. [200]

Despite initial results reporting reductions in hospital admissions, from which substantial financial savings were estimated, [201] more robust subsequent reports of the first 12 months did not report the same findings. [200, 202] No significant overall effect on emergency (unplanned) admissions was observed. [199] However the project did result in modest improvements in care processes such as provision of care plans for patients with dementia, as well as improved patient access and reduced waiting times for care. [199, 202] Some limited improvements in clinical parameters were also beginning to emerge, for example measures of blood glucose levels in diabetic patients. Less tangible but no less important positive outcomes were achieved relating to the process of integrating care. For example, communication with and between various healthcare professionals improved, as well as partial solutions to shared governance and finance arrangements. Several tensions and hurdles were overcome and clinicians were generally committed to the project. A particular barrier which had not been overcome was that relating to sharing clinical information via a single information technology platform. Not only had this not been delivered but it created and failed to resolve the various tensions and consequent barriers relating to its continued absence. One-year evaluations concluded that positive progress had been made but that “a minimum of three to five years is needed for such initiatives to show impact in relation to activity, patient experience and outcomes”. [199, 202]

Given that such a timeframe was stated as the minimum required to demonstrate an impact on healthcare activity it was not clear why the project had initially planned to deliver substantial financial savings in its first year relating directly to reduced healthcare utilisation. It concluded that “policy-makers and National Health Service managers expect too much too soon when testing initiatives”. [199]

5.1.3 Middle range theory

Middle range theory was described by Pawson & Tilley in their seminal 1997 text as: [63]

‘ ... “theory that lies between the minor but necessary working hypotheses ...and the all-inclusive systematic efforts to develop a unified theory that will explain all the observed uniformities of social behavior, social organization and social change” (Merton, 1968). In essence, “middle range” refers to the degree of abstraction and can refer to programme theory, generative mechanisms, CMOs, formal theories etc.’

Thus this evaluation can seek to identify and empirically establish the existence of the specific theories, the middle range theories, and the highly abstract and generalisable theories. [203] The former were taken to be the enabling and disabling factors which are reported in this section, the middle range theories are intricately and necessarily linked to these, and the latter is taken to be the theories of change. The theories of change identified are each considered separately in subsequent sections. A middle range theory is derived from the enabling and disabling factors.

5.1.3.1 Balance between enabling & disabling factors

There was, and will likely remain, an on-going tension between enabling and disabling (barrier) factors faced by the IBD pathway. The net effect of this tension will be a dynamic balance which will vary at different stages of the project and therefore at different points of time, i.e. at times the enabling factors will dominate and at other times the disabling factors will dominate. The enablers and barriers which affected the IBD pathway project and which were identified by the close of the evaluation were:

5.1.3.2 Enablers identified in the IBD Pathway project

- Motives and aims aligned with local and national healthcare policies and priorities
- Utilisation of pre-existing communication networks and relevant partnerships
- Financial incentives for primary care providers
- Credible and legitimate patient / user representation and involvement
- Sponsorship from a commercial party for a defined component of the project

5.1.3.2 Barriers identified in the IBD Pathway project

- Lack of consistent and effective strategic leadership
- Initially at least, sub-optimal project management
- Delayed introduction of effective and nominated clinical leadership
- Lack of effective communication strategy including sub-optimal clinician education and training
- Absence of effective communication and data sharing tools

- Lack of a defined role for patient / user representatives

The enabling factors were predominantly of a generative nature, i.e. they exerted their influence more in the initial phases at the commencement of the project; they enabled the project to commence although some will have had a longer-term impact on the project, such as third-party sponsorship and use of networks and partnerships.

At the point of closure of the evaluation the project was still active and delivering some planned components to variable degrees which indicate that the overall balance at that point was in favour of the enabling factors. The barriers had either been accommodated or overcome. The accommodation of disabling factors would appear to add significant delays to the expected or planned progress of the project.

The key enablers and barriers which influenced the IBD Pathway project and which have been identified were themselves composed of a number of different components which have been described in more detail elsewhere. These specific, descriptive, and granular enablers and barriers can be considered as the middle range theories identified by the evaluation of the IBD Pathway.

The middle range theory identified within this evaluation of the IBD pathway is summarised singularly and succinctly as:

The progress of change for a specific component of care within a large and complex healthcare system is determined by the sum effect of multiple enabling and inhibitory factors.

The enabling and inhibitory factors may exist internally, or be external to the change process. The overall balance of factors will be dynamic and some specific factors will be only transitory in nature. Therefore the future progress of the project cannot be easily predicted from its' position at a single point in time.

5.1.4 Theories of change

Using the perspective of Weiss, [204] it was assumed that several theories of change implicitly existed within the IBD pathway project, although some were more subtle than others. As stated by Stame, theories of change in social programmes such as the IBD project are seldom explicit or formally stated. [88] Instead they more often take the form of assumptions and tacit understandings, often for the same theories within the same programme. The theories are themselves linked to certain practical mechanisms which will potentially deliver the intended outcomes. [205]

The theory of project management was identified with explicit evidence of its existence within the project. Two other theories of change were identified implicitly within the pathway which was itself the outcome of the pathway design phase; those of patient empowerment and clinician empowerment. These also manifested themselves as a component of the pathway design process although to a lesser degree than their presence as a component of the designed pathway. Thus, three theories (project management, patient empowerment, and clinician empowerment) were identified within the IBD pathway project and each is described in turn. This list may not be exhaustive although every effort has been made to identify all the theories of change which existed within the project.

The contextual attributes which enabled or inhibited the observed outcomes were primarily design- and implementation-phase related outcomes. At the point of the evaluation close the project was probably too immature to have demonstrated the desired operational outcomes especially regarding hospital admissions and other measures of healthcare utilisation, and attendant costs. This is reflected in the CMO configurations presented in the following sections. The literature on complex health service change generally concurs that anything less than two years, and often more, is too short a period of time in which to observe meaningful changes in healthcare utilisation and other quantifiable outcomes relating to complex interventions such as new models of integrated care.[194, 197] With respect to the evaluation of such projects, the Nuffield Trust concluded in its evaluation of integrated care that 'A pilot may work partially and learning from that partial success is important. Or it may be, of course, that the beneficial outcomes were not measured or were measured too early.' [194] This evaluation has identified what has worked (enablers) and has not worked (barriers, inhibitors) within the IBD pathway project and has sought to identify and explain these. Their expression in the realist paradigm framed as Context-Mechanism-Outcome scenarios is thus presented.

5.1.4.1 Project management

The project management literature appears to be predominantly concerned with methods and processes and comparatively little was identified concerning the underlying theories of project management. Two reports that highlighted this point suggested that project management theory should be broken down into the combination of separate theories of 'project' and 'management' with the latter consisting of sub-theories relating to specific elements of management. [206, 207] However, this perspective appears unnecessarily complicated and relies upon some abstract concepts of project management. The theory of project management could be considered more simply and succinctly as: Projects are more likely to succeed on time and more efficiently if they are managed according to a defined and structured process than if they are managed on a less structured and somewhat *ad hoc* basis. This is the theory which was implicit within the IBD

pathway project and it is this theory which was essentially tested in the context of the PRINCE2 project management processes.

Project management theory was a constant presence throughout the evaluation as it permeated all phases. Key components of PRINCE2 that would have been particularly applicable to the IBD project were: [175]

- Constitution of a project board with defined membership
- Nomination of a project manager and if necessary other members of the project team
- Proper recording of project board activities with minutes of meetings
- Proper and advanced scheduling of project board meetings
- Production of a project plan with identification of deliverables alongside deadlines and nominated individuals or teams for each deliverable
- A defined mechanism for reporting exceptions and changes to the project board

The pathway design process was largely conducted through, and during, project board meetings. The project board was not formally constituted nor was it officially nominated as such, instead it grew and developed organically into the project board role. The project board consisted of a core membership supplemented by occasional other members or participants.

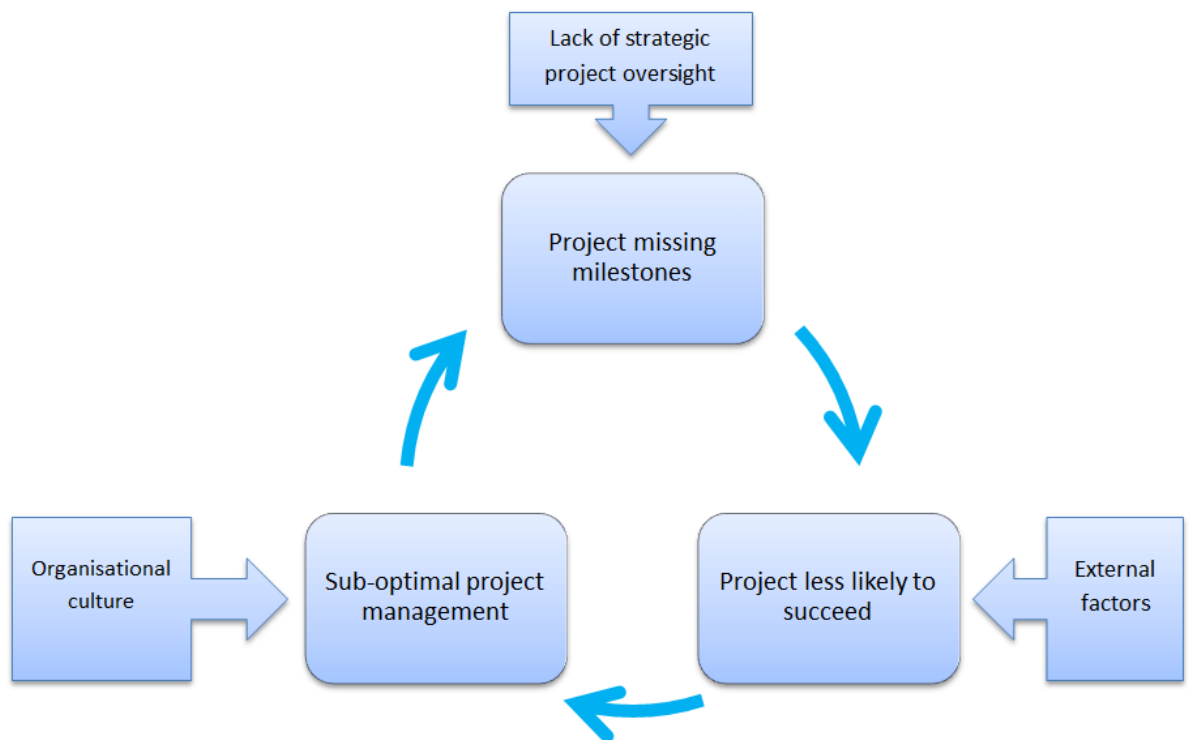
With respect to chairing project board meetings only, a senior individual from the host or sponsor organisation (the PCT) could have been a good choice for several reasons:

- Maintaining a focus on the strategic aims of the project, particularly with respect to its relationship with a contemporaneous local healthcare project.
- Providing greater external and internal credibility and lending a gravitas to the project.
- Ensuring that the project was managed according to best practice given the PCT's commitment to PRINCE2 methodology.

In addition to a lack of leadership at project board meetings, meetings also tended to be poorly organised, especially in the first half of the evaluation. Meetings often lacked agenda, minutes, or actions. This was, unfortunately, not an inadvertent oversight. As early as the fourth project board meeting in March 2010 the project manager declared to the board that he did not intend to organise meetings formally by, for example, taking minutes but instead he preferred to allow meetings to flow and only make a note of the actions required. No one disagreed with or contested this arrangement. That the IBD pathway project was managed sub-optimally has been objectively demonstrated with reference to the pre-defined project management methodology that was to have been applied to the project. The Department of Health integrated care pilots had structured professional project management support and it is noteworthy that poor or sub-optimal project management was not identified as an issue with its evaluation. [108, 197]

It is hypothesised that a vicious circle may have been in existence in respect to the project management aspect of the IBD Pathway (figure 4). Essentially, sub-optimal project management would lead to the project being less likely to succeed and this would in turn, through missed milestones and slipping deadlines, reinforce the decision to manage the project sub-optimally. This hypothesis remains untested and is presented as a possible explanatory hypothesis. It is postulated that factors outside of the vicious circle may also reinforce each factor within the cycle independently.

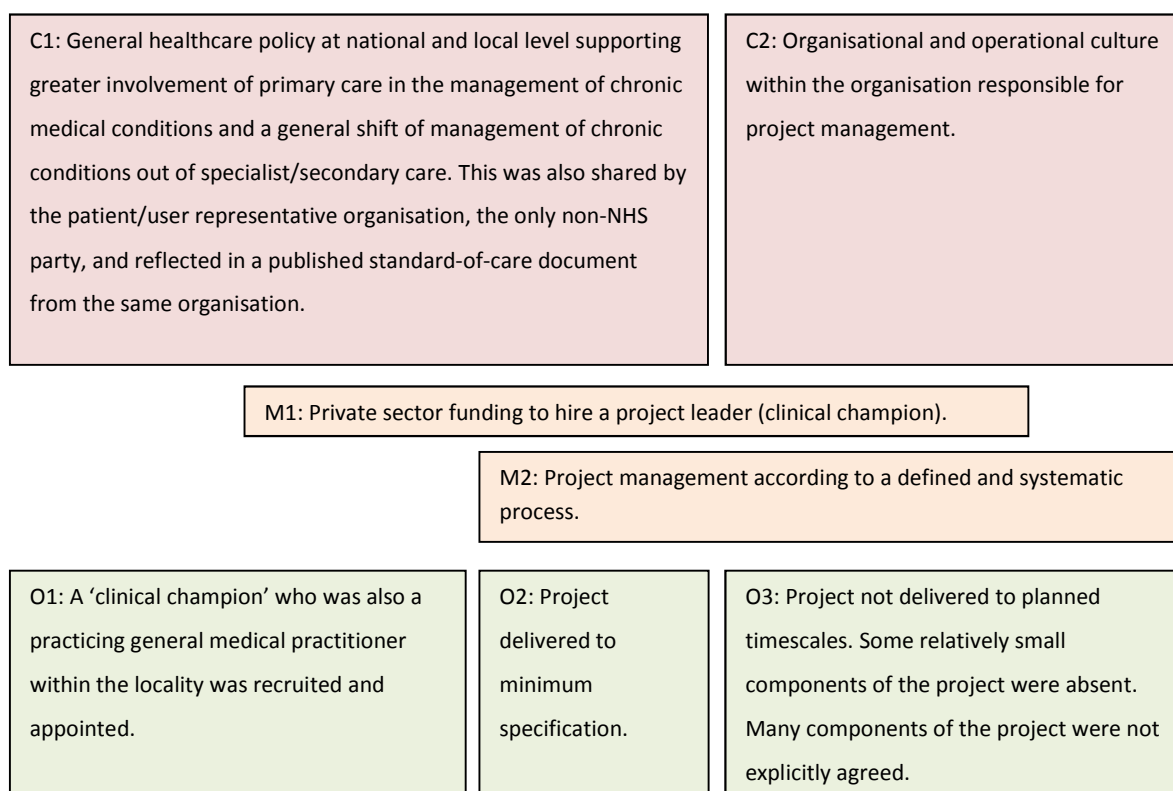
Figure 4. The hypothesised vicious circle of sub-optimal project management



Context-Mechanism-Outcome configurations relating to project management

Four unique CMO configurations were identified through a repeated and iterative process (figure 5). A relatively high level of abstraction has been incorporated into the resulting configurations although a more granular level of detail is provided concerning each configuration separately. In total two contextual factors, two mechanisms and three outcomes were elucidated.

Figure 5. CMO configurations relating to project management within the IBD pathway



Red boxes are contextual factors, orange are mechanisms and outcomes are in green. The four configurations are: (C1+M1 = O1), (C1+M2 = O2), (C2+M1 = O3), and (C2+M2 = O3).

C1 was a generative and motivational contextual factor which led to the project being created and led to positive outcomes. C2 was an inhibitive context which led to a negative outcome. O1 and O2 were positive outcomes, O3 was a negative outcome. O3 was only generated when combined with C2. O1 and O2 were only generated when combined with C1. The mechanisms yielded positive and negative outcomes depending on the contextual factors which they were subjected to, thus the same mechanism could have different outcomes depending on the context and this is an important message for the generalisability of this and similar research.

Each 'C' and 'O' component of the CMO configurations and their combinations are described in turn.

C1: For multiple reasons, it has long been governmental and health department policy in the NHS and many other health systems in other countries, for chronic or long-term conditions to be managed less in acute settings by specialists, such as hospital-based consultants, and more in primary and community care settings. [130, 178, 179] These policies were in turn reflected in the local Momentum project [59] and the IBD Standards. [1] It was this general policy environment, shared by all parties, which led to the creation of the project and provided the strategic motivation and remit for the project to continue.

C2: The organisational and operational culture of the project management organisation, the PCT, did not appear to have been conducive to permitting effective project management or at least not to the defined standard. This was a negative contextual influence which inhibited the progress of the project. It was exemplified through several observable aspects:

- Lack of leadership and contributions from senior operational management
- Unsystematic and untargeted selection of project management team
- Lack of robust governance and supervision of the project management team
- Lack of strategic resource planning for the project management team

Due primarily to a combination of the above points, less tangible cultural inhibitors were identified through observation and supported through interview data. Specifically, the strategic aims of the project and the objectives appeared to be disconnected from the project management team, or vice versa.

The project management team appeared to approach the project as another task that had to be completed and had to be fitted into their flexible and variable daily workload. In that respect, they did not appear to have subscribed to what the project was trying to achieve, the strategic aims of the project, and saw each outcome as a task in its own right as opposed to an interconnected series of tasks which were intended to operate synergistically towards a defined set of complementary objectives.

A rational approach for a project team to take is not to commit full effort to a project until it can be certain that the project will succeed or survive. This logical and rational decision can be described by game theory and the project management team is in effect applying a 'maximin' strategy. [208] Using this strategy the team was attempting to maximise the minimum outcome achievable. The choices which the team could make were either to apply full effort to the project from the outset, or commit only the minimum effort which the organisation would permit the team to commit. This can be described with a payoff matrix (figure 6). [208] The scores assigned to each outcome-combination in figure 6 are arbitrary and essentially represent a ranked position. The matrix demonstrates that the best outcome would be for the project to survive with

minimum effort from the team. The worst outcome would be for the project not to survive despite the team committing full effort. The matrix is valid until such time that the project team can identify whether the project will survive or not, at which point the team is assumed to commit full effort. Regardless of the effort committed by the project management team, project survival is a positive outcome and the non-survival of a project is a negative outcome for the team.

If the project team committed full effort from the outset, without knowledge as to whether the project will survive or not, the net expected payoff is -1. However if the team committed minimum effort the net expected payoff is +1. The rational strategy is therefore to commit minimum effort, at least until the team can identify whether a project will survive or not.

Figure 6. Payoff matrix for a project management team with imperfect information concerning project survival (ranked scores)

Project outcome → Project team approach ↓	Survive	Not survive	Net expected payoff
Full effort	1	- 2	- 1
Minimum effort	2	- 1	1

Project management teams may not operate in total informational ignorance as the payoff matrix may be affected by some knowledge or experience of the underlying risks, or probabilities, of each project outcome. For example, if a project management team has experience of greater probability of project non-survival then the team will be more likely to choose the minimum effort strategy as this will maximise the expected minimum payoff. The opposite, however, is not necessarily true because even if experience demonstrated that project survival is the dominant outcome, a team might still opt for minimum effort as the maximum outcome is preferred to that with the full effort strategy. This indicates that the rational strategy under different conditions could still be 'minimum effort'. Therefore project management teams may require external constraints to abandon a minimum effort strategy for a full effort strategy. This is particularly important because there may be a negative feedback mechanism between the efforts committed by a team and the probability of a project outcome; survive or not survive. In essence, the simple payoff matrix in figure 6 does not show a potential negative feedback between the survival of a project and the effort from the project management team, i.e. the two attributes are not independent and a project may be more likely to survive if the team commit full effort, and less likely to survive if the team commit only minimum effort.

An in-depth analysis of game theory and an attempt to prove its applicability to this situation is not attempted. Instead, it is presented as a hypothesis to explain why a well remunerated, resourced, externally credible and experienced project management team opted to work sub-optimally. Other attributes which have not been explicitly considered within the payoff matrix are; internal motivation (e.g. self-motivation from individual project team members, pride in own work), individual recognition within a larger team or organisation, the length of time required to determine whether a project is successful or not, and other factors.

It is postulated here that an organisational or operational culture within the project management organisation, the PCT, permitted, enabled, or encouraged the project management team to select the minimum effort strategy for project management. This was contrary to external commitments made by the same organisation.

Another aspect of the organisational culture which impacted negatively upon the project was in relation to the receipt of funds from a commercial party where a potential conflict of interest existed with respect to local NHS business. Despite extensive guidance for the NHS from the Department of Health concerning such arrangements, [209] the PCT appeared to be in a state of bureaucratic paralysis. The organisation did not respond swiftly or decisively to expediently resolve what was a relatively straight-forward issue. Knowledge of the availability of ex-NHS funding for the project existed at an early stage, for example detailed discussion ensued at the 4th project board meeting in March 2010. Even at this meeting contractual and financial arrangements were raised as a potential issue although they were not discussed in detail. Another risk which was included in the project plan was if the funding source either did not deliver the funds at all, or withdrew the funding at a later point. The solution to this risk was stated 'approach other sources for funding'. In the final project plan update of October 2010 the plan stated that the funding had been confirmed and the only outstanding issue was 'Still awaiting approval of sponsorship'. The new project management team reported at their first project board meeting in February 2011 that the issues had been resolved although this had taken almost 12 months. The precise nature or details of the issues were not explicitly stated; one issue related to the organisation being required to agree a contract which would outlast its own existence. Details were not reported by the project management team concerning how the issues were resolved.

M1: This mechanism represents the availability of a source of private funding specifically to recruit a project leader, known within the project as the 'clinical champion'.

M2: The second mechanism presented represents the approach of the project management team in using a defined and systematic project management process, specifically PRINCE2.

Outcomes 1, 2 and 3 are described in the context of the contextual attributes and mechanisms which produced them.

C1+M1 = O1 and C2+M1 = O3

These CMO configurations are related to the recruitment of a 'clinical champion' for the project. The role of clinical champion was discussed at a relatively advanced level at the second project board meeting in March 2010. At the 13th project board meeting in December 2011 the board was introduced to the clinical champion. That a clinical champion was successfully recruited and appointed was a significant achievement of the project (labelled as outcome 1). The major enabler to that achievement was considered to have been the provision of non-NHS funding, labelled as mechanism number 1. It was not clear whether such a post could have been filled without that funding, either through voluntary participation or from another funding source. It was highly unlikely that the post could have been filled through voluntary participation alone given the pressures on GP time and resources, especially as any GP undertaking the post during normal working hours would likely put pressure on colleagues. It was also unlikely that the post could have been funded using other NHS funds, e.g. from funds allocated to the practice-based commissioning group, as the amount of funding secured, approximately £15,000, would have represented a substantial investment for an unproven and non-essential role. If the post had been filled through voluntary participation or NHS funding then it may not have permitted the level of commitment secured with the private funding which equated to about one day per fortnight.

Although an individual was appointed, this only occurred after a substantial time-lag in excess of 12 months. The main reason for this delay, as explained repeatedly at project board meetings, was reported to be external to the project board; the PCT finance department was reluctant to accept and agree non-NHS funding for a post which would be arranged and contracted through the PCT. These issues were presented as being bureaucratic and engendered disparaging responses from the project management team when reported at project board meetings. However, the real extent of this issue was not clear. An alternative interpretation was that this issue may have served as a convenient distraction and deflected attention from the project team's own inactivity and overall lack of progress with the project. The continued delay to appointing a clinical champion was a repeated frustration to members of the project board and was frequently cited as a negative aspect of the project process during interviews. It is impossible to confirm the impact that this delay had on the project as there was no counter-factual scenario or control group. However, the project clearly lacked leadership for a prolonged period and would likely have benefitted from a recognised primary care clinical lead without a history of having been contracted to work for the PCT. The clinical champion would have been ideally suited to fulfil such a role. The delay to recruitment of a clinical champion was a negative attribute of the project management process and earlier recruitment could reasonably have been expected to

have had a positive effect on the project. The only advantage to the delay to recruitment of the clinical champion was that there would be a corresponding delay to the date at which the funding, available for two years from the date of appointment, expired.

C1+M2 = O2

The positive generative policy context which promoted the general aims of the project (C1) combined with a systematic and active approach to project management, however suboptimal (M2), did produce a pathway design which could be described as having met the minimum requirements of all parties (O3). The minimum requirements of each party can only be inferred from observations and notes as the project did not have any agreed aims or objectives. The pathway did not contradict any of the IBD Standards and would directly and indirectly contribute to local attainment of many of the standards. [1]

C2+M2 = O3

This was the most fundamental CMO configuration underpinning the progress of the project. Essentially, a project of this scope and scale was intended to have been managed according to a recognised and approved project management methodology, that of PRINCE2 (labelled as M2). However, the actual project management strategy employed could not be recognised as PRINCE2 and appeared at times to be haphazard, reactive and generally disorganised. For example several of the early meetings had no agenda or minutes of previous meetings. Actions were infrequently noted and even less frequently followed up, and consequently several actions were never completed or completed substantially behind schedule. There was a noticeable shift in project management style when the new project management team took over in January 2011. This change in project management style was particularly noticeable in the management of project board meetings with more advance notice of meeting arrangements, agenda provided, and minutes/actions noted. In addition, the new project management team progressed rapidly with organising the first training event and, somewhat slower, in recruiting a 'clinical champion'. However the fundamentals of PRINCE2 project management such as a project initiation document, overall project plan, and a formally defined project management board, had already been omitted from the outset and these would be difficult to retrospectively apply at the point at which the new project management team took over. In addition, the lack of a project plan, action plan, minutes and other essential project records meant that the new project team experienced difficulties in taking the project forward. The new project management team was even less purposefully appointed to the project than the first team.

Project teams were faced with a predicament in identifying projects which will survive and those which will not, possibly due to external factors beyond the project team's control. Of all the projects which a team, or team members individually, are involved with some will not survive for

reasons beyond the project team's control; i.e. even with optimal project management, for example full application of PRINCE2 methodology by the project team, some projects will 'fail'. The predicament therefore is in identifying at the outset which projects will survive and which won't. There is a considerable trade-off for teams and individuals as applying the effort required for full or even extensive application of PRINCE2 will be more time consuming than not, at least in the early stages of a project, and yet the result could be the same – a failed or uncompleted project. Therefore the project team collectively, or its members individually, must decide on the resources that they will, collectively or individually, put into a project. A rational strategy under certain circumstances is to apply minimum effort to a project until it becomes clear whether the project will survive. Once a team is able to identify, or feels confident that, a project will survive then it is assumed that the team will commit greater or even full effort to the project. If the project, however, does not survive then the team or its individual members have, in retrospect, chosen the optimum strategy from the outset. These are rational decisions in the context of a resource constrained and strained environment, i.e. the organisation is required to deliver more projects than it can actually deliver if all work was to be completed at optimum levels. Such a strategy can lead to a self-fulfilling vicious circle developing in which sub-optimal project management from the outset can itself make a project more likely to fail thereby justifying the decision to apply sub-optimal resources to a project. Projects which do survive will then share characteristics which can become the norm, such as sub-optimal project management, and weak governance and leadership. This was observed in the IBD pathway project but it is not known whether other projects managed by the same organisation shared such attributes. Optimal project management does not necessarily mean that a project will survive but a project which is managed sub-optimally is more likely to experience:

- Products, or project milestones, which are delayed, or otherwise delivered behind schedule.
- A project delivered to a lesser specification than that desired including the abandonment of specific components or products.
- A project which exceeds its budget or fails to achieve budgetary milestones.

One mechanism by which PCT senior management could have better overseen the project was with a substantive role on the project board such as chairing project board meetings. This may also have had an impact on the project team as they would be more closely observed by their senior managers. For example, an individual from the PCT board of directors such as the Director for Health Systems Development and Estates Development, who had been involved with the original integrated care pilots bid, was named as a core member of the Momentum programme team [59] and was a direct line manager to the project team, would have been an appropriate

candidate. However securing the commitment of such a senior individual may have been difficult and may not by itself have been sufficient to ensure optimal project management throughout.

A key feature resulting from the sub-optimal project management was that there was no single statement of the aims or objectives of the project or any specific part of it. This was demonstrated by none of the project board members or project team being able to succinctly and consistently describe the aims and objectives of the IBD pathway project.

The PCT appeared to struggle with the duplicate role of performing the project management function and providing strategic in-put with the latter role more severely affected. The two roles were not entirely complementary; that of a project overseer and decision maker, as given collectively and individually to members of the project board, and that of project 'doer' and delivery, as given to the project team. Conflict may arise where the same individuals are called upon to perform both tasks. Both project managers (project board members H and I) dealt with this dual role in a similar manner albeit to differing degrees. Both tended to favour the decision-maker role to the detriment of the project management function. Both sought to obtain a third party to carry out the day-to-day project management functions; for the first project manager this came with the temporary assistance of two 'organisational development managers' between September 2010 and January 2011 (J and K), and for the second project manager such an individual was already in place (L). The conflict between the decision-maker and project management function may have led to or contributed to suboptimal project management as described under CMO configuration 1 and can be considered as an effect stemming from a lack of leadership or senior level input from the project management organisation.

5.1.4.2 Patient empowerment

Four unique CMO configurations relating to the theory of patient empowerment were identified. These involve one contextual factor and three distinct mechanisms (figure 7). Data relating to two sets of outcomes, affecting two CMO configurations, were not obtained within the evaluation and therefore these CMO configurations have been identified but have not been evaluated. Each 'C' and 'O' is described in-turn as well as the resultant CMO configurations relating to the theory of patient empowerment.

C: The context within which the theory of patient empowerment existed was one of a general policy shift within the NHS nationally for greater influence and power for patients with respect to individual cases and also service developments. [47] This policy direction was reflected in the local Momentum programme and by extension the PCT and hospital trust partners who owned the programme. In addition, the policy was reflected and strongly supported by the patient organisation as embodied in the IBD Standards which the organisation had published with other parties. Thus, the theory of patient empowerment was enabled by a long history of top-down policies devised specifically to realise the theoretical benefits of empowered patients. All parties of the IBD pathway project were supportive of these policies. This was a positive contextual factor which enabled and promoted patient empowerment within the project.

M1: The first mechanism by which patients were empowered was reflected in the representation of patients or service users within the pathway design process and in the resulting pathway design. This mechanism, when combined with the contextual background, yielded two groups of observable outcomes, one set relating to the design process and one set relating to the pathway as was designed.

M2: The second mechanism by which patients were empowered was reflected by the provision of information to patients, with the majority of the defined sources originating from the patient organisation or other patient organisations. This latter aspect further reinforced the involvement of patients and patient representatives within the pathway. Outcomes associated with this mechanism, whilst observable in the pathway design (figure 1), have not been evaluated.

M3: The third mechanism was that of patient choice and the actual extent to which patients could exercise choice within the pathway design. As with the second mechanism, this mechanism was observable in the pathway design (figure 1) and associated pathway descriptions but could not be evaluated due to the limited operation of the pathway.

Figure 7. Context-mechanism-outcome configurations relating to the theory of patient empowerment within the IBD pathway project



As previously, red boxes represent contextual factors, orange represent mechanisms and outcomes are in green. However, dark green boxes represent outcomes which have not been evaluated within this evaluation.

C + M1 = O1

User representation within the pathway design process was extensive. Patient representatives constituted a considerable proportion of the project board and contributed significantly to board meetings and project events. There was further representation directly from actual local patients via the patient panel although this did not operate optimally.

C + M1 = O2

The designed pathway would deliver, fully or partially, twelve of the IBD Standards, six of which related entirely or principally to patient empowerment, each described in turn.

IBD Standard C1. Information on the IBD service

All IBD patients should have information describing the IBD Service and how it can be accessed. This should include information on how patients who have concerns about their condition or their care can request discussion of their case at the IBD Team meeting or request a second opinion. It should also explain how patients can give feedback on the care they receive or participate actively in service development.

The pathway did stipulate that all patients under the care of the hospital IBD team including newly diagnosed patients should be provided with a leaflet describing the hospital IBD service. A draft leaflet was produced and discussed by the patient panel. A final version of the leaflet was never presented to the project board and it is not believed that any such leaflet is available within the pathway.

IBD Standard C2. Rapid access to specialist advice

There should be a clear process for patients to obtain access to specialist advice and support from a named specialist nurse/ stomatherapist by the end of the next working day. Ideally there should be a choice of telephone and email contact.

The pathway did provide patients with direct communication with the hospital IBD team via a telephone helpline and a dedicated e-mail account. The pathway did not provide for direct patient access to a stomatherapist. The pathway did not stipulate a deadline by which e-mails and telephone calls would be answered.

IBD Standard C4. Supporting patients to exercise choice between care strategies for outpatient management

Patients may prefer continuing hospital management, shared care with their GP or supported self-management and they may wish to choose a different option at different stages in their illness. The appropriate administrative and clinical infrastructure must be in place to support these different strategies and patients should have written information,

preferably a care plan, explaining clearly what arrangements have been agreed with them for their care.

Within certain limits, the pathway permitted patients to exert a degree of choice concerning the management of their condition. The pathway did not make specific arrangements or reference to administrative and clinical infrastructure to support different care strategies. Primary care clinicians were required to undertake specific education and training to be able to participate in the pathway and therefore receive and manage patients who might opt to be managed in primary care. A care plan was not included in the pathway despite being discussed on several occasions by the project board.

IBD Standard C5. Involvement of patients in service improvement

Patients should have a voice in the development of the IBD Service. The service must be able to demonstrate that mechanisms are in place to obtain and respond to patient feedback about their IBD Service and to provide opportunities for more direct involvement.

Patients were represented on the project board by three members from the same patient organisation, although none of the individuals were themselves IBD patients and none lived in the locality. A patient panel was convened on three occasions and all members were local IBD patients and believed to be residents of the locality. No specific mechanisms for patients to provide feedback or to provide other modes of involvement with the IBD service were addressed by the pathway.

IBD Standard D1. Provision of information

All patients must be offered appropriate information about their care, treatment options and condition at all stages of their illness. Information should be appropriate to the age, understanding and communication needs of the patient and carers.

This point is assumed to refer to verbal communications which were not specifically addressed by the IBD pathway.

Written information about IBD in straightforward English should be provided in outpatient clinics, ward, and endoscopy areas.

The pathway defined specific information products which were provided by the patient organisation and also defined the points in the pathway and patient journey at which these products would be provided. The IBD Pathway was only for adult patients and all information products, both draft and complete, appeared to be appropriate for adult patients. The external

information products from the patient organisation had been validated by them for adult patients.

Information should be available in languages other than English where the catchment population requires this.

Standard D1 was not specifically addressed by the pathway. Some of the information products from the patient organisation were available in numerous other languages.

Communications relating to informed consent should be written in clear, straightforward language and staff should ensure they are understood by the patient before signing.

This was not specifically addressed by the pathway.

Patients being considered for surgery, especially pouch surgery or ileostomy, should be offered written and/or audiovisual information, and where possible the option to talk with patients who have had pouch surgery or a permanent ileostomy. They should also be provided with information about their post-operative care, including histology.

This was not specifically addressed by the pathway.

Information should be provided to all inpatients about their care following discharge and the arrangements for follow up.

Provision was made within the final pathway design to ensure that patients under the care of the hospital IBD team were provided with information concerning the IBD service. However, although draft versions of a hospital service patient information leaflet were produced, a final version was not ready by the point of the evaluation close. The leaflet was intended to address the necessary points.

IBD Standard D3. Information about patient organisations

All patients should be provided with contact information for the relevant patient organisations.

This standard was specifically addressed by the pathway although attainment was incomplete. The pathway specifically defined that information from the patient organisation was provided to newly diagnosed patients and this also included a voucher which patients could use to claim a free membership of the organisation for the first year. The draft hospital IBD service leaflet also provided contact information for the patient organisation. Other information products from the patient organisation would contain contact details for the patient organisation.

C + M2 = O3

This configuration relates to an outcome-based evaluation, both quantitative and qualitative, of the various ways in which the pathway could be expected to deliver patient empowerment. It should be noted that, due to the relatively immature state of the pathway at the evaluation close, none of these specific outcomes were evaluated and are instead stated here to support a future evaluation of the pathway. Useful and informative outcomes could include:

- The take up rate by newly diagnosed patients of the offer of free membership for one year of a specific patient organisation. For completeness, the evaluation should also include a measure of the number of vouchers provided or distributed against a baseline of the number of opportunities for provision of the vouchers. A descriptive analysis of the voucher distribution process should also be included particularly as late-emergent anecdotal evidence suggested that the distribution process had evolved in a manner which was not foreseen or intended by the patient organisation.
- A quantitative and descriptive evaluation of the provision of patient information to newly diagnosed patients as specified by the pathway design. The evaluation should include temporal measures relating to the sequential appointment at which information was provided (e.g. first vs. second appointment, etc.) and the overall time from confirmed diagnosis. A similar analysis should be conducted regarding the provision of information to patients about the hospital IBD service where this is specified in the pathway.
- Importantly, an evaluation should include the qualitative views of patients concerning the various service and disease information products provided within the pathway. Ideally, such an evaluation would address the appropriateness of the point at which the information was provided in the patient's disease journey, as well as the scope and content of the information and factors relating to its source and the manner in which it was provided. It would be useful if a qualitative evaluation could inform improvements to any aspect of provision of information to patients.

C + M3 = O4

A crucial element of empowering patients is in the expression of patient choice and the pathway did make explicit provision for patients to exercise choice within the pathway. This CMO configuration relates to obtaining outcomes from the contextual background and the collective patient choice mechanisms within the background. However, as with the previous CMO configuration, the pathway was not at a mature enough stage to reliably evaluate these aspects of the pathway at the evaluation close. Therefore these specific outcomes were not evaluated and are instead stated here to support a future evaluation of the pathway. Useful and informative outcomes relating to the evaluation of patient choice would include:

- The proportion of patients who attend for an annual IBD review out of the number of patients who are invited or otherwise eligible to attend. Patients should be differentiated by the invite sender and the actual review location (i.e. primary vs. secondary care in both cases). This would provide a measure of the opportunity to express choice and a measure of the expression of that choice.
- Importantly, the evaluation should include the views of patients concerning their planned and actual degree of choice regarding selection of their care providers. This could be useful in identifying the attributes which promote or prevent patients exercising choice.

Whether patients were genuinely empowered, and the extent of any such effect, was not identified within this evaluation. However there are several features of the IBD pathway which could reasonably be expected to deliver patient empowerment, including some features supported by sound evidence. Some components of the pathway would meet the requirements of the IBD Standards with respect to patient empowerment and related aims although there remained considerable room for improvement in that respect.

5.1.4.3 Clinician empowerment

One contextual factor was identified which influenced the application of the theory of clinician empowerment within the pathway. This contextual factor is described singularly as relating to explicit and prioritised healthcare policy for clinician-led commissioning, particularly primary care clinician-led commissioning, [210] and in tandem the on-going pre-eminence of the practice and implementation of evidence based medicine. [211] In this respect evidence-based medicine has been subjectively classified as a clinician-led initiative and is therefore itself an aspect of clinician empowerment. Four mechanisms were identified through an iterative process and seven outcomes were associated with these mechanisms. One of the outcomes links to two context-mechanism pairs hence there are eight unique CMO configurations. Three of the outcomes were not evaluated within this evaluation but they have been prospectively identified and stated to support any future evaluation.

Mechanism one (M1) related to the (implicit) aims of the pathway being founded in an initiative in which clinicians of various professional backgrounds were fundamentally involved and which, in part, was founded in evidence-based medicine, i.e. the IBD Standards. [1]

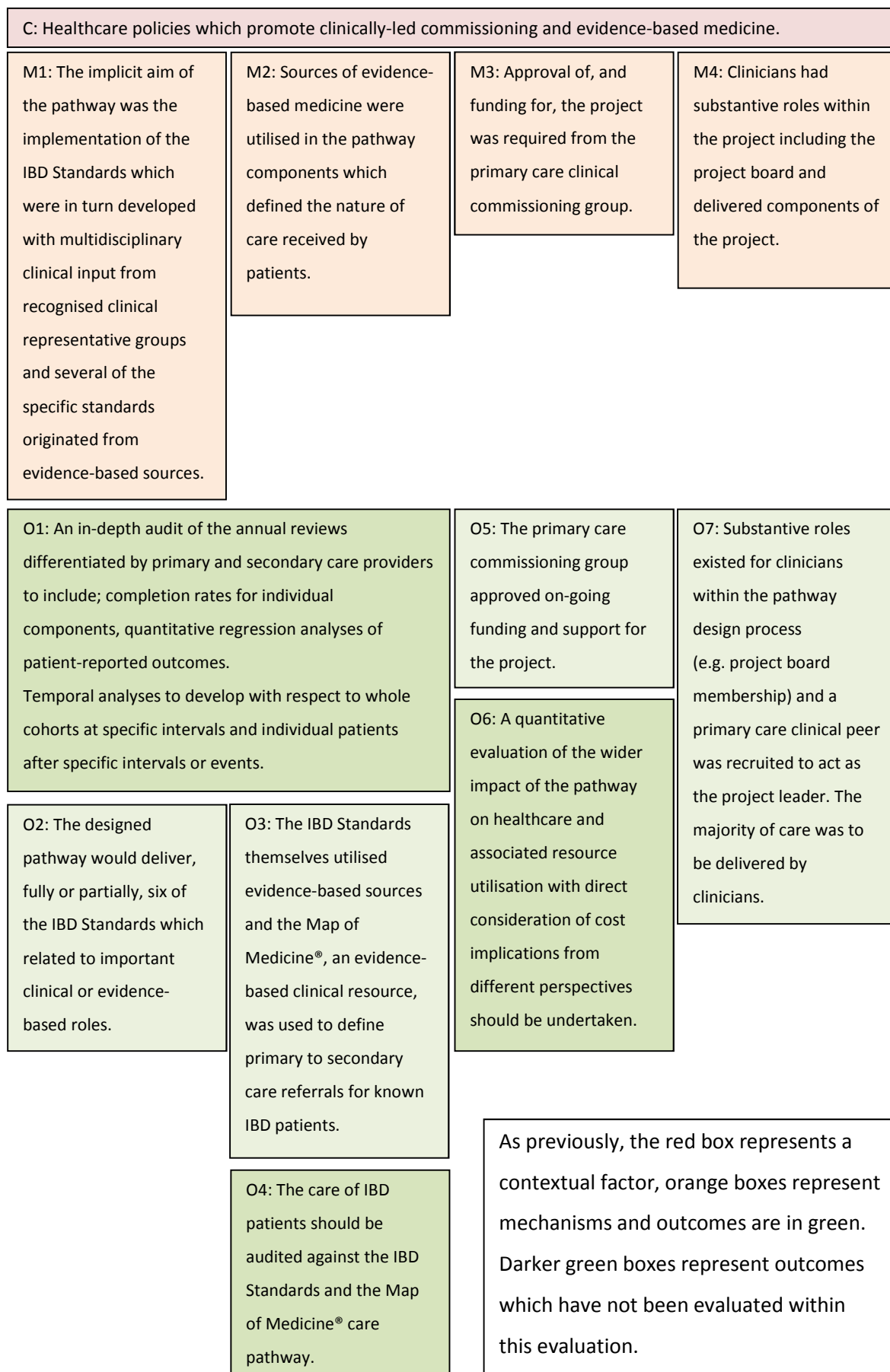
Mechanism two (M2) related to the actual or real application of care which was itself defined in large part by evidence-based medicine.

Mechanism three (M3) related to the gateway process by which a clinically-led group had the ultimate control, at least in a budgetary sense, to approve or otherwise the on-going funding of the project.

Mechanism four (M4) related to the roles which clinicians had, both in the pathway design process and in the outcome of that process, the pathway.

Outcomes are described in detail under separate headings for each of the eight unique CMO configurations.

Figure 8. Context-mechanism-outcome configurations relating to the theory of clinician empowerment within the IBD pathway project



C + M1 = O1

This configuration would yield quantitative outcomes relating to the internal performance and patient-reported outcomes of the patient annual reviews. It is important to note that, at the evaluation close the number of completed annual reviews was insufficient for formal evaluation. Therefore none of these outcomes have been robustly evaluated; this configuration remains to be evaluated and is stated for the purpose of supporting a future evaluation.

Internal performance indicators relating to the completion of annual reviews including temporal measures (i.e. the rate at which individual practices, and secondary vs. primary care, undertook reviews). Performance would also include a descriptive analysis of the overall review completion rate and individual component completion rates. Of greater interest, especially externally to the project, would be the actual review data. For example, the reviews required quality-of-life and symptom scores for most patients. These could in-turn be described and analysed, potentially via regression analysis, by different patient cohorts based on, for example, diagnosis, disease severity, principal care provider (self-care vs. primary vs. secondary), gender, etc. Whole cohorts could be followed up over time, from one year to the next using arbitrary cut-off points, or individual patients could be tracked anonymously and trends relating to changes in underlying quality-of-life or symptom scores could be identified. Any consistent trends could be associated with the pathway. At the least, such an analysis would provide a useful and informative epidemiological cohort.

The analytical and policy impact of such data could be potentially significant and would demonstrate, primarily, the clinical outcomes of the pathway from which cost impacts could also be derived.

C + M1 = O2

The designed pathway would deliver, fully or partially, twelve of the IBD Standards, six of which related entirely or principally to clinician empowerment. The relevant standards are each described in turn.

IBD Standard A4. Referral of suspected IBD patients

Guidance should be developed for the identification and referral of symptomatic patients in whom IBD is suspected.

This was not specifically addressed by the pathway.

GPs should be prepared periodically to review their diagnosis in patients with unresponsive, atypical or troublesome abdominal symptoms.

This was not specifically addressed by the pathway.

A communication pathway must be agreed for referral of possible IBD patients to the IBD Service for rapid consultation and assessment. Such patients should be contacted within 2 weeks of referral and seen within 4 weeks, or more rapidly if clinically necessary.

The pathway defined specialist assessment within 4 weeks following primary care referral and this was complementary to this part of the standard. The pathway did not define deadlines for contacting patients or make allowance for more rapid assessment if clinically needed.

Newly-diagnosed IBD patients for whom surgery is not an immediate consideration and who have initially been referred to a surgeon should normally be transferred to the care of the medical gastroenterology team.

This was not specifically addressed by the pathway.

IBD Standard A11. Outpatient care

All patients with confirmed IBD should have their details maintained on the Register of IBD patients even when they are no longer regularly attending outpatient clinics.

The pathway required that patients were properly 'coded' on primary care electronic patient records so that they could be readily identified. The only 'register' in local use was that held by the Hospital IBD team and maintained by the Specialist IBD Nurse. The pathway required that even patients who were not currently managed or under the care of that specific Hospital IBD team (i.e. patients managed at other hospitals, or managed entirely in primary care) would be notified to the Hospital IBD team so they could be recorded on the hospital database. Issues relating to patient confidentiality and communication strategies for patients who were not or had not been under that hospital's care were not conclusively resolved.

All IBD patients who are not under immediate or on-going care, including those in remission, should have an annual review and basic information recorded. This may be undertaken in a hospital or community clinic or by telephone follow-up, and should be done by a healthcare professional with recognised competence in IBD.

One of the key components of the pathway was the provision of an annual patient review for all patients with information recorded on practice records, shared with the Hospital IBD team for the patient's medical record, and audited by primary care commissioners. The review could be carried out in a number of settings and the option of a telephone review was discussed although this was not specifically included in the final pathway. The competence of healthcare professionals was assured through verified completion of specific education and training and on-going support from the Hospital IBD team. In addition, the clinical champion and primary care commissioning team established a network for primary care nurses conducting IBD reviews.

The criteria for annual review should be agreed by the IBD Team, but would normally include assessment of the need for colorectal cancer surveillance, renal function and bone densitometry.

The review components were derived from a project which had developed and tested an IBD annual review for use in primary care. The content of the IBD pathway review was then refined by the project with significant contributions from the Hospital IBD team. The IBD pathway review template included additional assessments for cancer surveillance, renal function and bone densitometry in accordance with this standard.

All IBD patients who have a concern or questions about their IBD should have access to a dedicated telephone service (IBD Helpline) that is either answered or has an answerphone facility providing a response by the end of the next working day.

The pathway provided access to the Hospital IBD team, specifically the specialist IBD nurse, via a telephone helpline. This was also available to patients who had been formally discharged from the hospital IBD service. The helpline was connected to an answerphone and arrangements were in place with hospital IBD team administrative (non-clinical) staff to manage the helpline at times when it was not directly managed by clinical staff. The pathway did not define a specific deadline by which responses were provided.

Patients experiencing a possible relapse of their IBD should have access to specialist review within a maximum of 5 working days.

The pathway specifically defined that a relapse for patients managed in primary care, or any other indication for an existing patient which required specialist review, would be seen or consulted by a specialist within five working days.

IBD patients should be able to choose from a range of arrangements for their outpatient care. These should include attending hospital as an outpatient, guided self-management with access to support when required, and care in a primary or intermediate care setting with defined links to the IBD Team.

The pathway would permit a limited degree of choice for patients with stable disease and in remission to choose their care provider. Patients who were currently managed in primary care or not under any formal care arrangements were not provided choice within the pathway. This was a specific suggestion from the patient panel. Patients who were currently managed in secondary care could choose to stay under the care of the Hospital IBD team or to be managed in primary care. Patients with unstable or active disease could not choose their care provider and were expected to remain under the care of the hospital IBD team until such time that their disease was

stabilised and in remission. The pathway did not make any provision for intermediate care. The pathway promoted and supported self-management through specific provision of information and sign-posting to, and promotion of, credible patient organisations.

IBD Standard B1. Arrangements for shared care

The arrangements and scope for shared care and the circumstances in which the patients should be referred back to hospital care must be clearly defined between the hospital staff and the GP. They must be explained verbally to the patient and written information on this provided to the patient, ideally as a care plan.

Referral arrangements within the pathway from primary to secondary care were defined by the Map of Medicine®. The pathway did not make a specific requirement for referral arrangements to be communicated to patients. A written care plan, although discussed on several occasions by the project board, was not included in the pathway. A final version of the IBD service leaflet, which was being produced by the Hospital IBD team as part of the pathway, was not delivered within the pathway.

A system for sharing of information about test results or treatment changes should be in place through the use of IT, written communication between the GP and hospital or a patient-held record.

The pathway did not make any changes to communication processes for clinical data, the majority of which would occur via hard (i.e. paper) copy. Primary care communication to secondary care was largely absent prior to the pathway and the pathway could have stimulated such communication as copies of primary care reviews were to be communicated to secondary care. There were already systems in place for electronic sharing of biochemical clinical data from secondary to primary care. A patient-held record or care plan was discussed on several occasions by the project board but was not included in the final pathway.

Treatment with immunosuppressive or biological therapies should only be initiated by clinicians with expertise in their use for IBD. Shared care protocols should be developed to support the on-going prescribing and monitoring of these drugs in general practice.

The pathway did not make any specific changes to arrangements for management of specific therapies.

Arrangements should always be made in discussion with the patient.

The pathway did not make any specific changes to arrangements for discussing treatment decisions with patients. However, better informed and empowered patients which were one of

the implicit aims of the pathway could rationally lead to patients being involved in discussions about their treatments.

IBD Standard E1. Register of patients under the care of the IBD service

Every IBD Service should maintain a local Register of all diagnosed IBD patients in the catchment area (including those who have been diagnosed but are not currently being managed in secondary care) recorded on a searchable database and with adequate clerical support to maintain this.

This standard was not specifically addressed by the pathway although the pathway did reinforce the importance of the pre-existing database created and maintained by the Hospital IBD service. In addition, the pathway sought to ensure that the hospital database could obtain information concerning local IBD patients who were not or had not been under its care. This standard is similar to the first point of standard A11 which has been described previously.

IBD Standard F1. Training and education

All members of the IBD Team should be expected and enabled to participate in local and national professional education to maintain their competence and knowledge in a fast developing subspecialty.

The 'IBD team' in this point is taken to include all primary and secondary care practitioners involved in the delivery of care for IBD patients. In that respect, the pathway did achieve this standard, principally through the provision of specific and mandatory education and training events for practice staff with verified and remunerated attendance. In addition, the pathway required a named GP lead in each participating practice to undertake a specific online educational package, the completion of which was verified and remunerated. Another outcome of the pathway which began to emerge at the end of the evaluation, and under the direction of the clinical champion, was an informal network for primary care practice nurses.

Advanced nursing practitioners within the IBD Team should have access to medical support as well as nursing supervision.

This point was not specifically addressed by the pathway. It was already covered by the Hospital IBD team which was the only IBD team within the locality known to have an advanced nursing practitioner.

The IBD Team should provide IBD awareness and education opportunities for GPs. These should focus on the initial presentation of IBD, as well as its treatment. A lead GP should be identified to assist in this.

This point was specifically addressed by the pathway. The project board provided two education and training events which were open to voluntary attendance from GPs and other primary care clinicians to attend. Participating practices were required to identify a GP to act as lead for IBD and this individual was required to attend one of the education and training events, as well as at least one practice nurse from participating practices. The content of each education and training session covered the specific criteria stated in the points and both sessions had contributions from the primary care medical lead and other clinicians. It was not clear whether there would be an on-going education and training commitment within the pathway after the initial events.

IBD Standard F3. Service development

IBD Teams should participate in local and national activities intended to improve the quality of IBD care and services.

The pathway itself and participation in the evaluation represented attainment of this point. The pathway did not mandate any specific contributions to this point.

IBD Teams should take an active part in clinical network arrangements and events with neighbouring IBD Services.

The pathway did not specifically address this point. The pathway did stimulate a recognised need for the Hospital IBD team to communicate with neighbouring hospital gastroenterology departments although it was not clear if these communications occurred. The academic adviser did allude to having communicated details of the IBD pathway to other healthcare organisations within the region.

IBD Teams should be encouraged to hold an Annual Review Day to reflect on their service and where appropriate to consult with relevant stakeholders.

This point was not specifically addressed by the pathway and no such event is known to have been planned after the pathway was launched.

C + M2 = O1

As with the other CMO configuration relating to outcome one (O1), this was not realised within this project evaluation. In this configuration outcome one was interpreted to also provide information about the realisation of mechanism two (M2), subject to the background context (C), both previously described. In this respect the configuration could inform whether the expectations of the impact of evidence-based care can be realised under the specific local conditions such as the context (C) and other objectively identifiable factors.

C + M2 = O3 and C + M2 = O4

Both of these CMO configurations relate to the local application of evidence-based medicine in IBD (M2). Evidence-based medicine is itself a clinically-led movement viewed as the highest quality expression of clinical care. It has therefore been interpreted as a form of clinician empowerment for the purposes of this evaluation although this is not necessarily a universally accepted interpretation.

The first of these configurations (C + M2 = O3) related to the pathway design and in that respect it was concluded that evidence-based medicine was incorporated into the pathway. This was achieved by defaulting to the application of the IBD Standards as the implicit aims of the pathway and the partial attainment of those standards, and by defaulting to the Map of Medicine® to define patient referrals from primary to secondary care. Both sources were themselves embedded in evidence-based medicine.

The other CMO configuration relating to the second mechanism (M2) of evidence-based medicine (C + M2 = O4) was not evaluated within the project evaluation and the associated outcomes are instead stated to support a future evaluation. In that respect a future evaluation of this configuration should involve an in-depth audit of the actual care delivered against the IBD Standards and the Map of Medicine® IBD care pathway. Both of these potential audit standards are founded in evidence-based medicine and by direct association an audit against them would be an indirect audit on the application of evidence-based medicine.

Box 10. Evidence-based medicine within the IBD Standards

IBD Standards [1]

Introduction

.... In developing the standards the Working Group has drawn on NACC's work identifying patients' needs and wishes, on existing evidence-based guidelines for the clinical management of IBD, the strategic report Care of Patients with GI Disorders published by the BSG in 2006 and evidence-based service statements produced by the various professional groups.

Standard F. Evidence-based practice and research

.... The principle of a knowledge-based service requires that necessary research should be identified and prioritised.

Box 11. Evidence-based medicine within the Map of Medicine®

Map of Medicine® [212]

Editorial methodology

.... Map of Medicine® specifically searches for well-reputed secondary evidence – systematic reviews, meta-analyses based on systematic reviews, and guidelines. ...

Every care map is peer-reviewed. Peer-reviewers are asked to consider the evidence base used, the practice-based knowledge added, and the clinical usability.

C + M3 = O5

An indicative budget had been prepared by the project management organisation, the PCT, as part of its application for the Department of Health integrated care pilots. This budget plan was based principally on the estimated number of patients using standard prevalence rates multiplied by the cost of individual components of care under an assumption of eventual 100% take-up by all parties (patients and primary care medical practices). This budget plan estimated comprehensive take-up by 26 practices with 842 IBD patients. The direct project costs for the first year were therefore estimated at £13,000 for practices and £29,470 for conducting patient reviews; total cost £42,470. It was not clear whether these were expected to be recurrent costs; certainly the cost for conducting patient reviews would be expected to be recurrent as would the additional £120 per practice (total £3,120) for submitting data pertaining to the reviews. The costs for clinician training, at £380 per practice (£100 per GP and £280 per practice nurse), may not have been recurrent.

Fundamental to the project was an assumption that the pathway would create savings based on reduced use of specialist, secondary and emergency care. The net effect of these savings was estimated at £154,140 per annum based on standard healthcare values for 2008-09. This figure

was itself based on a number of unreferenced or unclear assumptions. For example, the stated prevalence of IBD was 4.4 per 1,000 giving an estimated patient population of 842. However this figure was slightly greater than that found in an earlier epidemiological study from a similar locality of about 3.88 per 1,000. [2] A similar figure of 4 per 1,000 was reported in the IBD Standards. [1] The practice agreement which participating practices were required to sign for participation in the project used a figure of 9 per 1,000 (appendix 11) the basis of which was unclear. The budget plan assumed that 500 of the 842 patients (59%) were managed by specialists with an average of 1.5 outpatient attendances per annum (750) and there would be a 30% reduction in the number of outpatient attendances (i.e. 225 fewer attendances). The figure of 750 outpatient attendances per annum was based on actual local data. An increase of 20 new outpatient appointments was also factored-in along with the attendant costs. The majority of the estimated savings originated from reductions in emergency admissions, for which actual data indicated about 200 admissions per annum at higher cost tariffs plus 100 admissions per annum at the lower tariffs. The budget plan assumed a reduction of 10% in the former and 80% in the latter, yielding savings of £40,860 and £98,640 respectively.

The net budget impact was based upon a number of assumptions for resulting levels of healthcare utilisation which were not stated or referenced and appeared to have been arbitrarily elucidated. Nonetheless, it was this budget plan, which may have been periodically updated with new tariff values, which formed the basis of the financial argument for the project. The budgetary case was referred to implicitly and explicitly at several points during the project by both project managers. It was clear during project board meetings that the budgetary argument was crucial in securing on-going support and up-front funding for the project.

During the course of the project the ownership, or budgetary responsibility, shifted from a Practice-Based Commissioning (PBC) group budget to a GP commissioning consortium budget. The PCT would still provide strategic support and project management however on-going support for the project was required from the GP commissioning consortium board. This change coincided with the introduction of the new project management team in early 2011. The pathway launch was made to the PBC group board in November 2010. One of the first tasks undertaken by the new project manager, who took up the role in early 2011, was to secure on-going funding for the project from the GP commissioning consortium board. At the 10th project board meeting in May 2011 the project manager alluded to some issues relating to transfer of funding oversight although little detail was provided. At the 11th project board meeting in July 2011 it was reported that funding of £60,000 had been secured for the nine practices which had already signed-up to the pathway and any extra practices which subsequently agreed to participate in the project. As of the 31st March 2011 the direct project costs were estimated at £8,780, based on 21 practices signed-up, eight GP's and 14 nurses having undertaken the required training, and 44 annual

reviews completed. Therefore the actual costs which were estimated to have been incurred were substantially less than the funds which had been allocated. However the direct project costs do not include the cost of project management support and other operational expenses.

C + M3 = O6

As with outcomes O1 and O4, outcome six (O6) was also remained unevaluated. The individual outcomes which could be included within O6 related primarily to data which was readily available and already routinely recorded within local and national NHS data infrastructure. However the crucial step to making the data useful was being able to relate it to specific diagnoses or indications, or by linking it directly to patients defined by a specific disease such as IBD. This step was not readily achievable with current data sets or the available access to them and presented a substantial barrier to the useful evaluation of the data.

Assuming that this barrier could be overcome, outcome six (O6) would represent a collection of relevant and potentially correlated quantitative outcomes routinely collected as part of patient care and NHS systems. Such outcomes would take a certain amount of time to be realised, most likely measured in years as opposed to months, but would also be of paramount interest to healthcare commissioners and others with similar influence or interests.

The individual outcomes could include:

- Unplanned (emergency) admission rates
- Elective (planned) admission rates
- Procedure codes identifying specific procedures carried out for IBD patients or for the purpose of treating IBD
- Primary care medical and nurse consultation rates
- Secondary care medical and nurse consultation, and other contact, rates
- Prescription drug use analysed according to various standardised reference measures

This CMO configuration could help to identify whether the budget plan assumptions described under outcome five (O5) were realised and to the extent they were realised.

C + M4 = O7

As with user involvement, the pathway design process and the outcome of that process, the pathway to be delivered, included a substantial role for clinicians, both medical and nursing clinicians, and primary and specialist care. It could justifiably be said that the pathway was dominated by clinicians and the project could be described as 'clinically led'. There were many examples of clinician empowerment within the pathway both during the design process and with respect to the pathway which was actually designed.

- Project board: Of the eight regular project board members or roles, two were exclusively of a clinical background (the consultant gastroenterologist and the specialist IBD nurse). A further two members had substantial past (academic adviser) or current (primary care medical lead) clinical experience which frequently influenced their contributions to the project and project board meetings
- Project board meetings: Despite no special dispensation to ensure hospital clinician attendance and their consequent irregular attendance, the majority of board meetings were chaired by a clinician. All clinician representatives, with the exception of the specialist IBD nurse, contributed substantially to project board meetings. The specialist IBD nurse only attended two project board meetings and whilst there contributed comparatively little to discussions, although her presence alone was a positive development and may have had an impact on other project board members.
- Launch event: The individual who took the lead at the launch event was the primary care medical lead, also a practicing local GP (project board member); the audience consisted of GPs and practice managers being the '[Locality] GP commissioning forum'.
- Clinician education: The pathway design required that primary care clinicians, both general medical practitioners and practice nurses, undertook formal and verifiable training and education. Clinicians were also involved in delivering the bespoke training and education meetings within the pathway.
- Clinician to clinician communication: The pathway, if fully realised, would enhance communications and information-sharing between clinicians, primarily across the primary-secondary care interface. This aspect of clinician empowerment was not formally evaluated. Clinicians, both primary and secondary care, reported improved communication with colleagues in the other sector when interviewed. Anecdotal reports indicated that communication, particularly in the direction of primary care to secondary care, had increased.
- Clinician peer-to-peer leadership: Although a missed opportunity for significant and substantial clinician empowerment during much of the evaluation, the 'clinical champion' role was fulfilled and would provide a good example of clinical empowerment. This role was fulfilled by a primary care medical clinician recruited to work for, lead and promote the pathway amongst primary care clinical peers. However opportunities for the clinical champion to contribute to the initial design processes and significant events such as the launch event were missed due to delayed recruitment.

Clinical champion

The requirement for, and the eventual recruitment of, a clinical champion within the pathway was another example of clinical empowerment within the pathway and this was reflected in the CMO configuration $C + M4 = 07$.

Limited use of the term 'clinical champion' was identified in UK-orientated health literature. However one useful example was an article published in the Health Service Journal in 2009. [213] This described an initiative within a single PCT which co-incidentally was also located in the same SHA. In this example clinical champions were appointed by the PCT although not necessarily recruited from primary care. The posts were created to help the PCT develop clinical priorities and strategy, promote 'practice based commissioning', promote evidence-based care, and to act as focal points for communications. The clinical champions were expected to have direct involvement with clinical pathway and planning groups and service review and redesign mechanisms. [213]

The Royal College of General Practitioners has appointed 'clinical champions' for specific therapeutic and related fields since at least 2008. The college's description of the role described the aims and objectives as: [214]

- To pro-actively raise the profile and awareness of the clinical priority area among general practitioners, the wider primary health care community, and patient-related organisations and groups.
- To spearhead collaborative and partnership working with both internal and external stakeholders.
- To promote best clinical practice and develop the range and quality of training, educational and information resources in the priority area.

5.2 Community Pharmacy role in managing IBD

The survey and focus group analyses combined were generally supportive for the potential involvement of community pharmacy in the management of IBD for adult patients. The results of the survey also indicated a considerable opportunity for community pharmacists to be involved in the management of adult IBD patients given the high rates of prescription and non-prescription medication use, and the majority of patients regularly using community pharmacies.

5.2.1 Survey analysis

5.2.1.1 Baseline drug-related healthcare utilisation and services

The survey results demonstrated that this group of adult IBD patients had a high use of use of prescription medication for their IBD with 87% reporting current use. This was not an unexpected result given what was known about the management long-term conditions more generally. [215] However it was somewhat at odds with data published in 2000 which found in a similar locality that the rate of medication use for IBD amongst a general practice IBD patient population was 46%. [2] Data from an American database in 1997 found that 88% of nearly 4,500 paediatric and adult IBD patients were using any prescription medicine, although only 57% were using drugs specifically targeted at the alimentary system such as 5-aminosalicylic acid drugs. [216] Therefore the survey results in this respect should be interpreted cautiously as responses may not have been as intended and could relate to any indication not just IBD.

The relatively large difference between the rates of prescription IBD medicine use found in this survey and in the earlier work of Rubin [2] could be explained by a number of factors. Some of the more plausible include:

- Changes in disease management over time resulting in wider use of medication for IBD in general.
- Rubin's work focused on a general practice IBD patient population whereas this survey did not discriminate on this basis. Therefore the survey result could be inflated by a proportion of patients under specialist care, in turn associated with a different rate of medication use.
- Rubin's work was objectively verified from patient notes and practice records whereas these survey results were self-completed by patients and may be subject to recall bias or fabrication.
- Although the survey question specifically enquired about IBD medication respondents could have misinterpreted this, intentionally or unintentionally, and may have included other non-IBD medications thus inflating the apparent IBD-specific rate. Rubin's work focused only on a specific range of medicines commonly, but not exclusively, used for IBD. The evidence from the American database would support this notion. [216]

The survey results also demonstrated that responsibility for prescribing IBD medication appeared to be equally shared between primary and secondary care. Secondary care prescribers (hospital doctor, nurse or pharmacist) accounted for 50% of responses, and primary care prescribers (GP, practice or district nurse, or community pharmacist) accounted for 49% of responses. The most common prescriber was a GP with 62% of respondents indicating their IBD medication was prescribed by their GP. There were a relatively large number of multiple responses to this question which could indicate uncertainty or misinterpretation of the question amongst respondents. It was also possible that responses related to the professional who initiated a particular prescription as opposed to the professional who prescribed the medication, with this relatively subtle distinction not apparent to respondents. For example, hospital specialists will often initiate a new drug treatment and once the patient has stabilised with a maintenance dose prescribing is transferred to the patient's GP.

The survey results showed that the majority of prescriptions were dispensed in primary care with community pharmacies accounting for 75% of responses and GP's (assumed to be dispensing doctors) a further 11%. Hospital pharmacy accounted for a significant proportion at 17%. It was interesting that despite about one-half of respondents indicating that a hospital-based prescriber was responsible for prescribing their IBD medication only one-sixth of respondents reported obtaining their medication from a hospital. This disparity could be real, on the basis that hospital prescribers can prescribe drugs which can be dispensed by community pharmacies. However the size of the disparity supports the notion that responses to the preceding question were misrepresented in some way.

Of those who stated they collect their prescriptions from a community pharmacy, and allowing for a small number of responses from non-community pharmacy patients, the majority stated that they 'always' or 'usually' collected their prescription from the same pharmacy (80%). This data supports the notion that a specific community pharmacy could build-up a comprehensive medication record, at least with respect to IBD medication, and enable pharmacy staff, including the pharmacist, to develop a professional relationship with, and knowledge of, a particular patient. Where the rate for continuity of dispensing agent is high, as indicated in these survey results, a case for their involvement in the management of those patients is supported. However consistent use of the same pharmacy does not necessarily mean that a patient will have contact with the same pharmacist. Community pharmacy relies on a large locum work force [217] and therefore individual patients may often see different pharmacists at the same establishment.

The reasons why respondents were selecting the same pharmacy most of the time, termed patient loyalty, were evenly split between external factors outside of the pharmacy proprietor's control or influence (48%), and internal factors which could readily be influenced by the

proprietor (52%). The most frequently cited theme was for 'convenience' relating to some element of geographical proximity. The most popular category was similar, relating to 'geographical' reasons for patient loyalty. This category included the most popular single theme as well as others relating to parking, lack of choice, and specifically due to proximity to the patient's GP. Nonetheless, internal factors such as the conduct of pharmacy staff and provision of additional services accounted for just over half of all responses. Customer service themes such as 'service quality' and 'stock holding' were cited more frequently than clinically orientated services such as the provision of medication use reviews. Overall, these results were encouraging for community pharmacy as they indicated that considerable influence could be exerted by community pharmacy staff and proprietors in achieving customer loyalty, at least with respect to this survey sample. Attributes which pharmacy proprietors should focus on to build patient loyalty might include the potential provision of additional services, both clinical and practical, staff training in general customer care, and holding adequate stocks of prescription medication.

Little relevant research was identified relating to reasons for customer or patient loyalty with community pharmacies. A survey of nearly 400 members of the public aged 20 to 69 years in Estonia in 2005 found that 'appropriate location' was the most frequently cited reason for the choice of a pharmacy, accounting for 24% of the sample. [218] Although this result was similar to the findings of this survey, it is not clear how the question was presented to respondents. In addition, respondents to the Estonian survey may not have been actual patients, yet alone IBD patients, and may have submitted responses relating to attendances at a pharmacy for non-health purposes. A survey of Australian community pharmacy customers identified stronger feelings of loyalty in pharmacies which were identified as providing a high-level of drug information to patients compared with pharmacies identified as low information providers. [219]

The survey responses detailed a high level of prescription medication use, which was managed (prescribed and dispensed) predominantly in primary care, with most prescriptions being filled at community pharmacies and with high levels of customer or patient loyalty to those pharmacies. The survey also provided evidence that IBD patients usually collect their own prescriptions once dispensed. Although this data did not specifically relate to community pharmacies the most common place to obtain prescriptions for IBD medicines had already been indicated as a community pharmacy. Combined, this data supports the notion that community pharmacies provide an opportunity for patients, should they so wish, to engage regularly with a healthcare professional, i.e. a pharmacist. The reverse is also true inasmuch that community pharmacists would have regular opportunity to engage with IBD patients if necessary.

The survey identified a relatively high rate of non-prescription medicine use at about one in four patients (23%). The question included examples relating to the purchase of non-prescription

medicines for IBD, of which there were none known to be specifically licensed in the UK, as well as alluding to medicines commonly referred to as complementary and alternative medicines (CAM). The relatively high rate of non-prescription medicine use was not entirely unexpected. A review of CAM use in adult and paediatric IBD populations identified nine articles published between 1998 and 2006 which provided prevalence estimates on the use of CAM in North American and European IBD populations. [220] These estimates ranged from 11% to 34% for current use and from 21% to 60% when past use was included. [220] Two UK-based clinical surveys were included, one which reported current use at 28% and the other which reported current or past use at 50%. [220] These results were broadly in-line with the result obtained in this survey. A high rate of non-prescription medicine use, whether licensed medicines or unlicensed CAM-type medicines, might indicate an area of unmet need relating to either the reasons why patients resorted to such therapies, or in providing information about the medicines. In addition, such use is often unrecorded and unknown to physicians and creates an important gap in the patient medical record which community pharmacies could fill. [221]

When it came to purchasing non-prescription medicines the data indicated that most purchases were made at health food or vitamin stores accounting for 48% of respondents. This could reflect that a large proportion of non-prescription medicine use may be of the CAM-type rather than over-the-counter pharmacy medicines. Only 20% of respondents cited a community pharmacy as the place where they obtained such medicines although one-third indicated they obtained them from a supermarket including the pharmacy. Of interest was the proportion of respondents who obtained their non-prescription medicines from the internet or via mail order or catalogue companies (28%). The purchase of medicines via the internet creates the possibility that prescription-only or other regulated medicines are being purchased as these are widely available illegally from non-UK based operators. [222] Purchase via impersonal mediums means that patients have limited opportunities to ask questions about the item they are purchasing and any potential interactions with existing medication. Although CAM use amongst adult IBD patients in the survey population appeared to be relatively high, and there is evidence that patient records relating to CAM are often incomplete, community pharmacists have a limited capacity to intervene due to a significant proportion of non-pharmacy based purchases.

5.2.1.2 Patient satisfaction with pharmaceutical care and pharmacy

The overall completion rate for the patient satisfaction instrument was relatively high which provided a useful sample. A few surveys showed evidence of false or poorly considered responses indicated by an obvious pattern in responses such as all responses being placed into the same vertical column. As these surveys constituted a relatively small proportion of the overall sample, and it was not possible to objectively determine which were subject to this bias, they were retained in the overall sample for analysis. However this has created a weakness and potential

bias in the analysis. Response rates were generally higher for friendly explanation (FE) items than for managing therapy (MT) items and the 'no opinion' response was used more extensively for MT items compared with FE items. This was not an entirely unexpected outcome as the MT items related to a higher level of pharmaceutical care than FE items and a level of care which was felt might be less familiar to the sample population.

The mean FE score in this study was 3.80 compared with a mean of 4.31 when the instrument was initially developed in a rural mid-Western American population following a specific interventional programme aimed at improving pharmaceutical care. [161] The mean MT score was 3.31 compared with a mean of 3.94 obtained when the instrument was initially developed. [161] Both of these examples found the mean FE score to be about 0.5 points greater than the mean MT score. The difference between the FE and MT scores in this study, 0.49 points, was statistically significant ($p = 0.01$).

Interpretation of the pharmaceutical care satisfaction survey results was limited by the small size of the sample which constituted each dimension. Nonetheless, taken at face value, the results demonstrate a high degree of satisfaction with pharmaceutical care with most responses corresponding to either 'very good' or 'excellent'. Community pharmacists and interested others should consider putting resources into improving satisfaction with aspects of pharmaceutical care which relate to MT as this is associated with statistically less satisfaction compared with FE where there is less overall scope for improvement.

As well as the pharmaceutical care satisfaction instrument [161] the survey included twelve statements about pharmacists, pharmacies and medication. The overall impression from these results was less clear than that provided by the satisfaction instrument largely due to one of the most common responses being 'neither agree nor disagree'. However, in general terms, the overall results were more positive than negative with respect to pharmacies and pharmacists. Statements associated with a clearer trend related to coping with medication and dialogue with pharmacists. Statements which related to an information role for pharmacists and the availability and ease of access of pharmacists demonstrated a favourable trend for the profession. One statement relating to patient preference for pharmacists as a source of medication information did not demonstrate an obvious preference. Further exploration of the barriers to IBD patients actually seeking information from community pharmacists was not included in the survey. However this was explored to a degree in the focus groups. Statements which related to a greater role for pharmacists in managing IBD demonstrated an overall negative agreement distribution although the response trend was not consistently clear or strong. Statements relating to the expertise of pharmacists, monitoring of the condition in community pharmacy, and the privacy or

suitability of the community pharmacy environment all demonstrated little obvious trend in the results.

5.2.1.3 Baseline disease and demographic data

The demographic and disease characteristics of this survey sample were broadly in-line with other UK-derived samples and this provides some validity to the sampling. An earlier sample from a similar locality was 53% female, with a mean and median age of about 50 years; 59% had ulcerative colitis & 35% Crohn's disease. [2] A postal survey of 1,900 members of Crohn's and Colitis UK (a national patient charity) found that 63% were female with a mean age of 50 years; 47% had ulcerative colitis, 43% had Crohn's disease, and 6% had an 'other' diagnosis. [37]

5.2.2 Summary of combined survey and focus group data

The survey and the focus groups combined were undertaken as exploratory work to identify whether there was a need or desire for pharmacy involvement in the management of adult IBD patients, and what services could be delivered. In addition some baseline data relating to current provision of pharmaceutical care was obtained. The evidence demonstrated that there is significant potential for pharmacy involvement but this may not extend to a definite clinical need. It would appear that, although IBD patients frequently adjust their medication, often use or show an interest in non-prescription medication, and may have questions relating to their medication, they do not perceive there to be much if any unmet need in these respects. IBD patients appear to be quite confident in managing their medication and use a variety of information sources. The extent of medication non-adherence amongst IBD patients would indicate a high degree of need for interventions to improve adherence.

Evidence from the department of health integrated care pilots programme did not support community pharmacy involvement in models of integrated care. [108] One of the 16 pilots involved screening for cardiovascular disease (CVD) in community pharmacies in Greater Manchester. However, uptake of pharmacy-based screening was lower than expected, and lower than local health checks which also included CVD screening. [223] On this basis the Tameside and Glossop CVD pilot ceased pharmacy-based screening during the evaluation period because of patient reluctance to attend for health care services at pharmacies. 1[108, 223] There was a presumed patient preference for pharmacy-based screening on the basis of access and convenience however this was not borne out in practice and demonstrated a note of caution for any future pharmacy-based services delivered for the purposes of access and convenience alone.

UK-evidence from five focus groups of patient perceptions of clinical services provided by community pharmacies has been published. [224] Patients were recruited from groups of young mothers, older persons (age 52 to 94 years) and men, all from Glasgow (UK). In general these

patients reported little knowledge of clinical services provided by community pharmacies, recognised a hierarchy in which pharmacists acted subserviently to GPs, and pharmacists were often considered to be inaccessible due to being 'in the back' of the dispensary. Community pharmacies were also seen to be compromised by overt commercial interests. Consequently, trust in GPs was greater than that in pharmacists and the authors suggested that gaining GP support for extended pharmacy services could build public trust. [224] Some of the sentiments expressed in these focus groups also arose in the focus groups in this study although patient trust was not specifically probed. This evidence is useful in highlighting the need for GP support of pharmacy-led initiatives from the patient's perspective, which complements findings from the professional and system perspective. [225, 226]

Other evidence for the involvement of community pharmacies in the management of long-term conditions is provided by international experiences of initiatives focused on osteoporosis. A systematic review found three randomised controlled studies with, in each example, a degree of patient-identification or risk-stratification involved. [227] Nonetheless, the review identified modest benefits with increased service utilisation including medication adherence and surrogate measures of disease activity although the evidence base was limited and subject to bias. Encouragingly, each example included within the review involved a degree of integration between the pharmacy and other healthcare providers, most commonly the primary care medical practitioner. [227]

An audit conducted by the Royal Pharmaceutical Society of Great Britain identified a role for community pharmacies in the early detection of bowel cancer. [228] Over 70% of 223 pharmacies identified at least one patient based on the inclusion criteria, which identified the potential for patients to discuss bowel-related symptoms with community pharmacists. This audit provided evidence that pharmacists are considered appropriate healthcare providers by patients with bowel-related symptoms. Analysis of pharmacist actions also indicated that pharmacists were able to adequately discern the most appropriate course of action for patients and that the pharmacy environment provided an opportunity for imparting health messages and advice. [228]

Where enhanced levels of healthcare provision via community pharmacies have been utilised within the NHS previously a significant barrier was found to be the level to which pharmacists felt they were integrated within the primary healthcare team. [225] Specifically, access to patient information such as medical records and co-location with primary care medical professionals and facilities were found to substantially enhance the provision of pharmacist-led interventions. [225] These are aspects of care provision which should be considered and, where available, incorporated if pharmacy-led interventions for IBD are to be implemented successfully.

A Swedish study which involved patient and professional focus groups to elicit views and experiences related to specialist dermatological care [229] reported that all respondents, both patients and professionals, identified poor care and service co-ordination with the most apparent 'gap' being that between community pharmacists and other providers. In addition, pharmacist provision of support was constrained by the lack of privacy afforded by the community pharmacy environment and the lack of access to a patient clinical history. [229] Again, the lessons which could be learnt here for any successful implementation of a community pharmacy-led intervention for IBD would be to ensure that pharmacists can access the relevant patient information and that they have appropriate facilities, especially with respect to privacy and confidentiality, to provide the intervention.

5.2.3 Limitations of the community pharmacy evaluation

The potential limitations relating to the community pharmacy evidence identified in this evaluation must be acknowledged. These included two consecutive steps of self-selection with the group of patients having first selected to join the national patient charity which was used for sampling and then self-selecting themselves to complete and return the survey. Thus those who actually responded to the survey could be distinctly different to other or general IBD populations. However the disease and demographic characteristics did not demonstrate gross deviations in those respects. [2, 37]

Although most of the survey questions were specifically about IBD and IBD medication it is possible that this was not understood by respondents or in some cases respondents could not differentiate IBD-specific experiences from other health experiences. Additional data about non-IBD medication use and co-morbidities was not collected so any associations of these factors cannot be assessed.

Another issue was that of defining a 'community pharmacy' which was integral to the survey. The term 'community pharmacy' has a specific meaning in the provision of healthcare and is distinct from dispensing doctors, both legislatively and professionally. This aspect was considered *a priori* and consequently a bespoke lay-person definition was included on the front page of the survey. However respondents may have simply regarded any dispensing activity as a pharmacy and answered questions irrespective of whether it was a community pharmacy or dispensing doctor. This was not identified as an issue during pilot testing. Another concern was that some members of the public may not perceive a supermarket pharmacy as being a community pharmacy. Therefore, to further assist respondents, a distinction was made between a 'community pharmacy' and a 'supermarket pharmacy' even though, in both legislative and professional terms, a supermarket-based pharmacy is a community pharmacy.

Additional potential for misunderstandings or misinterpretation of terms used within the survey may also have existed. For example, two external reviewers of the survey identified the term 'manage' or 'managing' in relation to IBD as having potentially multiple meanings or interpretations. Consequently a bespoke lay-person definition was added to the front page (appendix 4). Other definitions included on the front-page were for 'IBD' which was abbreviated throughout, and 'monitoring' which was also considered as having potentially multiple interpretations.

With respect to the focus groups, again these were limited by multiple factors:

- Only three groups were convened involving nine participants which constituted a small overall sample size.
- None of the themes identified reached what could be considered saturation.
- As with the survey, the sample was a self-selected group of a self-selected group. i.e. participants had first chosen to join the patient charity and had then volunteered to participate in a focus group. This particular group of patients might be unrepresentative of other adult IBD patients.
- All participants were aware that the group facilitator and assistant were both registered pharmacists and the research was part-funded by a pharmacy research charity. Therefore a subtle influence due to a feeling of expectation to please cannot be ruled out.

5.3 Reflections

In conducting this doctoral research project I have encountered a considerable volume of new learning and experiences. With respect to my own conduct, I was expected to act impartially as a non-participant observer, aiming to exert as little influence on the project as possible. However this was not always achieved and may have arisen in ways so far unnoticed.

This presented a particular issue for the project's academic adviser who, whilst being an integral member of the *de facto* IBD pathway project board, was also my lead academic supervisor and by inference part of the research team. This created the incongruous position whereby I was evaluating my own supervisor's role in the pathway. In the event this dichotomous relationship did not appear to have a negative impact either within the research team or with the project board.

A similar albeit less overt and conflicting relationship arose in my interactions with patient representatives, particularly the chief executive of the patient organisation to which all three were allied. The patient organisation had provided substantial funding to the evaluation of the pathway which would lead to me having to, in part, evaluate the actions of an organisation which had contributed to my academic funding. In addition the patient organisation would have

influence over the evaluation. In the event this did not present any significant or obvious barriers. On a few occasions I was requested to provide brief and informal updates to the patient organisation with respect to the progress of the project. These were honestly presented and well-received.

Towards the end of the evaluation observation period a new relationship emerged between a member of the project board (B) and the University when the consultant gastroenterologist was appointed as an honorary lecturer. However this appointment appeared to have arisen through separate relationships between these parties and did not present any obvious conflicts in conducting the evaluation. The gastroenterologist did not have any involvement in the evaluation other than via his role on the project board and as part of the hospital IBD team.

Other professional relationships existed and developed between myself and members of the project board & other actors within the scope of the evaluation, as might be expected for a relatively small team working together over a protracted period of time. For these reasons it would not be accurate to claim that the evaluation process was wholly independent of the subject under evaluation. However, neither would it be an accurate reflection to describe the evaluation as subject to undue internal influences or bias. Despite the various overt and subtle relationships that existed between the various parties the evaluation was largely independent of the IBD project under scrutiny.

As to whether I was able to maintain the desired outcome of non-participation, again in the main this was the case however there were examples where I strayed from these bounds. In one example, after specific questions had been directed during a project board meeting, I delivered a frank and honest summary of the project management up to that point. The effect of this report to the project manager was immediately apparent and there followed a noticeable upshift in project management activities and practice recruitment. General project management functions, particularly in relation to managing board meetings, also improved. My intervention was an example of a researcher moving beyond the non-participant observer role. Other examples included provision of advice to the second project management team which related to the previous phase of project management and included provision of some project documents. More subtly, I engaged in numerous conversations outside of the formal project meetings where the project was discussed in more liberal terms however on each occasion comments remained tactful and considered. More obvious were meetings with my lead supervisor during which the project was often discussed in frank terms. I also undertook more active roles with the hospital patient panel, a group which counted two project board members within its membership. However the influence of the panel on the project board was itself somewhat limited and passive. On each occasion that I undertook activity which could exert influence it was considered and

undertaken in full recognition of the potential impact on the evaluation and the project. My experiences up to the end of the evaluation observation period indicated that my judgments were fair.

A more significant reflection is that the evaluation plan had been designed primarily to collect outcomes, and the contextual affecters of them, from the *operation* of the IBD pathway. In hindsight it was optimistic to expect that such a pathway could be designed by multiple agents, implemented across a defined health economy with multiple agents (GP practices, GPs, nurses, and hospital services), and be operationalised to such an extent that the desired outcomes could be identified within the time frame available. In the event the evaluation, even with an extended observation period, was only able to evaluate the pathway design and implementation phases with little relating to its operationalisation. This subtle but important change in focus of the evaluation could have been identified at an earlier point in time and plans amended accordingly, focusing exclusively on the design and implementation phases. This could in turn have negated the use of patient focus groups which proved limited in the information revealed. The outcomes of the evaluation and the extent of pathway 'success' should therefore be considered in the context of reasonable timeframes for such projects. In that respect, the pathway was designed and implemented, largely from scratch, in less than two years. Outcomes relating to healthcare utilisation and associated with the operational phase of the pathway would only appear at a later point in time and after a significant time lag. This would appear to be consistent with other evaluations of projects of health system changes.

The patient focus group conducted within the context of the pathway evaluation was disappointing. Although it may appear that little useful information about the actual impact of the pathway was obtained, seemingly because it had had no impact and many of the participants had no knowledge of it, this was itself a useful finding. But that finding was perhaps a poor return for the efforts of both the researchers and crucially the participants, and this could have been elucidated by other means. Other findings from the focus group, whilst interesting and enlightening concerning the local management of IBD and real patient experiences, were not of direct relevance to the evaluation.

With respect to data collection, one important strand was the collection of all relevant electronic mail communications for analysis. I had made an explicit request to be copied into all such communications so that a complete record could be created. However, reference to specific communications at various meetings indicated there was a volume of potentially useful correspondence that I was not party to. Therefore the collection of e-mails as an important source of data was incomplete and the extent of the missing data is unknown. An additional consideration is my notes relating to project board meetings. The project board meetings were

important events during the evaluation however several were not supported by any official minutes or notes and when such were available they were often scant in detail. Therefore my notes became the primary record of these meetings however this left them open to significant subjective and unvalidated interpretation.

With respect to conducting the pharmacy-oriented research component of the doctoral research project, a number of specific learning experiences were gained. Firstly there were practical learning aspects such as designing and constructing a postal survey, and conducting patient focus groups. In addition, the pharmacy component provided a first experience of dealing with a research ethics application and committee. This provided experience in learning the practical and theoretical steps required to ensure a successful application. Particular consideration had to be given to the course of actions that would ensue if a focus group participant subsequently decided to withdraw. This was an interesting conundrum which was considered with the co-operation of the research ethics committee chair. The likelihood of such an occurrence, its implications on the overall research, and dealing with it in a practicable way were all considered.

The pharmacy project also provided a salutary experience in dealing with one's own prior assumptions about a defined population, in this case members of a patient organisation. It had been assumed that all (adult) members of the local branch of the national patient charity:

- Resided in the locality
- Were themselves a current adult IBD patient

This second assumption, although apparently true for the majority, was found to be erroneous due to a number of reasons, specifically:

- Proxy patient members, such as parents taking membership as a proxy for a child with IBD
- Healthcare professional members, such as nurses and dieticians
- Members who had been effectively surgically cured of IBD and were therefore no longer an IBD patient but who retained membership of the group

My own professional experiences of working within community pharmacy inhibited a full consideration of some aspects of being an IBD patient such as receiving medicines from hospitals, having medicines administered in hospital, and receiving items other than medicines (e.g. medical devices, dressings or appliances) on prescription. This expressed itself in subtle ways for example in the construct of some questions both in the survey and focus groups, but was only realised during data analysis. On a purely technical basis, an error was made in collecting postal code data and linking this to other post code-sensitive data sets.

With respect to the pharmacy focus groups, these provided a useful learning experience both within the pharmacy project but also in preparation for the focus groups which was subsequently undertaken within the IBD pathway evaluation. Within the pharmacy project there was a clear and steep learning curve from the first to the third (final) focus group convened. In the first focus group I, as the facilitator, accounted for a significant proportion of the conversation. This may have been in part due to the particular participants of that group and because only two individuals were present. With the second group, which consisted of five participants, I ensured that all participants had a fair and equal opportunity to contribute even if they did not wish to exercise it. In the third focus group, also with two individuals, I felt more relaxed and allowed the conversation between participants to flow more easily and extensively. I was still able to subtly incorporate the desired questions and topics into the general conversation. In particular, with the first focus group the service scenarios were presented in a formal and step-wise manner with printed guides shown to participants in a similar fashion to a slide presentation. At subsequent focus groups the scenarios were more subtly introduced and were not formally presented in this way.

Working with the local branch of the patient charity was rewarding. The response rate to the survey was about 20% greater, in absolute terms, than anticipated which was welcome especially as it was distributed at a busy period of the year and at a time when many people are away. However the response rate could support an argument that the sample or target population was in some way unrepresentative. By comparison a contemporary survey which was also about medicines, and included questions of similar construct, posted to 5,900 members of a national IBD patient charity achieved a response rate of 32%. [37] However the initial interest in focus groups was relatively low and fewer individuals followed up that initial interest by making arrangements for a focus group, and fewer again actually participated in a focus group. The reasons for this lack of interest and attrition were not clear and it is an area to consider for further improvement should similar research be conducted in the future.

Chapter 6: Conclusion

6.1 The IBD integrated care pathway

Whether the IBD integrated care pathway was successful or should not be answered with a simple 'yes' or 'no'. The process under evaluation included the design, implementation and operational phases of the pathway and each should be considered on its own merits.

With respect to the design, the project can be considered to have been successful as a pathway was designed which was acceptable to all parties, concordant with the IBD Standards, and which was founded on clinical evidence and relevant experience from an earlier project. The pathway design underwent much refinement during the evaluation. Some specific products required to ensure that the designed project could be operated were, however, not delivered.

With respect to implementation the pathway appeared, superficially at least, to have been successful with almost all eligible practices making an explicit and affirmative choice to participate. The majority of practices and many primary care health professionals attended a training and education session. However behind these headline figures lie details which demonstrated that the pathway launch was delayed, practice participation took longer than expected, that although agreement for participation had been secured actual pathway-related activity appeared to be much less, and there were some deficiencies in the training and education sessions.

With respect to the operational phase of the pathway, initial results would appear to indicate that only a small volume of the expected work had been delivered and that communication between clinical teams across the interface had not been effective. In addition, certain aspects of the pathway did not appear to be operating as intended and communication about the project to patients was poor or non-existent. Consequently none of the expected health service benefits from the pathway, such as reduced admissions and burden of disease, could be identified. However success must be considered alongside temporal parameters. For example, the problems with the operation of the pathway may, in the longer term, transpire to be mere 'teething problems' but only observation for a longer period of time will reveal which.

Objectively, the IBD pathway did not deliver a significant degree of integration. The area in which it had the greatest potential to deliver a more tangible level of integration, informatic integration, appeared not to have been realised in the pathway's operation, or at least not in the early stages of operation observed by this evaluation. However, the pathway did deliver integrated care, as opposed to integration, in more subtle ways. Integrated care for IBD patients might not necessarily result in the removal of boundaries but easier and clearer negotiation across the

primary and secondary care interface. In this respect the pathway can be considered to have delivered integrated care although there was still plenty of scope left for further gains. Examples of attainment of integrated care were the stipulation of deadlines for access to specialist care, expanded access to the IBD specialist nurse including the introduction of novel modes of communication to the hospital IBD team, and standardisation of a key component of care through consistent application of the annual review in both primary and secondary care.

A less tangible, but no less important, aspect of integrated care which the pathway did generate was greater communication between primary and secondary care clinicians. The project board could serve as the basis for a local IBD clinical network. Both primary and secondary care clinicians reported, anecdotally, improved levels of, and confidence with, communicating with their colleagues in the alternative sector. This could serve as the foundation to realising more observable and tangible levels of integration or integrated care. However, the conclusion of the impact of the pathway on integrated care at the close of the evaluation was that it was limited in scope and extent and few of the pre-existing barriers had been noticeably influenced.

The involvement of clinicians in key roles within the pathway design process can reasonably lead to the pathway being described as clinically led. The empowerment of clinicians was not uniform with primary care clinicians (GPs and practice nurses) appearing to gain more in this respect than hospital-based clinicians both empirically and through the pathway itself.

Overall, the pathway did address directly and indirectly a significant number of the IBD Standards, either wholly or partially. However, in the main this appeared fortuitous, and seldom were the IBD Standards explicitly referred to during the discussion of the finer details of the pathway design. Crucially, however, no part of the pathway was in direct conflict with any of the IBD Standards. As the connection between the pathway and the IBD Standards was more implicit than explicit linking project components and milestones to specific standards may be useful to reinforce that connection and to maintain focus and engagement for the project.

The overall impression of the pathway at the point of the evaluation close was one of unfulfilled potential and underachievement. That is not to say that it won't achieve its full potential and deliver its implied objectives in the longer term, but the project was beset by a number of small and subtle challenges which collectively served to delay and inhibit successful operation at the point of the evaluation close.

The fundamental shortcomings were a lack of leadership, strategic direction, and proper project management. Crucially the project lacked a set of explicitly defined, consistent and agreed aims or objectives. It is difficult to deliver a project where members of the project board are not necessarily working to the same or an agreed agenda. A key aim for the project for some members of the project board was a reduction in hospital admissions with an attendant reduction

in healthcare expenditure. However the basis for the assumed reductions in admission rates was not provided and is best be described as aspirational than founded in any reliable evidence-base.

However, despite some crucial and fundamental problems with the project set-up, the project survived and did deliver a pathway which could reasonably be considered to meet the minimum specification, albeit significantly behind schedule and to a lesser specification that had been envisaged at earlier stages of the project.

Some of the challenges which the project experienced were of its own making and some would have been difficult to foresee. However a lack of a project plan and active, robust project management meant that the project neither identified nor coped as well as it could have. Individually, each of these challenges was of a relatively small impact but the cumulative effects led to a significant impact.

The project was not obviously beset by protectionist behaviour from any party, or personal disagreements between members of the project board. Although the end-of-evaluation interviews did reveal some organisational tensions of limited extent these did not appear to impair the project.

Occasionally brief episodes of tension relating to clinical or care parameters did emerge but these were negotiated amenablely by all parties. This should be seen as a major strength of the project as it was not afflicted by one of the recognised organisational barriers to integrated care. The general feeling generated by the project board was one of genuine co-operation and partnership between parties. It was not clear if this cordiality would have been maintained had the project moved into a more active and broader operational phase where organisational tensions may have become more overt.

At the end of the evaluation the pathway was in a strong position to deliver its implied aims and objectives, not least with the appointment of a clinical champion who appeared to possess useful attributes to perform such a role. However, the fundamental deficits identified would still need resolution and the project board should plan for future challenges, particularly those relating to further reorganisations within the local and national NHS.

Validation of the findings of the IBD pathway project can be inferred from the common findings not just with the Department of Health evaluation but with the wider healthcare-change research field.

6.2 Community pharmacy

The overall impression from the focus groups was that pharmacists and pharmacies were well regarded and respected, although some issues existed regarding the pharmacy environment. IBD

presented several barriers to patients interacting with community pharmacists in pharmacies. Issues relating to medication were common and may often present subtly.

The evaluation identified that there is some scope for community pharmacists and community pharmacy as a whole to become more involved with the management of IBD in adult patients. Pharmacy-based services for IBD patients should be introduced cautiously and initially at a basic level. There was a substantial potential unmet need in the care of IBD patients with respect to medications and drugs as indicated by the survey responses. However the level of involvement may need to vary considerably between patients with some not requiring or not feeling comfortable with community pharmacist involvement and others very comfortable. Pharmacists could offer a range of services for patients to choose from. Service developments will need co-operation from general medical practitioners and local specialist IBD teams, which are usually hospital based. Pharmacists can build on a number of positive aspects relating to the profession and existing facilities. Pharmacies may need to improve infrastructure, primarily through provision of adequate private consultation facilities, in order to deliver some services for adult IBD patients. Pharmacists must be sensitive to the specific needs and requirements of IBD patients. The healthcare system should seek to improve community pharmacy integration with other primary and secondary healthcare service providers, particularly in the domain of information sharing.

6.3 Integrated care and community pharmacy: Combined findings

If the IBD integrated care pathway project is to be supported in the longer term then it could develop to include a role for community pharmacy as described. However the position of the pathway at the time of the evaluation close did not support further complexity and uncertainty with expansion to include novel service delivery with community pharmacy.

6.4 Closing statement

As at the evaluation close in March 2012 the IBD integrated care pathway project had overcome several barriers, challenges and internal deficiencies. It was in the strongest position it had been during its history and crucial to this was the appointment of a clinical leader for the project. However, effort, communication and networks will need to be maintained and developed if the project is to realise its aims of improved patient outcomes, satisfaction, and reduced healthcare utilisation. Additional resources, especially in continued project management and oversight, will likely also be required. A dynamic balance between separate but not necessarily independent enabling and inhibitory factors is determined by complex interactions. New and unexpected challenges may appear and change processes need to be resilient or opportunistic depending on the nature of the challenges faced.

Change within a large and complex healthcare system is achievable but most likely at a slower rate and in a different direction to that which was planned or expected.

William Horsley. April 2015.

Appendices

Appendix 1. Final specification of the IBD annual review summary

IBD Annual Patient Review	
Patient Name: _____	D.O.B: _____
NHS Number: _____ GP Practice: _____	
Date and Place of Review: _____	
Is the patient on the practice IBD register?	
Yes <input type="checkbox"/>	No (Give Reason) <input type="text"/>
Is there a documented diagnosis?	
Ulcerative Colitis <input type="checkbox"/>	Crohn's Disease <input type="checkbox"/>
	Indeterminate IBD <input type="checkbox"/>
Has the patient information been given?	
Crohn's and Colitis UK <input type="checkbox"/>	CORE <input type="checkbox"/>
	Patient UK <input type="checkbox"/>
	None <input type="checkbox"/>
Have the patient support group details been provided?	
Yes <input type="checkbox"/>	No (Give Reason) <input type="text"/>
Has advice been provided on smoking?	
Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Non Smoker <input type="checkbox"/>
Is the patient on 5-ASA medication?	
Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Details <input type="text"/>
Has adherence to medication been assessed?	
Yes <input type="checkbox"/>	No (Give Reason) <input type="text"/>
Has symptom control been assessed? (If yes, provide score)	
Yes <input type="checkbox"/>	No (Give Reason) <input type="text"/>
Has quality of life been assessed? (If yes, provide score)	
Yes <input type="checkbox"/>	No (Give Reason) <input type="text"/>
Have you screened for depression?	
Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Details <input type="text"/>
Does the patient know how to access hospital / IBD nurse for flare ups?	
Yes <input type="checkbox"/>	No (Give Reason) <input type="text"/>
Does the patient have access to a dietician?	
Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Refused <input type="checkbox"/>
Have complementary and alternative therapies been discussed?	
Yes (Provide details) <input type="text"/> No <input type="checkbox"/>	
Has the annual review been carried out? (Please enter details below)	
FBC <input type="checkbox"/>	CRP <input type="checkbox"/>
	Flu Vacc <input type="checkbox"/>
LFTs <input type="checkbox"/>	U&Es <input type="checkbox"/>
	Pneu Vacc <input type="checkbox"/>
B12 <input type="checkbox"/>	Creatinine <input type="checkbox"/>
	Other <input type="text"/>
	Assessment for (date): <input type="text"/>
	Bone Health <input type="text"/>
	Colonoscopy <input type="text"/>

Appendix 2. ICD-10 codes relevant to IBD

Non-infective enteritis and colitis (K50-K52)

K50. Crohn's disease [regional enteritis], incl. granulomatous enteritis, but excl. ulcerative colitis

K50.0 Crohn's disease of small intestine, incl. Crohn's disease [regional enteritis] of duodenum, ileum, jejunum, ileitis: regional, terminal; but excl. Crohn's disease of large intestine

K50.1 Crohn's disease of large intestine, incl. colitis; granulomatous, regional Crohn's disease [regional enteritis] of colon, large bowel, or rectum; but excl. Crohn's disease of small intestine

K50.8 Other Crohn's disease, incl. Crohn's disease of both small and large intestine

K50.9 Crohn's disease, unspecified, incl. regional enteritis not otherwise specified

K51. Ulcerative colitis

K51.0 Ulcerative (chronic) pancolitis, incl. backwash ileitis

K51.2 Ulcerative (chronic) proctitis

K51.3 Ulcerative (chronic) rectosigmoiditis

K51.4 Inflammatory polyps

K51.5 Left sided colitis, incl. left hemicolitis

K51.8 Other ulcerative colitis

K51.9 Ulcerative colitis, unspecified

K52. Other non-infective gastroenteritis and colitis

K52.3 Indeterminate colitis

K52.8 Other specified non-infective gastroenteritis and colitis, incl. collagenous colitis, eosinophilic gastritis or gastroenteritis, lymphocytic colitis, microscopic colitis (collagenous colitis or lymphocytic colitis)

Appendix 3. Participant information sheet for Focus Groups – pathway evaluation

An Integrated Care Pathway for patients with Inflammatory Bowel Disease

We would like to invite you to take part in a research study which is evaluating the [redacted] integrated care pathway for patients with inflammatory bowel disease (IBD). Before you decide whether to participate you need to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully. Talk to others about the study if you wish, especially your friends and family, fellow IBD patients, advisers from Crohn's & Colitis UK and your doctor & nurse.

This information leaflet will provide you with details of the purpose of the study and what will happen to you if decide to take part. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. If you do wish to take part then there is a consent form for you to complete and return to us. We have provided a stamped addressed envelope to return it in if you do decide to participate.

What is the purpose of the study?

The [redacted] IBD pathway is the first example in the UK of such a package of care being delivered for IBD patients. The pathway is designed to deliver the service standards for IBD healthcare which were published in 2009. We will be evaluating the pathway to determine what factors influence its success or otherwise, as well as measuring any changes in use of healthcare and health outcomes.

An important part of the evaluation is to find out what the impact of the pathway is on patients with IBD. This is important information to obtain so that if other areas in the UK which wish to introduce a similar pathway for their IBD patients they will have extra information available and might do things differently.

We would like to speak with IBD patients in [redacted] and conduct group interviews with five or six patients at a time. These are known as focus groups.

Why have I been invited?

You have been invited to take part because you are an IBD patient from one of the participating medical practices in [redacted]. This information leaflet, along with the introductory letter and consent forms, have been sent to you directly from your medical practice on behalf of the research team so your confidential details have not been shared with us. It is possible that more people will volunteer to take part in the focus groups than are required. If that happens then we will write to everyone who has volunteered and let them know whether we would like them to participate or not.

What will I have to do?

You are being invited to take part in a focus group with four to five other IBD patients from [redacted]. In the focus groups you will be able to discuss your experiences of care for IBD both before and after the introduction of the new care pathway. We anticipate that each session will last up to two hours. Sessions will take place at a time that is convenient for all participants, so this could mean possibly an evening or a weekend. The sessions will take place at Durham University's Stockton Campus near the Tees Barrage and transport assistance is provided.

What will happen to me if I take part?

We are keen to obtain your frank and honest views about the topics discussed. We can assure you anything that happens in the sessions will be anonymous and confidential, and nothing that is said will be passed on to anyone else in a way that will identify you. However we would also like you to regard any information discussed by other participants as confidential.

We will make a sound recording of the focus groups so we don't miss any important information when we write reports on them. After the focus groups we will copy what is said into a typed document and then delete the sound recording. Each focus group will be directed by the lead researcher, Mr William Horsley.

He will also have an assistant present to make brief notes during the session and to arrange the sound recording.

Following each focus group there will be a period during which you will be free to ask further questions or discuss other issues relevant to the topics discussed with the person running the group or their assistant. These discussions will not be recorded at all. We will do our best to provide any further information that you request at that time.

What are the possible benefits of taking part?

The focus group will provide you with an opportunity to share your experiences and listen to the experiences and views of other people with IBD.

We can't promise you that your participation in a focus group will help you individually but the information we get could help improve the introduction of similar care pathways for IBD patients in other parts of the UK, or indeed it might help shape the future of the [redacted] pathway.

Do I have to take part?

Participation in these focus groups is entirely voluntary and it is up to you to decide if you take part. After you have read this information sheet, if you still want to participate, please complete the consent form and sign it to show that you have agreed to take part. There is a copy of the consent form for you to keep with this information sheet.

Of course, if we have more people volunteering to take part than we require for the focus groups then unfortunately some people will not be able to take part in a focus group. We will inform you at the earliest opportunity whether you will be required for a focus group, but if you are not required at first we would be grateful if you could act as a reserve participant in case someone else drops out.

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

You are free to withdraw at any time, without giving a reason. This will not affect the care you receive or your registration with your general practice or membership of Crohn's & Colitis UK (if applicable). If you decide to withdraw after a focus group has started then anything you say up until the point of withdrawal will be kept and used as part of the analysis for this study.

If you do change your mind and decide not to attend the focus group for any reason, please let us know as soon as possible because we may be able to find a replacement.

Will my taking part in the study be kept confidential?

Yes. The only people who will know that you have taken part will be the research team and the other patients who participate in the same focus group as you. The research team will not share your details with anyone else and all reports of the sessions will be anonymous. The discussion at the focus group will be recorded and typed up, but your name will not be put on the transcript. Participants will be asked to keep everything that is discussed in the focus group confidential; however it is possible that members of the focus group may discuss what happened at the group with, for example, members of their family; therefore absolute confidentiality cannot be guaranteed. The only information that we will keep is a consent form which you will be required to fill in. This will be kept in a locked cabinet within Durham University and will not be accessible to anyone outside of the research team.

What will happen to the results of the research study?

We intend to write up the results of our overall evaluation of the care pathway in 2012. The focus groups will be included within that overall evaluation but they may also be reported separately either before or after that. We will publish results of the evaluation in an academic journal and we will share our findings at academic conferences. In publishing details of the focus groups we may wish to quote statements, comments or conversations that occurred, although as with all details they will be anonymous. The research team will be happy to provide copies of these reports on request, and discuss and explain them if required.

Will it cost me anything to take part?

No, but we are asking you to give up some of your time. The focus group sessions will be held at Durham University's Stockton Campus with facilities that are accessible to all.

If you require help with transport we can arrange for taxis, and if you make your own transport arrangements we will reimburse the cost. Parking at the site is free. We will also provide some light refreshments. You will be handed an expense claim form to complete when you arrive and we will aim to reimburse you with cash on the same day. If you prefer we can send a cheque to you instead.

Will my GP or consultant or nurse be involved?

No. No one other than you, the research team and the other patients in the group will know that you have taken part. All reports from the focus groups will be anonymous. Of course, if you wish to tell people that you took part in a focus group then you are free to do so.

Who is organising and funding the research?

This research is funded by Crohn's & Colitis UK, also known as the National Association for Colitis & Crohn's Disease (NACC), a leading charity for patients with IBD and their families. The lead researcher is William Horsley, a researcher at Durham University.

Who has reviewed the study?

This research has been approved by the Research Ethics Committee at Durham University and by the NHS National Research Ethics Service Committee East Midlands – Derby 2.

Harm

We do not foresee anything harmful happening to you in the focus groups, which you are free to leave at any time. If talking about your condition or anything else that arises makes you upset in any way we will make sure someone is able to offer you help at the earliest opportunity. If you wish to speak to someone confidentially after the focus group then you can contact Dr Greg Rubin on 0191 33 40031.

Is there any reason why I shouldn't take part?

This invitation is only open to persons aged 18 years or older at the time of providing consent to participate. In addition, you should have a diagnosis of ulcerative colitis or Crohn's disease, both forms of inflammatory bowel disease.

What if there is a problem?

We will be following all appropriate ethical and legal practice and all information about you will be handled in confidence.

If you have a concern about any aspect of this study you should in the first instance contact the lead researcher who will do his best to answer your questions and address your concerns: William Horsley on 0191 33 40804, or E-mail: william.horsley@durham.ac.uk

If you remain unhappy and you still have concerns then you can contact:


Rebecca Perrett
Research and Development Manager
Wolfson Research Institute, Durham University, Queen's Campus, Stockton-on-Tees,
TS17 6BH. Tel: 0191 334 0425. E-mail: rebecca.perrett@durham.ac.uk

Further information and contact details

If you would like any more information or if you would like to discuss anything verbally or in person please contact the lead researcher, Mr William Horsley, on 0191 33 40804, or E-mail: william.horsley@durham.ac.uk

Please keep this information sheet and one copy of the consent form for your records.

Appendix 4. IBD patient pharmacy survey



Durham University
School of Medicine and Health

Community Pharmacy and Inflammatory Bowel Disease
A short survey for members of the
[redacted] branch of Crohn's & Colitis UK
December 2010

Within this survey there are some terms and expressions used which have the following meanings:

A community pharmacy: This could be a local high street chemist, or part of a national chain such as Boots the Chemists or Lloyds Pharmacy, or a pharmacy located in the same building as your doctor's surgery or health centre but run as a separate business, or a pharmacy in a supermarket or out-of-town shopping centre. It does not include pharmacies that are run by doctors in their own surgeries or practices.

IBD: Inflammatory bowel disease, most commonly ulcerative colitis or Crohn's disease, but also including other diagnoses.

Monitoring: In relation to medicines this has a number of meanings of which some examples are provided. This could mean checking whether a drug is working by assessing how symptoms have responded to a treatment, or taking and checking blood test results, or checking for and reporting of side effects.

Manage or managing: In relation to medicines this has a number of different meanings of which some examples are provided. This could mean helping you avoid side effects by adjusting the way you take your medicines, helping you to choose a medicine that is more convenient to take for example with fewer doses or more convenient packaging, or it could relate to helping you remember to take your medicines using a chart, or packaging your medicines into a daily dose device, or helping you order your prescriptions on time so you do not run out of medicine. Please return completed surveys at the earliest convenience and not later than Friday 7th January 2011.

By return of this survey you are providing consent to participate in this project

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Firstly, we have eight questions about your medicines.

1. Do you currently use medicines prescribed for you for IBD?

Yes

No go to question 7

2. Who currently prescribes your IBD medication? (tick all that apply)

Hospital doctor

General practitioner (GP)

Hospital nurse

Other nurse (e.g. working in practice or district nurse)

Hospital pharmacist

Community pharmacist

Other (please indicate): _____

3. Where are your IBD medicines dispensed? (tick all that apply)

Community pharmacy

Supermarket in-store pharmacy

Hospital pharmacy

General practice surgery (e.g. if your doctor also dispenses medicines)

Internet pharmacy

Other (please indicate): _____

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4. If your IBD medication is dispensed by a community pharmacy or an in-store supermarket pharmacy, is that at the same pharmacy? (tick only one)

Always	<input type="checkbox"/>
Usually	<input type="checkbox"/>
Sometimes	<input type="checkbox"/>
Barely	<input type="checkbox"/>
Never	<input type="checkbox"/>
Not sure	<input type="checkbox"/>

5. If your prescription is usually or always dispensed at the same pharmacy, what are the factors that influence that decision? List the three most important.

1.
2.
3.

6. Who usually collects your prescription once it has been dispensed? (tick only one)

You	<input type="checkbox"/>
Family member	<input type="checkbox"/>
Friend or neighbour	<input type="checkbox"/>
Social services carer	<input type="checkbox"/>
A health care professional (e.g. district nurse)	<input type="checkbox"/>
It is delivered	<input type="checkbox"/>

Other (please indicate):

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7. Do you take other medicines for IBD which are not prescribed for you? This might include medicines that you buy from a pharmacy, supermarket or grocery store, or herbal or vitamin preparations.

Yes	<input type="checkbox"/>	go to question 8
No	<input type="checkbox"/>	go to question 9

8. If you answered 'yes' to question 7, where do you obtain these medicines? (tick all that apply)

Community pharmacy	<input type="checkbox"/>
Supermarket (including the in-store pharmacy)	<input type="checkbox"/>
General store (e.g. local convenience store)	<input type="checkbox"/>
Health food, herbal or vitamin store (e.g. Holland & Barrett)	<input type="checkbox"/>
Internet / online	<input type="checkbox"/>
Mail order, or from a magazine or television advertisement	<input type="checkbox"/>
Given to you by family or friends	<input type="checkbox"/>
Other (please indicate): <input type="text"/>	

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9. Here are twenty short statements about community pharmacists and their staff and services. If you usually use the same pharmacy then your answers should relate to that pharmacy. Otherwise, please relate your answers to the most recent visit to a community pharmacy that you can recall. If you do not recall visiting a community pharmacy please tick the box and go to question 10.

	Poor	Fair	Good	Very Good	Excellent	No opinion
The professional appearance of the pharmacy						
The availability of the pharmacist to answer your questions						
The pharmacist's professional relationship with you						
The pharmacist's ability to advise you about problems that you might have with your medications						
The promptness of prescription drug service						
The professionalism of the pharmacy staff						
How well the pharmacist explains what your medications do						
The pharmacist's interest in your health						
How well the pharmacist helps you manage your medications						
The pharmacist's efforts to solve problems that you have with your medications						
The responsibility that the pharmacist assumes for your drug therapy						
How well the pharmacist instructs you about how to take your medications						
Your pharmacy services overall						
How well the pharmacist answers your questions						
The pharmacist's efforts to help improve your health or stay healthy						
The courtesy and respect shown to you by the pharmacy staff						
The privacy of your conversations with the pharmacist						
The pharmacist's efforts to assure you that your medications do what they are supposed to						
How well the pharmacist explains possible side effects						
The amount of time the pharmacist offers to spend with you						

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10. Here are twelve short statements about community pharmacy and pharmacists. Please indicate your response to each statement by placing a tick in the appropriate box.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
When I visit a community pharmacy I feel that I can discuss medication issues with the pharmacist					
My community pharmacy lacks privacy for me to discuss issues with the pharmacist or other staff					
I would like my community pharmacist to be more involved in the overall management of my condition					
If I have a question about my medicines the pharmacist is always available					
There is no need for a pharmacist to be involved with the management of my condition					
My community pharmacist does not have the time to discuss medication related issues with me					
I would be happy to have my medication monitored in a community pharmacy					
Pharmacists are suitably qualified to take on a bigger role in the management of my condition					
At times I struggle to manage my medication					
I would not feel comfortable with a community pharmacist being more involved in the management of my condition					
If I have a question about one of my medications I ask my pharmacist first					
My community pharmacy has a suitable place for me to discuss confidential issues if I need to					

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Finally, we would be grateful if you could answer five questions about yourself:

11. Are you

Female

Male

12. Which age group are you?

Under 18 years

18 to 29 years

30 to 39 years

40 to 49 years

50 to 59 years

60 to 69 years

70 to 79 years

80 to 89 years

Older than 89 years

13. What form of inflammatory bowel disease do you have?

Crohn's disease

Ulcerative colitis

Other IBD diagnosis

14. Regardless of your official diagnosis, how would you personally describe the severity of your IBD?

Mild

Moderate

Severe

15. What is the first part of your postcode? e.g. TS17, DL3

Thank you for completing this survey. Please return it in the pre-paid envelope provided. We will endeavour to relay the results at a future meeting of your local Crohn's & Colitis group.

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This section has been left blank for you to provide any comments or suggestions regarding any aspect of this survey or any issues you may have relating to the use of and access to medicines.

Thank you for completing this survey.

Please return it in the pre-paid envelope provided at the earliest convenience.



Durham
University

School of Medicine and Health
Genio W Hendry

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Appendix 5. Introductory letter accompanying pharmacy survey



Durham
University

School of Medicine and Health

Shaped by the past, creating the future

William Horsley
Researcher
Durham University
School of Medicine and Health
Wolfson Research Institute
Queen's Campus, University Boulevard
Stockton on Tees, TS17 6BH
Tel: 0191 3340804
e-mail: william.horsley@durham.ac.uk

29th November 2010

Dear Crohn's & Colitis UK Member

Please find enclosed a short survey being conducted by Durham University in conjunction with Crohn's & Colitis UK (formerly the National Association of Colitis and Crohn's Disease, NACC). The aim of this research is to understand current arrangements for use of and access to medicines for patients with inflammatory bowel disease (IBD), and to understand the extent and the perception of contact that you might have with community pharmacies. Information obtained is anonymous so responses cannot be associated with any individual. These surveys have been sent to you directly by Crohn's & Colitis UK so that your confidential details have not been shared with us. This research has been partly funded by the Pharmacy Practice Research Trust.

We estimate the survey will take up to ten minutes to complete and there is a pre-paid stamped addressed envelope for you to return it to us. You do not have to answer all the questions if you do not wish to, in which case you can leave a question blank. Returned surveys will not be kept and will instead be securely disposed of after the results have been recorded. We hope you will be able to spare some time to complete the survey and return it to us at your earliest convenience and not later than Friday 7th January.

We would also like to conduct some interviews with groups of five or six patients at a time to investigate further the nature of interaction between patients with IBD and their community pharmacies. These sessions will be held in Stockton and transport assistance is provided. If this is something that interests you and you would like more information please contact me using the details above or return the yellow card in the yellow stamped addressed envelope provided.

We will endeavour to report the research results to the [redacted] branch of Crohn's & Colitis UK in the near future. Please do not hesitate to contact me using the details above if you or your friends or family have any questions.

Many thanks in advance for your help,

Yours sincerely

A handwritten signature in black ink that reads "William Horsley".

William Horsley, on behalf of the research team

School of Medicine and Health, Wolfson Research Institute, Queen's Campus, Stockton-on-Tees TS17 6BH.
Telephone +44 (0) 191 334 0373 Fax +44 (0) 191 334 0374 www.durham.ac.uk

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Appendix 6. Focus group (pharmacy) notice of interest response card

Please send me information about the patient group interviews that you will be carrying out as part of research into community pharmacy and inflammatory bowel disease by Durham University and Crohn's & Colitis UK. I understand that after I receive this information I will not be contacted again unless I wish to proceed, that the details I provide on this form will only be used for the purpose of providing me with information about the project, that these details will not be retained and that this card will be securely disposed of within ten working days of receipt.

Name:

Address:

e-mail address:

Please indicate your preferred method of contact: E-mail Post

VERSION 2 (20/12/2010)

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Appendix 7. Focus group (pharmacy) introductory response letter



Durham
University

School of Medicine and Health

Shaped by the past, creating the future

William Horsley
Researcher
Durham University
School of Medicine and Health
Wolfson Research Institute
Queen's Campus, University Boulevard
Stockton on Tees, TS17 6BH
Tel: 0191 3340804
e-mail: william.horsley@durham.ac.uk

[DATE]

Dear Crohn's & Colitis UK Member

Thank you for your interest in participating in a focus group interview regarding community pharmacy and patients with inflammatory bowel disease. For that purpose I enclose a patient information leaflet and two copies of a consent form. I hope the leaflet contains all of the information you require. Please read it thoroughly and if you would still like to participate you are requested to complete both copies of the consent form and return one of them to me in the pre-paid envelope provided. You should then keep the other copy of the consent form and the leaflet for future reference. If you do not wish to proceed with participation then you need do nothing more.

I hope to arrange the focus groups during February on a day and at a time that is convenient to all participants. This will be arranged once a sufficient number of individuals have volunteered. I will be back in touch in the New Year with those who do volunteer.

If you have any questions please do not hesitate to contact me.

Once again, many thanks in advance

Yours sincerely

A handwritten signature in black ink that reads "William Horsley".

William Horsley, on behalf of the research team

School of Medicine and Health, Wolfson Research Institute, Queen's Campus, Stockton-on-Tees TS17 6BH.
Telephone +44 (0) 191 334 0373 Fax +44 (0) 191 334 0374 www.durham.ac.uk

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Appendix 8. Focus group (pharmacy) consent form

Consent Form

Community pharmacy and inflammatory bowel disease

Lead researcher: Mr William Horsley, School of Medicine & Health, Durham University. 0191 3340804

	Please tick one		Please
	Yes	No	initial box
1. I confirm that I have read and understand the information sheet dated December 2010 for the above study. I have had the opportunity to consider the information and ask questions and, where relevant, these have been answered satisfactorily.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without affecting the care I receive.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I understand that all relevant regulations regarding data protection will be adhered to, and that confidentiality will be protected and anonymity assured by the research team.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. If so requested, I agree to take part in the above study and confirm that I am aged 18 years or older.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Name of participant Date Signature

Address: _____

Telephone: _____

E-mail address: _____

I would prefer to be contacted by: Post Telephone E-mail

In order to help us organise the focus group interviews we would be grateful if you could provide the following information.

I am aged 18 to 49 years I am aged 50 years or older

I have Crohn's disease I have ulcerative colitis

Appendix 9. Focus group (pharmacy) scenarios

Medication adherence: How would you feel if your community pharmacy was to provide specific services to help with adherence to medicines, for example

- a. Providing leaflets and other written information
- b. Education and counselling
- c. Monitoring of prescription volume use
- d. Providing devices that help with adherence, such as dispensing medicines into daily dose dividers

Supplemental and enteral feeds: How would you feel if your community pharmacy was to provide advice about which supplemental or enteral feeds might be suitable, for example

- a. Providing information and other written information about the different products available
- b. Providing direct verbal or written advice about which might be the most suitable products following discussion of your needs
- c. Providing samples of products for you to try whilst present
- d. Providing samples of products for you to take home and try
- e. Taking responsibility for ordering sufficient quantities of a suitable range of products to meet your needs

Managing a relapse: How would you feel if your community pharmacist was able to support you when you experience a relapse, for example

- a. Providing counselling about practical measures
- b. Providing counselling about purchasing appropriate over-the-counter (non-prescription) medicines and dietary products
- c. Providing a supply of pre-defined medication that can be dispensed to you when a relapse is experienced
- d. Prescribing appropriate medication for you to help manage your relapse

Monitoring of medication: How would you feel if your community pharmacy was to provide specific services to help with monitoring of your medicines, for example

- a. Providing information and other written information about possible 'danger' symptoms, and how often certain medications need monitoring
- b. Providing a reminder of when certain tests are due
- c. Taking samples required for tests and ensuring they are properly dispatched
- d. Receiving results of tests and providing these to you or directly to your GP
- e. Making adjustments to the doses of your medicines depending on test results

Choice of medication: How would you feel if your community pharmacists advised you on the choice of medication for your condition, for example

- a. On selecting between dietary or medical control of your symptoms
- b. On selecting the most suitable type of medication following discussion of your needs (e.g. steroids vs. aminosaliclates)
- c. On selecting the most suitable presentation following discussion of your needs (e.g. oral vs. topical, or modified-release vs. standard preparations)

Looking after your associated health care needs: How would you feel if your community pharmacy provided other health care services that are of particular benefit to IBD patients, for example

- a. Checking for signs of osteoporosis (e.g. conducting a simple scan of bone mineral density)
- b. Providing smoking cessation advice and services
- c. Providing advice and services relating to the identification and management of depression
- d. Weight and body mass monitoring

Appendix 10. Participant information sheet for Focus Groups (pharmacy)

Community pharmacy and management of IBD

We would like to invite you to take part in a research study on whether there is a role for community pharmacy in the management of patients with inflammatory bowel disease (IBD). Before you decide whether to participate you need to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully. Talk to others about the study if you wish, especially fellow members of Crohn's & Colitis UK (formerly the National Association for Colitis and Crohn's Disease, NACC). This information leaflet will provide you with details of the purpose of the study and what will happen to you if you take part. Please do not hesitate to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. If you do wish to take part then there is a consent form for you to complete and return to us. We have provided a stamped addressed envelope to return it in if you do decide to participate.

What is the purpose of the study?

The study aims to discover if there is any need or desire from patients with IBD for their community pharmacy, including community pharmacists and other staff, to be involved in the management of their condition. The study will also explore what that role might be.

If the results do indicate that there is a role for community pharmacy then this could result in pharmacies offering specific services in the future. Of course, there might not be any need for community pharmacy to be involved, or any desire from patients for community pharmacy to be involved, and we would report this message in our research findings.

You may have already completed a short survey about the extent, nature and your perceptions of contact between you and your community pharmacy. The survey results will be combined with the results of these group interviews in one study which will show whether IBD patients have any need or desire for specific services from their community pharmacies and, if applicable, what those services could be.

Why have I been invited?

Working with the [redacted] branch of Crohn's & Colitis UK and building on the close links between our research team and Crohn's & Colitis UK, we are inviting members to take part in interviews in groups of five or six. These are known as focus group interviews.

As a member of Crohn's & Colitis UK we have assumed that you have a form of inflammatory bowel disease. We would like to seek your views about the extent and nature of contact that you have with your community pharmacy and to explore some potential roles and tasks that could be undertaken by community pharmacies and pharmacists in the management of IBD.

Do I have to take part?

Participation in focus groups is entirely voluntary and it is up to you to decide. Once you have read this information sheet, if you do wish to participate please complete the consent form and sign it to show that you have agreed to take part. You are free to withdraw at anytime without giving a reason. This would not affect the care you receive or your membership of Crohn's & Colitis UK. There is a copy of the consent form for you to keep with this information sheet. It is possible that we might have more people wishing to participate in the focus groups than we need. If you are not chosen to participate we will contact you to inform you of this.

What will I have to do?

You are being asked to take part in a focus group with four to five other people with IBD and also members of Crohn's & Colitis UK. In the focus group you will be able to discuss your experiences of community pharmacy, how you perceive community pharmacy services, and what you would think if community pharmacies were to provide some additional services for IBD patients. We anticipate the discussion lasting up to two hours. The sessions will take place at a time that is convenient for all participants, so this could mean possibly an evening or a weekend. The sessions will take place at Durham University's Stockton Campus near the Tees Barrage.

What will happen to me if I take part?

We are keen to obtain your frank and honest views about the topics discussed. We can assure you that everything that happens in the sessions will be anonymous and confidential, and nothing that is said will be passed on to anyone else in a way that will identify you. However we would also like you to regard any information discussed by other participants as confidential.

We will make a sound recording of the focus groups in order not to miss any important information when we write reports on them. Soon after the interviews we will copy what is said into a typed document and then delete the sound recording entirely. The group interviews will be directed by the lead researcher, Mr William Horsley. He will also have an assistant present to make brief notes during the session and to arrange the sound recording.

We will be pleased to make these reports available to you once they are finished and we hope to be able to present the study to your local group at some point in the future.

Following the group interview there will be a period during which you will be free to ask further questions or discuss other issues relevant to the interviews with the person running the group or their assistant. These discussions will not be recorded at all. We will do our best to provide any further information that you request at that time.

What are the possible benefits of taking part?

We cannot promise the study will help you individually, but the information we get from it could help improve the range of services available for IBD patients from community pharmacies. The focus group will provide you with an opportunity to share your experiences and listen to the experiences and views of other people with IBD.

Will my taking part in the study be kept confidential?

Yes. The only people who will know that you have taken part will be the research team and the other persons who participate in the same group interview as you. The research team will not share your details with anyone else, including Crohn's & Colitis UK, and all reports of the sessions will be anonymous. The discussion at the focus group will be recorded and typed up, but your name will not be put on the transcript, only what was said. Participants will be asked to keep everything that is discussed in the focus group confidential; however it is possible that members of the focus group may discuss what happened at the group with, for example, members of their family; therefore absolute confidentiality cannot be guaranteed. The recordings of the interview will be provided to a professional transcription service that will type a transcript of the recording and will be bound by a confidentiality agreement.

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

You are free to withdraw at any time without giving a reason and your future care and membership of Crohn's & Colitis UK will not be affected in any way. If you do change your mind and decide not to attend the focus group for any reason, please let us know as soon as possible because we may be able to find a replacement. If you withdraw during or after a focus group we will do our best to remove your data and comments from reports but this might not always be possible.

What will happen to the results of the research study?

We intend to write up the results of our study in 2011 and to publish them afterwards in an academic journal. We will share our findings at academic conferences with colleagues who will be interested in the study. We are also offering to present the results to your local Crohn's & Colitis UK branch.

Will it cost me anything to take part?

No, but we are asking you to give up some of your time. There is free parking at Durham University's Stockton Campus. The facilities are accessible to all. If you require help with transport we can arrange for taxis, and if you make your own transport arrangements we will reimburse the cost. We will also provide some light refreshments. You will be handed an expense claim form to complete when you arrive and we will aim to reimburse you with cash on the same day. If you prefer we can send a cheque to you instead.

Will my local community pharmacy or pharmacist be involved?

No community pharmacies or pharmacists are aware that this research is being conducted locally and they will not be involved. However when the research is eventually published they will have access to the same information as everyone else, which will be the published reports. They will not be able to identify any participants.

Who is organising and funding the research?

We are working with Crohn's and Colitis UK (formerly NACC) to help us identify people who might have a diagnosis of IBD and who are willing to participate in this type of research.

The research is being organised by William Horsley, a pharmacist and researcher at Durham University. He will be supported by colleagues at Durham University and also from Sunderland University. The research is funded by the Pharmacy Practice Research Trust (www.pprt.org.uk), which is a charity that specifically funds research into community pharmacy and related topics. However none of the research team are community pharmacists themselves and none have a vested interest or bias towards community pharmacy.

Who has reviewed the study?

This research has been approved by the Research Ethics Committee at Durham University to protect your safety, rights, well-being and dignity. The study has the support of Crohn's & Colitis UK. The lead supervisor, Professor Greg Rubin, is an experienced and well-respected researcher in the field of IBD and gastroenterology and has worked with Crohn's & Colitis UK (formerly NACC) for many years.

Please keep a copy of this information sheet and the consent form for your records.

Appendix 11. Practice IBD pathway agreement

Local Audit Agreement

Integrated Care Pathway for Inflammatory Bowel Disease

Background

Through a collaboration between [redacted: PCT, hospital trust, patient organisation], an integrated care pathway for patients with inflammatory bowel disease, a UK first, is being established in [redacted: locality]. There is evidence that suggests integration can be an effective way of delivering health care and that it can provide opportunities to break down barriers between primary and secondary health care, as well as health and social care. The pathway builds on current research, funded by the Health Foundation, to develop quality criteria for IBD care in general practice. This has resulted a structured review template which was piloted in 5 North East practices in 2009. The care pathway to be used in [redacted: locality] utilises this template and also follows closely the recommendations of the DH National Standards of Care for IBD (2009). This initiative will be evaluated by a research team at Durham University.

Aim

By auditing the care for patients with inflammatory bowel disease, the aim is to build upon current good practice and to develop an integrated model of care. This will ensure that individuals with IBD have high quality and appropriate management at all stages of their illness. Practices will be provided with support to develop their knowledge and skills base for IBD management

Contract Details

Application from practices will receive notification of agreement from the PCT lead within 7 working days of sending the completed application.

For information the average number of patients with IBD is 9 per 1000 registered population. The practice will be required to submit an estimated number of records to be reviewed based on this average against their registered list size as of September 2010.

The practice is required to complete the attached signature sheet in order to participate. The anticipated number of records to be reviewed is required to be submitted as part of the application and this will be reviewed and agreed by the PCT Lead for IBD. A variance of 10% against this anticipated activity will be accepted but any further variance to this must be discussed and agreed with the IBD Lead during the contract period. Please note failure to complete the anticipated number of records reviews (without a timely agreement) may incur adjustment of the registration payment (see below).

Termination of the contract by either party will require a minimum 3 months notice period, however the PCT reserves the right to terminate this contact immediately if there is evidence that the terms of this specification are not being met.

(continued on next page)

Payments

A registration payment of £120 will be paid on submission of the attached signature sheet and following agreement of activity by the PCT Lead for IBD.

A total payment of £380 to support e-learning activities for one GP and the participation of one practice nurse in 2 training sessions per year provided by the IBD nurse. This money will provide funding for back fill for nurse time if it is a lunch time or half day session. £100 will be paid on receipt of an electronic certificate of learning being provide by the GP following successful completion of an online module and £280 will be paid following nurse attendance at one of the nurse training sessions. Certificates should be forwarded to [redacted]

A payment of £35 per patient reviewed against the completed audit template will be made on receipt of satisfactory submission. The payment of £35 will be broken down into two parts £15 for validation of the register by the clinician and £20 for the subsequent nursing review.

Requirements for the IBD Audit.

Practices must conduct a review of all their patients with IBD.

In this review practices will be asked to:

- Complete the audit template to comply with the accompanying requirements.
- Review and discuss at a practice meeting the completed template prior to submission
- Patients who have died or who have moved away should be excluded.

Reporting Requirements

- Reports must be submitted electronically using the audit template. The template must be fully completed for each patient.
- Where requested, practices must be prepared to discuss the results of the review with the IBD lead or the project manager
- Participating practices must be prepared to share their returns with the researchers undertaking an evaluation of this initiative (the team is based at Durham University School of Medicine and Health and is headed by Professor Greg Rubin)

Guidance on Using the Audit template

The template has been designed to be as straight forward as possible. The information required is detailed at the top of each column and further details if needed can be found on the 'comments box' indicated in red at the corner of the 'cell'.

Some information such as, 'patients year of birth' is simply typed into the template. Other information is entered from a drop down list; in this case an arrow appears in the corner of the cell.

All fields must be completed for each patient. If a piece of information is not available enter 'NK' instead. Payment will only be made for each complete record submitted.

Submitting Your Data

You need to submit the data that you have collected to date at the end of each quarter.

Templates should be emailed to [redacted]

(continued on next page)

Signature Sheet: Integrated Care for IBD Audit

Signature on behalf of the Practice:

Signature	Name	Date

Practice Stamp

Anticipated records to be Reviewed (please use the average 9 per 2000 registered population as at September 2010).

Signature on behalf of the PCT

Name.....

Position.....

Date.....

One copy of this Agreement is to be retained by the practice, and one copy to remain with the PCT.

Appendix 12. Summed ADQ data set

Data displayed by month, quarter, and financial year for each of the PCT, the Strategic Health Authority (SHA) and the SHA data set excluding the PCT.

Year	Month	PCT	SHA	SHA less PCT
2009	April	14239	195535	181296
	May	14417	192428	178010
	June	15321	203463	188141
	1st Quarter total	43977	591425	547448
	July	15920	212911	196990
	August	13888	195844	181956
	September	16889	212959	196070
	2nd Quarter total	46697	621713	575016
	October	15249	213615	198366
	November	14442	202728	188285
	December	17141	231946	214806
	3rd Quarter total	46833	648289	601457
2010	January	15343	199469	184126
	February	13342	195520	182177
	March	17709	220141	202432
	4th Quarter total	46394	615129	568736
	Year total	183901	2476557	2292656
	April	15536	217497	201962
	May	15809	205871	190062
	June	16191	217064	200873
	1st Quarter total	47536	640432	592897
	July	17385	227820	210436
	August	15773	214013	198240
	September	16292	227238	210946
	2nd Quarter total	49450	669072	619622
	October	16384	212528	196144
	November	16639	221594	204955
	December	18505	242170	223665
	3rd Quarter total	51528	676292	624764
	2011	January	15927	209307
February		15787	205863	190076

	March	18245	238919	220675
	4th Quarter total	49959	654089	604131
	Year total	198472	2639885	2441414
	April	16652	214232	197579
	May	16637	220598	203961
	June	16752	228900	212148
	1st Quarter total	50041	663730	613689
	July	17175	228713	211538
	August	17099	225902	208804
	September	18170	237855	219685
	2nd Quarter total	52444	692471	640026
	October	16779	220925	204145
	November	17974	234125	216151
	December	18494	249446	230953
	3rd Quarter total	53247	704496	651249
2012	January	18394	226171	207777
	February	16694	225722	209028
	March	18496	248223	229727
	4th Quarter total	53585	700117	646532
	Year total	209317	2760813	2551496
Total		591690	7877256	7285566

Appendix 13. Summed DDD data set

Data displayed by month, quarter, and financial year for each of the PCT, the Strategic Health Authority (SHA) and the SHA data set excluding the PCT.

Year	Month	PCT	SHA	SHA less PCT
2009	April	14360	197750	183390
	May	14701	195005	180304
	June	15720	206690	190970
	1 st Quarter total	44781	599444	554664
	July	15866	214860	198993
	August	13876	195007	181131
	September	16892	214875	197984
	2 nd Quarter total	46634	624742	578108
	October	15620	215299	199678
	November	14628	203475	188847
	December	16978	233912	216934
	3 rd Quarter total	47226	652685	605459
2010	January	15320	202129	186809
	February	13291	196745	183454
	March	17806	222357	204551
	4 th Quarter total	46417	621230	574813
	<i>12-month total</i>	<i>185058</i>	<i>2498102</i>	<i>2313044</i>
	April	15824	219932	204108
	May	15540	207882	192342
	June	16340	220163	203823
	1 st Quarter total	47704	647977	600273
	July	17310	227935	210625
	August	15849	217049	201200
	September	16379	229200	212821
	2 nd Quarter total	49538	674184	624646
	October	16771	214985	198214
	November	16512	223139	206627
	December	18819	245130	226311
	3 rd Quarter total	52102	683254	631152
	2011	January	16258	212974
February		16249	208618	192369

	March	18318	240636	222317
	4 th Quarter total	50825	662228	611403
	<i>12-month total</i>	<i>200170</i>	<i>2667643</i>	<i>2467474</i>
	April	17172	216869	199697
	May	16934	223847	206913
	June	17193	232579	215386
	1 st Quarter total	51300	673295	621995
	July	17275	232215	214940
	August	17687	231317	213630
	September	18737	243381	224644
	2 nd Quarter total	53699	706913	653214
	October	17189	225872	208683
	November	18648	237795	219147
	December	19121	256400	237279
	3 rd Quarter total	54959	720067	665108
2012	January	18521	230484	211964
	February	17432	230974	213541
	March	18991	253623	234631
	4 th Quarter total	54944	715080	660136
	<i>12-month total</i>	<i>214901</i>	<i>2815355</i>	<i>2600454</i>
36-month total		600130	7981101	7380972

Appendix 14. Enablers and barriers to integrating care identified in the integrated care pilots evaluation (full list)

Enablers	Simple, single-faceted interventions*
	Fewer different partners
	Widespread agreement and shared values among participating staff*
	Clear communication about contributions required from different participants
	Rules to govern how partnerships should work
	Participants confident that that senior management or team leaders were strongly committed to implementing lasting change
	On-going, planned communication between senior executives in the partner organisations
	Improved communication and problem solving through co-location and face-to-face contact between participants
	Creating shared beliefs about the benefits of change*
	Effective macro- , micro- and clinical leadership
	Project 'champions', appointed or emergent*
	Sustained motivation
	Relevant training provision*
	Ability of project to deliver cost efficiencies*
	External policy reforms*
Barriers	Multiple components / interventions
	Multiple partners*
	Different information technology systems across partner organisations*
	Poor implementation of shared information (technology) solutions*
	Legal barriers to sharing data
	Absent or poor pre-existing relationships between participants and/or organisations
	Lack of professional engagement, general or specific groups – in particular primary care medical practitioners
	Absence of clear and consistent communication from leaders within organisations about what work was required and the required participant contributions*
	Uncertainty about what participants were allowed to do
	Mandated, or 'forced', changes
	Poorly shared sense of vision or strategic aims
	Poor macro- and micro- leadership
	Perceived erosion of professional identities and loss of previous roles and tasks
	Absence of, or inadequate, training*
	Management responsibilities in professionally-led processes leading to internal tensions from professional and patient perspectives

Barriers (continued)	Unaligned professional and patient views in new models of care*
	Increased participant workloads
	Poor recognition of, or response to, project risks
	Change in 'success' outcome to cost-based
	Public service bureaucracy, particularly where it caused temporal delays*
	Different employment conditions between organisations
	Budgetary regulations
	External policy reforms
	Concurrent internal reorganisations*
	Staff turn-over
	Organisational culture, including local perceptions of professional boundaries and a 'blame' or oppositional culture*

(*) Indicates also identified in the IBD pathway evaluation

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