EXAMINING THE IMPACT OF A NOVEL INTEGRATED CARE PATHWAY FOR FAECAL INCONTINENCE ON PATIENTS AND WITHIN A NATIONAL HEALTH SERVICE ORGANISATION.

by

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Abstract:

Background:

Faecal incontinence (FI) is a common healthcare problem. The management of FI patients is widely reported as being disjointed. In response to this and governmental guidance, an integrated care pathway (ICP) was implemented at a local NHS trust.

Aim:

To assess how the implementation of a community-based ICP affects the key stakeholders and to observe the process of organisational change within the trust using normalization process theory (NPT).

Methods:

Mixed methodology combining semi-structured interviews of key stakeholders, narrative interviews with patients, focus group discussion, observational work and clinical quantitative data. Qualitative data was analysed using thematic analysis and the Framework Method, with NPT being used to structure the qualitative findings.

Results:

Key facilitators to the implementation of the ICP included clinical leadership, staff commitment, teamwork, adequate clinical capacity and good clinical outcomes.

There was a delay in the implementation due to lack of organisational management input and key stakeholder time

From a patient perspective, benefits were identified such as improved access to the service and symptom improvement.

Conclusions:

An ICP for FI could provide an answer to the long-standing issues that have blighted continence services. Patients report satisfaction based on improved access to the service alongside good clinical outcomes.

Dedication:

This work is dedicated to my family, to whom I owe everything. Without you, this would not have been possible. You have all contributed to this work in more ways than I could ever describe. I remember the day when I received the call which meant I was moving to Birmingham to start a new chapter in my career. It was truly a bittersweet moment. Leaving you all for the first time was difficult but I have gained so much from my time away, both personally and professionally, and this is the culmination of that time. The memories over the years it has taken me to complete this bring a smile to my face and I will remember this time with great fondness.

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List of Abbreviations

BFNS: Bowel function nurse specialist
CCG: Clinical commissioning group
CCL: Centre for Creative Leadership
CLAHRC-BBC: Birmingham and black Country Collaboration for Leadership in Applied Health Research and Care
CNS: Colorectal nurse specialist
DDM: Deputy Divisional Manager
DGP: Dynamic graciloplasty
FMLM: Faculty of Medical Leadership and Management
FI: Faecal incontinence
FIQOL: Faecal incontinence quality of life index
GP: General practitioner
ICP: Integrated care pathway
IT: Information technology
MDT: Multi-disciplinary team
NHANES: National Health and Nutrition Examination Survey
NHS: National Health Service
NICE: National Institute for Health and Clinical Excellence
NPT: Normalization process theory
NSF: National service framework
PEC: Percutaneous endoscopic colostomy
PCT: Primary care trust
PROMS: Patient reported outcome measures
PTNS: Percutaneous tibial nerve stimulation
QALY: Quality adjusted life year
QOF: Quality and outcomes framework
QOL: Quality of life
SCCT: Sandwell community continence team
SCP: Surgical care practitioner
SEM: Standard error of the mean
SF-36: Short form 36
SNS: Sacral nerve stimulation
SWBHT: Sandwell and West Birmingham Hospitals NHS Trust

CHAPTER 1: INTRODUCTION

This chapter introduces the main topics related to the thesis including an introductory summary explaining the problem of faecal incontinence (FI) and a brief introduction to the issues related to FI services nationally. After this an insight into the background behind the study, including the standard pelvic floor dysfunction service is given, followed by a description of how and why the research project was developed. This is followed by a more detailed description of the FI service delivery issues and the government guidance issued related to this. The chapter will conclude with an outline of the aims of the research and the research questions.

Introductory Summary

FI, the inability to control the release of flatus or stool, is a major but largely hidden health issue, with a prevalence ranging from 1.5% in children to more than 50% in nursing home residents (1). In the UK, it is estimated that up to 15% of adults in the community may experience FI symptoms (2,3). Symptoms are under-reported due to embarrassment or poor access to appropriate services; one study suggests that only 15-45% of sufferers seek treatment (4). FI is clearly both distressing and debilitating, leading to social isolation and loss of confidence, especially in older people (5), and an enduring condition whose treatment traditionally ranges from containment of symptoms, through specialist nursing treatment to specialist surgical interventions (6).

Current treatment provision occurs in the community with treatments, such as containment and pelvic floor rehabilitation or within the secondary care services for the same pelvic floor rehabilitation, as well as more specialised management such as biofeedback or surgery. Whilst the treatment of FI requires sophisticated and coordinated management across a number of service boundaries, in reality the care provided is often disjointed, with patients and their carers obliged to navigate complex, fragmented systems over extended periods, with poor access to the social, psychological and specialist support needed to address their specific needs (7–9). Individuals who have a negative experience at their first attempt at seeking help will often be discouraged from seeking help again (10). For this reason it is fundamental to ensure that patients are identified and treated with evidence-based practice in an efficient, streamlined 'seamless' manner in order to achieve the best possible outcomes from conservative management and to ensure that appropriate specialist care is available for those who require it.

Thus the successful management of patients with FI clearly requires well-organised, coordinated healthcare support. The need for integrated management has been widely recognised, and over the past decade a number of Government policies have been published advocating integrated, inter-professional care for these individuals (6,11). However, despite the explicit call for integration made in these policies, services still remain largely fragmented (12,13). This is due, in part, to the fact that FI service delivery has been beset by a number of problems that have prevented the implementation of the recommendations of various Government papers and NICE guidelines in this area. Amongst these have been:

- Poor acknowledgement by sufferers of the problem, and lack of awareness that help is available (14–16)

- Lack of recognition of the problem by clinicians and/or awareness of new, more effective techniques (17)

- Changes to working practices including increased workload for community health care professionals (18)

- Poorly developed services or lack of awareness of existing services amongst clinicians (19)

The remaining parts of the introduction will focus on the service in place at the commencement of the study, the researcher and research background, the problems surrounding delivering a continence service, followed by a review of the current best practice guidance available on continence service provision for the assessment and management of patients with incontinence.

Background

Current Service

In 2008, a pelvic floor dysfunction service was developed at SWBHT, following the appointment of a Consultant Colorectal Surgeon with a specialist interest in pelvic floor disorders. This service had previously been provided by one of the Consultant Colorectal Surgeons within the Trust, who did not have a specialist interest in pelvic floor disorders but was able to offer a limited service for these patients. Following the appointment of the Consultant, a business plan was drawn up to implement and develop a pelvic floor dysfunction service, which would identify, assess and manage patients suffering from chronic constipation and FI. The business plan included the appointment of a bowel function nurse specialist and the development of specialist pelvic floor assessment techniques (pelvic floor scanning, anorectal manometry, proctography) with the help of a specialist care practitioner and the radiology department.

By 2011 the pelvic floor dysfunction service was established within the trust, providing patients with a complete service based solely within the Trust, where they could be assessed and managed without needing to travel to other hospital trusts for any diagnostic studies, which was not the case prior to this pelvic floor dysfunction service being set up. The clinical outcomes of patients were continuously measured throughout the development of the pelvic floor dysfunction service and vast improvements in outcomes were made, to a standard whereby outcome data was being presented to national and international scientific surgical and nursing meetings (9).

Following the publication of a number of government documents related to continence, including the National Institute for Health and Clinical Excellence (NICE) guidelines on Faecal Incontinence (6); Good Practice in Continence Services (11) from the Department of Health (DOH), the lead Consultant and multidisciplinary team decided to focus on improving the pelvic floor dysfunction service for patients suffering from FI. The multidisciplinary team agreed that patient access to the service; referrals into the service, the triage process and the management of people with FI could all be improved locally based on the publications by NICE[6] and the Department of Health (11). Following further dialogue between the multidisciplinary team, management within the Trust and the local Primary Care Trust (PCT), it was felt that the improvements within the service could be achieved through the development of an integrated service across primary and secondary care. A review of service provision was undertaken, and this showed that SWBHT, Sandwell PCT and its community continence service were well placed to develop a fully integrated FI service. The combined team then developed a proposal for an integrated care pathway (ICP) for the management of FI that was intended to underpin such a service and the implementation of this new, integrated model for the management of FI was commenced at the latter end of 2012 (9).

Researcher and Research Background

Following graduation from Liverpool Medical School in 2007, the researcher actively pursued a career in general surgery with a particular interest in the field of colorectal surgery. Upon completion of core surgical training, the researcher identified completing a research project in a colorectal surgery related subject as their next career goal.

At this time, August 2011, the Birmingham and Black Country Collaboration for Leadership in Applied Health Research and Care (CLAHRC-BBC) Theme 1 team (20) at the University of Birmingham were liaising closely with the pelvic floor dysfunction team at Sandwell and West Birmingham Hospitals NHS Trust (SWBHT) to produce a proposal based on evaluating the implementation of a new integrated care pathway for FI management, that was submitted to the National Institute of Health Research (NIHR) Service Delivery and Organisation Programme (SDO) (21). The CLAHRC-BBC (20) was one of nine pilot CLAHRCs funded by the NIHR to undertake high-quality applied health research based focused on the needs of patients and to support the translation of research evidence into practice in the NHS. The CLAHRC-BBC Theme 1 team's research work was based on how healthcare organisations manage major change, and how they involve clinicians, managers and patients (20). CLAHRC-BBC Theme 1 developed expertise in reviewing such changes from different perspectives that allow a more complete, rounded view to be formed (20). This approach has the advantage of being carried out in a timelier manner than traditional academic studies, and the findings can be fed back to the studied organisation/service in a regulated way so that the process of change can be adjusted as necessary.

The joint proposal was based on performing a formal evaluation of an ICP approach to the management of FI across primary and secondary care. The aim of the proposal, produced in collaboration with the clinicians involved in the design and implementation of the ICP, was to determine how successful the move to an integrated, community based (compared with secondary care based) setting was, and the comparability of the costs and outcomes of the changed pathway. The study was also examining any issues associated with its implementation and the process of change, and the perceptions of service users in areas such as impact and acceptability.

The researcher was appointed in the October of 2011 to help with the proposed SDO bid and to set up and carry out the baseline evaluation to be commenced in early 2012, prior to the implementation of the ICP. With regards to the SDO bid, the researcher was involved in the formulation of the bid with regards to the literature review and methodology. The baseline evaluation was commenced in January 2012, prior to the outcome of the bid being known, due to the timescale within which the ICP would be implemented, and so to avoid delay to the implementation. The baseline evaluation was designed and performed by the researcher, as this would be used within the researcher's study, regardless of the outcome of the SDO bid. It was important that the effectiveness of the implementation be reviewed objectively, and in a way that was both relevant and timely. Therefore, the baseline evaluation was factored in to both the SDO bid and also into the researcher's study proposal. Ultimately, the bid was unsuccessful, however having factored this potential issue into the researcher's proposal, the baseline evaluation had been commenced and the researcher's proposal was not affected as only specific aspects of the implementation were going to be evaluated within the proposal. Due to the limited resources available a comprehensive, rigorous and complete service evaluation would be deemed unrealistic to achieve.

Problem: Faecal Incontinence Service Delivery Issues

A recent broad scoping study of pelvic floor dysfunction (of which FI is a part) found current services to be characterised by fragmented approaches with asynchronous delivery, limited investment and poor inter-professional integration (22). The authors argued that an improved service delivery model had the potential to improve outcomes through better inter-disciplinary collaboration and efficient use of resources (9).

An additional need for full evaluation is to allow better understanding of the financial implications of FI in the NHS. It has been acknowledged that the economics of FI generally require more research (23) and that this seems especially to be the case in the NHS. A US study found FI to be associated with up to 55% higher costs compared to continent patients in primary care (24). Some of this may be attributed to the costs for absorbent products for incontinence, (estimated at £94 million in the UK) (25), but a study in the Netherlands highlighted that the combined socio-economic costs of healthcare and job absenteeism far outweighed the costs of absorbent products in FI (26). The integration of FI services, as suggested by the DOH/NICE (6,11) documents, would provide a dynamic way to overcome these barriers to care and achieve better quality whilst increasing efficiency. The benefits of the proposed integrated service for patients with FI are intended to include:

- Improved access to assessment, investigation and treatment
- Better and more acceptable treatment of symptoms (treatments themselves will not generally change because of the ICP)
- Reduced number of hospital admission and re-admissions
- Fewer outpatient appointments and direct access to appropriate secondary clinicians in

secondary care, if relevant

- Increased efficiency linked to appropriate therapeutic interventions, not just containment[1] (i.e. a streamlined pathway achieving symptom control more quickly)
- Cost benefits to the wider economy with better healthcare utilisation, less job absenteeism and lower overall carer burden
- Quality of life that is at least equivalent to that offered by existing services for patients in terms of confidence, self-care and health maintenance.

As already mentioned, the numerous NICE and Government policies drawing attention to FI and integrated care, and the espoused NHS philosophy of delivering care that is responsive, adaptable and patient-centered (27), have not affected the majority of FI services, which remain largely fragmented, with poor access and variable outcomes (9,22).

Overall, there is a paucity of quality evidence about the most effective ways of delivering truly integrated care, and even whether these ways would make any discernible difference to outcomes. In general, ICPs and clinical guidelines are thought to be good concepts. For a number of years the successful introduction of clinical guidelines has been shown to significantly improve the quality of care that patient's receive (28). Within the general literature available on the implementation and effectiveness of ICPs there have been a number of systematic reviews, with two of the more recent ones providing evidence that ICPs can be effective in some settings (29,30). However, both of these systematic reviews, and most other relevant systematic reviews, only looked at ICPs that had been implemented within a hospital setting with neither containing any data on community care pathways. There are currently no systematic reviews or meta-analyses based on the effectiveness of ICPs specifically for FI.

The other key point to note is that these two are the most recent systematic reviews, suggesting a dearth of research in this area. There is an international example (in Australia) of setting up an evidence based community care model for adult FI management, which was piloted and then adopted into national clinical (nursing) guidelines and policies (31), but no formal evaluation of patient outcomes or implementation was performed. Despite the potential benefits that ICPs can bring to patient care, the fact still remains that since 2000 when the call was first made for integrated continence services, progress has been extremely limited, but it is not just in continence services that issues arise with either the failure to implement or to sustain an ICP. Exploring the reasons why this could be the case leads to an analysis of the potential problems with ICPs. Throughout the available literature there are recurring themes with regards to the theoretical disadvantages of ICPs, these include the 'dehumanisation of work' (32), whereby healthcare professionals may feel that the care pathway is too rigid and therefore takes away their own personal and professional judgement, leading to decreased job satisfaction and a decline of diversity in the health professional's work. Another potential disadvantage of ICPs is the difficulty in engaging senior healthcare professionals in the potentially lengthy design and implementation phases of the care pathway, with their increasing service commitments and ever-increasing clinical workloads. These disadvantages, amongst others, are critical reasons as to why an ICP may fail to be implemented and developed further.

From the two systematic reviews (29,30) there were conclusions drawn that described ICPs as being effective in contexts where patient care is predictable but this effectiveness is not so clear cut in contexts where patient care is more variable, alongside the fact that ICPs are at their most effective when there are clear, illustrated deficiencies within the service that they are implemented. These two conclusions highlight the key areas in which continence services as a whole, but more specifically FI, could potentially benefit from an ICP. Despite there being some evidence there is not a great deal of high quality research that has been performed in the area of ICPs, with only limited data available on the effectiveness of outcomes-mainly coming from one of the systematic reviews (30) and there is no evidence on the evaluation of the implementation of ICPs in FI services.

To improve the delivery of integrated care, the SWBHT proposal for a local ICP is built on NHS outcomes frameworks and NICE quality standards, which require commissioners to involve all relevant healthcare professionals in designing care that is both effective and efficient (13). More specifically, the proposed pathway aims to provide a coordinated seamless FI service that prevents both duplication and omission.

To this end the study described in this thesis will evaluate the benefits and challenges of implementing this new pathway of care for patients with FI that includes novel approaches to planning, communications and co-working amongst healthcare professionals, managers, patients and commissioners, applicable in both primary and secondary care. The evaluation will review the process of its implementation, evaluate its clinical impact, examine acceptance and uptake by professionals, and comment on its acceptability and satisfaction to service users.

Current Guidance on Continence service Provision

Since 2000 (up until the commencement of this study), there have been three key government documents that have been published (6,11,33), which have either focused on continence services or issues related to continence services. These documents had not primarily focused on FI up until the publication of the NICE guideline on the management of faecal incontinence in adults in 2007 (6), with the other documents focusing on general continence issues. The three key documents that will be discussed are:

- Good practice in continence services. Department of Health. 2000 (11).
- National service framework for older people. Department of Health. 2001 (33).
- Faecal incontinence: the management of faecal incontinence in adults. National Institute for Health and Clinical Excellence. 2007 (6).

All three documents have similar themes running throughout them with regards to continence services and the management of patients with incontinence, which will be discussed in this section.

Good practice in continence services (11) raised the issue that prompt, high quality, comprehensive continence services were an essential part of the National Health Service (NHS). A working group was set up in 1998 to analyse the continence services available at the time and formulate guidance that would help to provide an effective range of services that would be available for people with continence problems. The aims of the group were to improve the quality of the continence services by highlighting the extent of the problem of incontinence and setting out clear and achievable targets for the continence services, whilst ensuring a nationwide availability of high-quality services (11). The overarching conclusions drawn from this working group were that organising continence services in an integrated way that focuses on identifying patients, assessing their condition and putting appropriate treatment in place, were essential.

The guidance, issued by the DOH, tried to assess the impact of incontinence on the individual and their family, as well as looking at the prevalence of incontinence and current problems with service delivery. Herein lies a recurring theme with FI: much of the literature in relation to incontinence is based around urinary incontinence rather than FI. This can lead to issues when assessing the needs of patients with FI in documents that provide information on joint continence services; however these will be discussed further on in the thesis. This document highlighted that there are a number of problems nationwide which compromise the delivery of continence services (11). Once again, this is a recurring theme in the majority of these documents. There is a very clear emphasis on organising the continence services in an integrated manner throughout this document, of which the main principles are: systematic efforts for identification of patients with incontinence, ensuring that users and carers are involved in the planning and provision of services, therefore, being able to provide a service that enables treatment to be delivered in the most appropriate setting while still being cohesive and comprehensive (11).

The guidance goes on to focus on the assessment process of patients presenting with incontinence and how an individualised management plan should be agreed with each patient and a copy of the treatment plan given to each patient. A key element of any assessment or management plan is that the services have a comprehensive multidisciplinary team of health professionals involved, including doctors, continence nurse specialists and physiotherapists (11). This is also key for providing public education awareness, which within this guidance was deemed a critical factor in the delivery of good continence services; however, this is still offset by detection being made more difficult due to the embarrassment of the condition for patients. From a management point of view, the guidance suggests that there should be ‘designated medical and surgical specialists’ offering access to investigation and treatment facilities for all aspects of continence and also access to consideration of specific operations such as repair of anal sphincter (11). One of the tools, suggested by this guidance that was potentially thought to be useful in improving the delivery of continence services was the introduction of a care pathway (11).

Shortly after the publication of ‘Good practice in continence services’, the National Service Framework (NSF) - for older people (33) was published. This publication was produced to try to adequately address the needs of older people, as they are the main users of health and social care in this country and this demand is ever increasing (33). The aim of this document was to attempt to ‘ensure fair, high quality, integrated health and social care services for older people’ (33). This guidance was based on the health and social care needs of older people in general, therefore not specifically focusing on continence services, but throughout the document there are clear and specific references to these services. These references are along similar lines to the guidance issued by the ‘Good practice in continence services’ document (11).

The NSF (33) focuses on four standards; rooting out age discrimination, pride in person-centered care, promoting older people's health and independence and fitting services around people's needs. The majority of the references to continence services lie in the second standard: person-centered care. The main aim of this standard was to ‘ensure that older people are treated as individuals and they receive appropriate and timely packages of care which meet their needs as individuals, regardless of health and social service boundaries’ (33). The DOH felt that continence services were particularly important for older people, as incontinence is a distressing problem for the individual and their carers (11). Again, the identification that access to continence services is a major problem has been identified with regards to older people as part of the review in this document (33). The standard suggests that a proper assessment of the range and complexity of needs for older people can improve their ability to function independently and reduce the need for emergency hospital admission, despite this however the issue still remains that although older people have more frequent contact with health or social care services, issues with incontinence can often be missed or go unreported (33). As part of the key intervention section within the standard, integrated continence service establishment was deemed a priority for service improvement (33). Again there is no distinction between faecal and urinary incontinence, but it was felt the integrated continence services should be able to ‘link identification, assessment and treatment across primary, acute and specialist care’ (33). There is a specific reference to the Good Practice in Continence Services document (11) highlighting that this document provides evidence based policies, procedures, guidelines and targets for the establishment of integrated continence services, whilst also giving a summary of what an integrated continence service should include.

The main issue surrounding the two documents (11,33) previously described is that there was no specific focus on FI as these documents concentrate on continence services as a whole. Whilst most of the key messages will be transferable to either faecal or urinary incontinence it was clear that specific guidance for the management of FI was needed. This was provided by the NICE clinical guideline 49 on the management of FI (6).

This guidance issued in 2007 aimed to offer evidence-based, best practice advice for adult patients suffering from FI. As with the NSF (33), this guideline was based around person-centered care, allowing patients who suffer from FI to be assessed and managed by a multidisciplinary team of healthcare professionals who have the relevant skills, training and experience in the condition. Ideally, these healthcare professionals should work within an integrated continence service (6). There is a strong sense throughout the document of local clinical teams being able to raise public awareness of FI, whilst encouraging people with the condition to seek appropriate help and decreasing the taboo surrounding the condition. The aim of this will be to increase the number of patients reporting symptoms of FI. Continuing to strive for good practice in managing FI includes making sure that patients and carers are fully informed about their condition and the management of their condition, along with being made aware of any psychological or social support mechanisms that are needed (6).

This clinical guideline (6) highlights the need for healthcare professionals to actively inquire about symptoms of FI in certain high-risk groups, along with outlining the need for a focused baseline assessment with appropriate initial management, including dietary advice, bowel habit and toilet access advice, medication and coping strategies. The need for review of treatment was specifically outlined so that improvements can be identified or discussions about further treatment options can be had. The location of where the baseline assessment and initial management takes place is not specifically detailed in the guidance. However, when moving on to the specialised management stage, referral to a specialist continence service is alluded to (6). The specialist continence service should include: pelvic floor muscle training, bowel retraining, specialist dietary assessment and management, biofeedback, electrical stimulation and rectal irrigation. Obviously these treatments will not be required in every patient, but the service should make these treatments available. The majority of the treatments will also be patient specific and progress will be monitored with standard assessment techniques. The next issue to consider is if these conservative specialised management techniques failed to improve symptoms, this is when further specialist assessment and potential surgical input may be required. Through the whole of the guidance it is only at this point (when conservative management has failed) that referral to a specialist surgeon for discussion of the benefits and limitations of surgical versus non-surgical management is advocated. There are a number of potential surgical options, but due to the potential limitations of each surgical option, particularly in relation to long-term results, patients have to be given realistic expectations for the effectiveness of those surgical management options.

Given the potential limitations of surgical management for patients with FI specific guidance was issued on the long-term management of these patients. This specific guidance was related to patients who have symptoms that do not wish to continue with active treatment or who have intractable FI. This guidance mainly relates to advice on social issues, continence products, skin care along with the provision of psychological and emotional support should the patient require this. All of these factors relate to trying to preserve the patient's dignity and if possible, independence.

All three documents (6,11,33) contain some common themes within them. They advocate the use of an integrated continence service within which there is a multidisciplinary team of health care professionals that have the relevant skills and expertise to manage patients with FI. The documents also give some guidance as to what a good continence service should provide for people with FI. In the case of the NICE guidance (6), this also provides a structure within which healthcare professionals can assess and manage patients with FI to a high-quality and standardised format. The benefit of the NICE guidance is that it is not prescriptive, but it encourages healthcare professionals to personalise each patient's treatment plan depending upon the outcome of their assessments and improvement from previous management strategies.

Interestingly, the documents do mention issues with the delivery of continence services. The Good Practice in Continence Services document (11) highlighted that there were a ‘number of problems across the country which affect access to and delivery of content and services’, of which they deemed identification; lack of involvement of users in service planning and delivery and geographical variations in numbers of staff, quality of service and waiting times to be the most troublesome. A telling sign is that since the Good Practice in Continence Services document (11) was published in 2000, despite further consolidation of this guidance from the NSF-for older people (33), by 2007, there had clearly been no change in the provision of continence services for patients with FI, with issues still remaining into 2010. This confirms that one of the biggest problems with FI care in this country remains the problem of service delivery (34).

It should be noted at this point that since the completion of the study, two further documents have been published:

- Faecal incontinence in adults. Quality standard 54. National Institute for Health and Clinical Excellence. 2014 (35) .
- Excellence in Continence Care. NHS England. 2015 (36).

The faecal incontinence in adults document (35) has five quality standards that have been derived from the previous NICE guidance 2007 (6):

Table 1: Five Quality Standards from the faecal incontinence in adults document (35)

Standard Number	Description of Standard
1	Adults in high-risk groups for FI are asked in a sensitive way, at the time the risk factor is identified and then at times according to local care pathways, whether they have bowel control problems.
2	Adults reporting bowel control problems are

	offered a full baseline assessment, which is carried out by healthcare professionals who do not assume that symptoms are caused by any existing conditions or disabilities.
3	Adults with FI and their carers are offered practical support, advice and a choice of appropriate products for coping with symptoms during the period of assessment and for as long as they experience episodes of FI.
4	Adults with FI have an initial management plan that covers any specific conditions causing the incontinence, and diet, bowel habit, toilet access and medication.
5	Adults who continue to experience episodes of FI after initial management are offered referral for specialised management.

These standards have been identified as the areas in which quality improvements in the care of patients with FI can be made. Interestingly, these are not too dissimilar to the areas identified in literature dating back to 2007 (6), further highlighting the fact that care in FI has not progressed in a number of years. Alongside this document, excellence in continence care (36) has also been published subsequently. This has been published with the aim of improving the quality of care for patients with continence issues, through the need for commissioning of services that achieve measurable outcomes. This identified deficiencies in current care startlingly similar to those identified in the Good practice in continence services document 2000 (11), once again highlighting that not much progress has been made from when the initial document was published fifteen years previous.

Study Aims and Research Questions

Aims

As described earlier, a West Midlands based NHS acute hospital trust decided to implement a new ICP for the management of FI in 2012. The primary aim of this study was to assess how the implementation of an integrated, community based (compared with secondary care based) care pathway affects the key stakeholders, whilst also observing and analysing the actual process of organisational change within the Trust, focusing on the barriers and facilitators to the implementation of the ICP.

The study focused on the perceptions of key stakeholders in areas such as impact, acceptability, barriers/facilitators and their general experience throughout the implementation of the ICP. Using both quantitative and qualitative data, issues have been examined that are associated with the implementation of the ICP and the process of change within the multidisciplinary team. As the process of change in organisations such as the NHS can be an unpredictable journey, taking a pragmatic and reflexive approach was essential.

An element of the study also focused on the perceptions of service users in areas such as impact, acceptability and the general experience throughout the implementation of the ICP.

Research Questions

- What are the facilitators or barriers to the implementation of an integrated care pathway for FI at a local and organisational level?
- How do these affect the key stakeholders (including patients) involved in the process?
- How does the introduction of the ICP affect clinical outcomes and referral rates?

To understand the dynamics of implementing, embedding, and integrating this new ICP for FI, normalization process theory (NPT) (37) was used to structure the analysis. This allowed the researcher to focus on the dynamic processes that led to the ICP becoming embedded in everyday work. NPT consists of four core constructs, with each of these constructs having four specific components, which attempt to identify factors that promote and inhibit the routine incorporation of complex healthcare interventions or organisational innovations into everyday practice (37). This theory also explains how these interventions work, not just in the early implementation stages but also beyond this, to the point where an intervention becomes embedded into routine practice so that it becomes “normalized” (37).

Following this chapter, the thesis then goes on to review the current literature on FI, ICPs, change management and NPT in chapter two, with chapter three describing the methods used in the study. The results of the study are divided into two chapters with chapter four detailing the qualitative results and chapter five the quantitative results. The final chapter, chapter six contains a discussion of the main findings from the study and their importance.

CHAPTER 2: LITERATURE REVIEW

This chapter will review the published literature on FI (including the definition, epidemiology, risk factors, assessment and management and the use of qualitative research in FI), ICPs (advantages and disadvantages), change management, leadership, shared purpose, teamwork, capacity, clinical outcomes and the normalization process theory. Understanding all of the elements discussed within this chapter will be vital to provide a contextual picture of the study and its results.

Faecal Incontinence

Definition

Faecal incontinence (FI) is the involuntary loss of liquid or solid stool that is a social or hygienic problem (38). There are three clinical subtypes (39):

1. Passive incontinence- involuntary discharge of faeces or flatus without awareness
2. Urge incontinence- the discharge of faecal matter despite attempts to retain the faeces
3. Faecal seepage- the leakage of faeces following normal defecation

Following thorough assessment, it is possible to make a clinical distinction between these three groups (although there may be some overlap), which will help to guide subsequent investigations and management choices, as each of the three groups will have differing pathophysiology.

Epidemiology

The estimated prevalence of FI varies widely, from 1.5% to 50% (1–3,40) . The study that provides the best estimate of FI prevalence is the National Health and Nutrition Examination

Survey (NHANES). This study surveyed both sexes, all ethnicities represented in the US, and the full range of adult ages. The age-adjusted prevalence of FI in the non-institutionalised US population was found to be 8.9% in women and 7.7% of men (41). One of the key limitations of this study is that institutionalised individuals (i.e. nursing home residents) were not included. This will affect the prevalence rate, as the prevalence in the institutionalised population is known to be higher (38). When the prevalence estimates are broken down by type of incontinence then we see that liquid incontinence is 2 -3 times more common than solid incontinence, with incontinence of flatus being 2 -3 times more common than the combination of liquid and solid incontinence (42–45). There are a number of reasons for the wide variation in the prevalence estimates, including the definition of incontinence used, the clinical setting (i.e. nursing home or community) and the influence of social stigma on the patient, which can lead to under reporting of the condition. All of these issues mean that it is difficult to obtain a true reflection of how prevalent FI is, which has a subsequent impact on the management of this socially isolating, distressing condition.

Anorectal Anatomy and Physiology

The neuromuscular integrity of the rectum, anus, and the adjoining pelvic floor musculature helps to maintain normal faecal continence (39).

The rectum is the most distal part of the colon and functions as a reservoir for stool, as well as a pump for emptying stool. Both of these functions are due to a unique muscle arrangement, whereby the rectum is composed of a continuous layer of longitudinal muscle that integrates with the underlying circular muscle (39). The rectum expands to receive a threshold amount, beyond which there is normally an urge to defecate. The anus is a 2-4cm muscular canal, which at rest forms an angle with the axis of the rectum. This anorectal angle varies dependent upon the action required at the anus, starting off at rest at 90°, whilst during defecation the angle becomes more obtuse at approximately 110-130° (39).

The anal sphincter consists of the internal and external anal sphincter. The internal anal sphincter is an expansion of the circular smooth muscle layer of the rectum, while the external anal sphincter is an expansion of the striated levator ani muscles (46). Closure of the anus is achieved by tonic activity of the internal anal sphincter with this being reinforced by voluntary contraction of the external anal sphincter. The combination of anal mucosal folds and the anal vascular cushions help to provide a tight seal when the sphincters are contracted. Alongside these mechanical barriers, the puborectalis muscle creates a flap-like valve that pulls the anorectal anatomy forward, subsequently reinforcing the anorectal angle to prevent FI (46). Innervation to the anorectum is supplied by sensory, motor, autonomic parasympathetic nerves and by the enteric nervous system. The key nerve is the pudendal nerve, a mixed sensory and motor nerve, which arises from the second, third and fourth sacral nerves (47).

How defecation works

Continence and ordered defecation depend on the coordinated sensory and motor innervation of the structures mentioned above.

When a threshold volume in the rectum is reached, stretch receptors are activated in the myenteric plexus in the walls of the rectum and along the pelvic floor, leading to a sensation of urge. There are two reflex mechanisms important for continence:

- The rectal-anal inhibitory reflex**:** A threshold distension of the rectum inhibits the tone of the internal anal sphincter, allowing the contents of the rectum to transiently pass into the anus. This process, known as anorectal sampling, periodically senses the rectal contents (48–50). The sensation of rectal distension travels along the parasympathetic system to S2, S3 and S4 (51).

- The rectal-pudendal reflex: Rectal distension also leads to reflexive somatic motor contraction of the external sphincter, allowing for maintenance of continence.

Motor activity within the rectum is also important for anorectal function. At the appropriate time, orderly peristalsis with reflexive relaxation of the internal sphincter and voluntary relaxation of the external sphincter allows for defecation.

Taking all this into account it is clear to see that the pudendal and sacral nerves are key components in maintaining continence as they are involved with the sensory, motor, and autonomic function of the anorectum (39). Disturbances of the normal anatomical and physiologic mechanisms will result in FI.

Pathophysiology and Risk Factors

FI occurs when one or more of the mechanisms described above are disrupted to an extent whereby the other mechanisms are unable to compensate (39). The cause of FI is often multifactorial with anal sphincter disruption/weakness, pudendal neuropathy, impaired anorectal sensation, impaired rectal accommodation, or incomplete evacuation all potentially contributing to the pathogenesis of FI (52–54). Table 2 describes the high-risk groups for FI.

Table 2: Risk Factors for Faecal Incontinence (39)

Characteristic	**Specific Description of Risk Factors**
Patient Characteristics	Increasing age Nursing home residence Gender: equivocal evidence Ethnicity: Caucasian/ Asian Obesity, poor general health, physical limitations, urinary incontinence, pelvic organ prolapse Neurological disease (dementia, spinal cord injury, multiple sclerosis, spina bifida, stroke)
Patients with gastrointestinal symptoms and disorders	Diarrhoea or loose stools Drugs (antibiotics, laxatives), dietary supplements Urgency Constipation

	Irritable bowel syndrome Inflammatory bowel disease Haemorrhoids Congenital anomaly (imperforate anus)
Obstetric factors	Parity Sphincter laceration Instrumental delivery Episiotomy Large baby, prolonged second stage
Sequelae of surgical procedures	Colectomy and ileo-rectal anastomosis or pouch Sphincterotomy Haemorrhoidectomy Radical prostatectomy Pelvic radiotherapy

One of the major predisposing factors for FI is obstetric trauma in adult women (55). Obstetric trauma can cause injury to either the external anal sphincter, the internal anal sphincter, the pudendal nerve or all three structures (56). Given that the pathophysiology of FI is multifactorial, it is likely that more than one of the risk factors above will be present in any individual patient. In one prospective study, 80% of patients had more than one pathogenic abnormality (52). Clearly, this has implications for the assessment and management of patients with FI.

Assessment and Management

Having identified the high-risk groups and that the pathophysiology of FI is multifactorial, it is essential that a detailed clinical assessment with appropriate physiological and imaging investigations are performed. By combining the information gained from both the clinical assessment and investigations, this will provide the healthcare professional with the data required to assess the severity of the problem, the underlying aetiological factors, and the impact of FI on the patient's quality of life. Once this information has been acquired, only then can an appropriate management strategy be commenced.

According to NICE guidance (6), a detailed and structured approach to initial assessment and management is needed. The division of FI into three clinical subtypes aids this initial phase, as by making a clinical distinction we can make some assumptions with regards to the underlying aetiology, therefore guiding investigations and management:

1. Passive incontinence- occurs due to a loss of perception and/or impaired recto-anal reflexes either with or without sphincter dysfunction.
2. Urge incontinence- occurs due to disruption of sphincter function or the rectal capacity to retain stool.
3. Faecal leakage- due to incomplete evacuation of stool and/or impaired rectal sensation (57,58).

To be able to delineate which of the clinical subtypes that a patient is suffering from healthcare professionals should perform a focused baseline assessment, comprising:

– relevant medical history

– a general examination

– an anorectal examination

– a cognitive assessment, if appropriate.

The first key step in the assessment of patients with FI is to confirm the existence of the condition whilst trying to establish a good baseline rapport. With regards to eliciting a history of FI the following points are essential (39):

- Onset and precipitating event
- Duration, severity and timing
- Stool consistency and urgency
- Coexisting problems/surgery/urinary incontinence/back injury
- Obstetric history–forceps, tears, presentation, repair
- Drugs, caffeine, diet
- Clinical subtypes–passive, urge incontinence or faecal leakage
- Clinical grading of severity
- History of faecal impaction

During this assessment process the use of a standardised bowel diary, including details such as the number of bowel movements, stool consistency, urgency and number of incontinent episodes is beneficial. In addition to the bowel diaries, validated quality-of-life outcome measures can be used to provide further information on the impact of FI on the quality of life of the patient.

All patients should undergo a general examination including a detailed physical examination of the abdomen and perianal/perineal region alongside a neurological examination of the back and lower limbs to ensure that there are no obvious systemic or neurological disorders. Following this complete assessment, the healthcare professional should be able to place the patient in one of the three clinical subtypes. This will then allow for appropriate investigations to be ordered for the subsequent assessment and management of these patients. Investigations should be tailored to the patient's symptoms, clinical subtype and therefore potential aetiology.

At this point clinical management can be guided by the information gained from the assessment.

Management

The ultimate goal when managing patients with FI is to restore continence as fully as possible and to improve their quality of life. There are a number of potentially beneficial conservative and interventional management strategies for adults with FI (see table 3).

Table 3: Management Strategies for Faecal Incontinence (38–40)

Conservative management	Treat underlying cause Dietary advice (fibre, reduce caffeine

	intake) Education/counselling/bowel habit training Correct defecatory dynamics Pelvic floor muscle exercises Anal hygiene/skin care Pharmacological therapy (loperamide, codeine) Biofeedback therapy (neuromuscular conditioning) Anal plugs Continence products e.g. continence pads Hypnotherapy Psychological support
Interventional management	Rectal Irrigation Percutaneous tibial nerve stimulation

	(PTNS) Sacral nerve stimulation (SNS) Sphincter bulking agents Surgery- sphincteroplasty, neosphincter, colostomy

Initial management will often need to include a combination of interventions based on the findings from the initial assessment but tailored to the individual patient and their circumstances. Interventions can include dietary advice, whereby a diet that promotes an ideal stool consistency and predictable bowel emptying is recommended. Ensuring toilet facilities are adequate with sufficient time allowed for defecation alongside encouraging the patient to adopt a standard sitting or squatting position when emptying the bowel (correct defecatory dynamics) are important conservative management techniques. Pelvic floor muscle exercises are used as an early management strategy despite the weak evidence suggesting efficacy (40). Reviewing a patient’s medication is vital to ensure any drugs that may contribute to FI are stopped and alternatives are considered. Anti-diarrhoeal medication can be offered to patients with FI associated with loose stools once other causes (such as excessive laxative use, dietary factors and other medication) have been assessed and excluded. The anti-diarrhoeal medication of choice is loperamide (6). A placebo-controlled study of loperamide has been shown to reduce the frequency of incontinence, improve stool deferment time and increase colonic transit time (59).

During the initial period of assessment and management patients will normally be finding it difficult to cope emotionally and psychologically with having FI. Potential coping strategies include advice on the use and supply of continence products and the availability of emotional and psychological support (6). All initial treatments should be reviewed regularly with bowel diary and quality-of-life questionnaire outcome assessment. If the initial management strategies have not improved the patient's symptoms, further specialised management should be discussed with the patient as this potentially brings more invasive procedures for diagnostic and therapeutic purposes. At present, with the current set up of FI services, the majority of assessment and management will take place in secondary care.

The specialised management strategies include biofeedback and/or sensory re-training; electrical stimulation (Percutaneous Tibial Nerve Stimulation (PTNS) and Sacral Nerve Stimulation (SNS)), rectal irrigation and consideration for surgical procedures (6,38–40).

Biofeedback is an "operant conditioning" technique that has been shown to improve bowel function and incontinence (60). The individual patient acquires a new behaviour through a learning process that is repeatedly reinforced with constant feedback. Biofeedback therapy has three main goals in patients suffering with FI:

1. To improve the strength of the anal sphincter muscles;
2. To improve the coordination between the abdominal, gluteal, and anal sphincter muscles during voluntary squeeze and following rectal perception;
3. To enhance the anorectal sensory perception

Until recently, in those patients for whom conservative management strategies had not improved symptoms, the management of FI has been limited to either major irreversible anal sphincter surgical interventions or stoma formation. Such procedures may be costly, are often unsuccessful and carry a high risk of associated morbidity (6,61,62). Recent attention has therefore focused on non-invasive or minimally invasive therapies to optimise the residual continence mechanisms by altering the nerve impulses to this area (termed neuromodulation), including sacral nerve stimulation (SNS) or percutaneous tibial nerve stimulation (PTNS) (63). Unlike the more invasive SNS, however, PTNS can be administered within an outpatient setting and without the need for surgery, confirming percutaneous stimulation of the tibial nerve is a low cost, low risk technique with almost no associated morbidity (64).

Surgery

Surgery may be an option for some patients who have had an unsatisfactory response to conservative management or have FI that is refractory to medical or minimally invasive interventional treatment, such as PTNS/SNS. As surgical intervention is invasive and, in the case of FI, carries a high risk of morbidity, it is essential that patients receive specialist assessment to check their suitability for surgery. It is vital that those undergoing surgery have realistic expectations and are aware of potential complications (6). It is essential to assess the efficacy of surgery, incidence of adverse events and whether results of the operation are sustained over time (6,39).

Overall, evidence for the different management strategies in FI is sparse and most studies, especially involving interventional management strategies, have low numbers of patients (6). This means that treatment strategies are generally given to patients who fit specific criteria that have been used in these studies, therefore potentially marginalising some patients suffering from FI (6). Another area in which NICE (6) reported that there is a severe lack of data is qualitative research. This is a significant finding as patients' views should be used to help build and refine services for a particular condition and if there is a paucity of views then that service is missing a vital input into how it should be constructed.

Qualitative Research in Faecal Incontinence

Overall, there is a lack of qualitative research around FI, and there is no qualitative research on ICPs related to FI. A systematic review was performed as part of The NICE Guidance on Faecal Incontinence (6) of the available qualitative research. This systematic review of patient views was performed to attempt to identify qualitative studies of patients' experiences, perceptions, attitudes and opinions about the causes of FI, coping strategies and the methods of managing FI. It comprised eight studies involving 728 patients, with comments made within the guidance that the studies identified seem to be biased towards older female patients. The systematic review performed within the guidance (6) highlighted the patient perceptions on the causes of FI and also the coping strategies that patients and carers adopt when faced with this condition. One of the key findings was the repeated comment of how alone and embarrassed patients felt with this leading to not seeking help (6). Interestingly, patients also perceived that health professionals were not understanding towards their condition and in patients in one study found that access to advice or information regarding FI was inconsistent and hard to find (6). What this systematic review (6) made clear however, is that there is a lack of information on patients' views with regards to the topic, something that in the future will need to be addressed.

As has already been alluded to previously in the introduction, the numerous NICE and Government policies drawing attention to FI and integrated care, along with the espoused

NHS philosophy of delivering care that is responsive, adaptable and patient-centered (29), have not affected the majority of FI services, which remain largely fragmented, with poor access and variable outcomes (15). A potential solution could be provided by the introduction of an ICP.

Integrated Care Pathway

ICPs have become increasingly popular within the UK as a tool for managing clinical processes and patient outcomes in the last 30 years (65). A definition agreed by the National Pathway Association in 1994 is (66):

‘An integrated care pathway determines locally agreed, multidisciplinary practice based on guidelines and evidence 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.’

Defining characteristics of ICPs include (32):

- An explicit statement of the goals and the 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, the patients and their relatives;
- The documentation, monitoring and evaluation of variances and outcomes, and
- The identification of the appropriate resources

The aim of an ICP is to enhance the quality of care by improving patient outcomes, promoting patient safety, increasing patient satisfaction, and optimising the use of resources (32). ICPs are essentially multidisciplinary plans that can predict the course of events in the treatment of patients with similar problems. There are a number of important aspects to ICPs that should be considered. Firstly, a care pathway can only be called integrated, when it recognises the contributions of all people involved within the pathway (all healthcare sectors/professionals and patients) and includes a strong element of primary care. Secondly, an essential component of ICPs is the care pathway document. The content of the pathway documents will be highly variable. However, all of these documents should include basic information in chronological order, with events grouped under key headings and organised in time, stages or phases. Thirdly, variance monitoring is essential. An ICP should always include recording by healthcare professionals of deviations from planned care in the form of variances. The recording of variances allows a continuous review with regards to the process and quality of care delivery allowing you to adapt your pathway accordingly and contributes to quality improvement. Variances will usually be due to: (65)

- “The service user” e.g. failure to attend appointments, lack of compliance with therapy
- “The healthcare professional” e.g. an omission or delay in providing the intervention
- “The system” e.g. practice patterns, policies or procedures
- “The community” e.g. transport problems, lack of placements

In summary, the aim of an ICP is to have (65):

- “The right people”
- “Doing the right things”
- “In the right order”
- “At the right time”

- “In the right place”
- “With the right outcome”
- “All with attention to the service user experience”
- “And to compare planned care with the care that is actually provided”

ICPs should be both a mechanism and concept that help to embed guidelines/protocols and local evidence-based, patient centered best practice into everyday use for the individual service user.

Advantages and Disadvantages of ICPs

There are many potential benefits of developing and implementing an ICP within certain health conditions. These advantages extend to both patient and to healthcare professionals and include (32,67,68):

- Enhanced professional practice-due to an increased use of the evidence/research base
- Streamlined care documentation that enables real-time recording of the actual care that is given-this involves simplifying the process of multidisciplinary care documentation and reducing duplication
- Improved multidisciplinary communication, collaboration and teamwork
- Reduced patient distress
- The increased involvement of service users, relatives, volunteers- allowing mutual goal setting
- Increase consistency with explicit expectations about assessment, treatment and care
- Reduced variations in the care that is provided
- Reduced length of stay and associated costs

- Enhanced clinical outcomes
- Efficient auditing-the integrated care pathway document with integrated variance tracking represents a concurrent audit tool, which promotes quality improvement
- Provides an infrastructure that supports clinical governance

Despite these numerous reported advantages, there are also some disadvantages or concerns that have been expressed within the literature on ICPs. These concerns include a fear of litigation that following a standard protocol results in the loss of healthcare professional autonomy in decision-making, a lack of evidence that ICPs improve patient care and the development process being lengthy (69). With regards to healthcare professional decision-making it has been reported that following a protocol or pathway may conflict with personal judgement, therefore resulting in the loss of spontaneous clinical assessment and threatening the therapeutic, intuitive nature of professional practice (70). If an ICP is implemented correctly based on good quality evidence, then the pathway should have a high quality assessment and intervention process that means that patients are receiving the best available treatment, resulting in very little need for healthcare professionals to deviate from the pathway. However, if healthcare professionals do feel the need to deviate from the pathway there is the option of variance recording that allows for the pathway to be reviewed and changed or updated if necessary.

When looking at the evidence base for the effectiveness of integrated care pathways on improving patient care, there were two recent systematic reviews (29,30). No systematic reviews or published articles on the implementation or effectiveness of an ICP for FI have been identified following a systematic PubMed search. The two reviews included a Cochrane review (29) and a review from the Wales Centre for Evidence Based Care (30). Both of the reviews differed in their objectives, inclusion criteria and methods. Whilst the Cochrane review had the objective of assessing the effects of integrated care pathways on professional practice, patient outcomes, length of hospital stay and costs, Allen et al (30) attempted to identify the circumstances in which integrated care pathways are more or less effective by reviewing 'high-quality' randomised controlled trials. The Cochrane review did include a wider range of study designs such as controlled before and after and interrupted time series. The reason for doing this is that it is often not feasible or practical to evaluate changes in service delivery or organisation of care within the confines of a randomised controlled trial. Most of the studies in both reviews compare treatment guided by an ICP with 'usual care'.

When comparing the results and conclusions of both of these systematic reviews there are clear differences. Allen et al (30) included seven studies in their review with the main conclusions of the review being that:

- ICPs are most effective in a context where patient care is predictable, but their value is less clear in settings where recovery is more variable
- ICPs are most effective in bringing about behaviour change where there are identified deficiencies in services
- The value of ICPs in contexts where multidisciplinary working is well-established is less certain

There were a limited number of trials included in this review with the wide range of populations and settings meaning that the potential generalisability of the author's conclusions is difficult to judge. None of the included trials involved incontinence and only two of them were performed in the UK.

The Cochrane review by Rotter et al (29) comprised 27 studies including interrupted time series and controlled before and after studies as well as randomised controlled trials. The review concluded that when compared with usual care, the use of an ICP significantly reduced in-hospital complications and improved documentation of care. There were no differences in mortality or readmission to hospital. Most of the studies within the review reported significant reductions in hospital length of stay associated with the use of an ICP compared with usual care. The Cochrane review also examined whether evidence informed strategies have been used for developing and implementing pathways in the included studies. The most commonly reported implementation processes were use of evidence-based content, adaptation of evidence local circumstances and clinician involvement in pathway development. However, the review authors did conclude that because of poor reporting of these elements within the studies it was not possible to draw conclusions about the impact of implementation on ICP effectiveness. Like the Allen et al (30) review, the Cochrane review was well conducted, with the authors conclusions appearing likely to be reliable but again the relevance of the findings to FI or continence-based services is uncertain as only two of the included studies were from the UK and none involved FI.

From the systematic reviews it appears that ICPs have a place within healthcare. Given the conclusions reached however, ICPs should be targeted at areas with clearly identified deficiencies in provision or where change is required. Developers should be clear on why and how they wish to change practice and the constitution of best practice should be agreed locally. When taking all these conclusions into account, an ICP seems like a genuine mechanism for improving FI services. It can also provide a quality improvement approach to distinct issues that have already been discussed with regards to FI services including:

- Poor co-ordination of care
- Lack of collaborative work between primary and secondary care
- Care plans of variable and questionable value purpose
- Lack of therapeutic intervention and evidence-based practice
- The increasing need to demonstrate the implementation of national guidance
- Ongoing concerns over service users' experiences of care

Evidently an ICP for FI services would be a promising development. Unfortunately, it is not a simple process to implement an ICP and there are some factors that are deemed critical to the success of the implementation process (65,71–73). Firstly leadership, organisational and clinical leadership alongside effective project management are seen as critical success factors in the development and evaluation of ICPs. Organisational and clinical support and leadership is especially key to ensure that the pathways are based on research evidence or evidence of clinical effectiveness (71,73). The second critical success factor is to have a powerful champion or champions within all levels of the organisation. Ideally that should include senior management, middle management and the clinicians involved in the particular area of care provision (65,71–73). Education and training to prepare staff for their extended roles and to develop the skills needed to manage patient care using care pathways is essential, which subsequently will lead to the understanding, ownership and acceptance of care pathways (32). Facilitation in the development and implementation of care pathways is also highlighted as a critical success factor, with care pathway facilitators being able to (69,74,75):

- Support and work closely with clinical staff
- Have a knowledge of the project

- Understand change management theories
- Have teambuilding skills

One of the important aspects of an ICP facilitator is being able to understand change management theories and the process of change. Change within any organisation, including the NHS, brings many challenges and some uncertainties for all members involved. The implementation of an ICP, for any condition, represents a challenge.

Change Management

Medicine is based on the Cartesian method of reductionism, where a problem is broken down, examined, and the information obtained is then used to draw conclusions about the nature of the larger reality (76). The key element to this approach is that the problem being examined, normally clinical, must be in a linear system (76). When that problem is in a linear system then this approach is generally successful, and the clinician can feel confident in the conclusions they have drawn. A clinical example of this is the response of blood glucose to the ingestion of a glucose rich substance. The difficulties arise when the problem that we would like to examine behaves in a non-linear fashion. Predicting outcomes in this situation becomes a source of frustration for many as there is a clear difference between real world and reductionism, this was where complexity theory emanated from (76). A complex system is defined as one in which many independent agents interact with each other in multiple ways. The premise underlying complexity theory is that there is a hidden order to the behaviour and evolution of complex systems (77,78). The NHS and every organisation within it are complex systems. Table 4 describes the differences between linear and non-linear systems.

Table 4: Linear and Non-linear Systems (76,79)

Linear System	**Non-linear System**
Output is proportional to input	Output disproportionate to input
Output is reproducible over time for a given input	Output for the same input value may not be constant over time, or be reproducible
Events occur sequentially	Events occur both sequentially and simultaneously
Each variable within a linear system acts independently of another	Each component of the system influences the other, i.e. shows interdependence

Older change management models, such as the Burke-Litwin model (80) and Kotter's 8-step model (81), have tended to view organisations as machines, composed of multiple individual components each of which can be 'fine-tuned' separately to improve performance within the organisation as a whole (76,82,83). From the traditional management models' perspective, a top-down approach is often taken when attempting to introduce new practices and resistance to change implies that the machine is not working effectively. Similarly, any variation of the new practice is thought to be eliminated by the introduction, or more appropriately imposition, of further protocols or guidelines. This model works when a genuine consensus exists as to the new practice being implemented, however in the real world this is very rarely the case. In the situations where there is not a consensus, adopting an alternative viewpoint, informed by complexity theory, may allow more productive solutions to emerge (76,83).

There are a number of reasons why change may occur within an organisation and how this change is managed is a key element in whether the change will be successful or not (84). Change can be classified in numerous different ways, but three common classifications will be discussed; planned versus emergent change, episodic versus continuous change, development, transitional and transformational change (84–87).

Planned versus emergent change

Planned change is deliberate and a product of conscious reasoning and actions (84). However, change that unfolds in a spontaneous and unplanned way is known as emergent change. It should be noted that no matter how carefully change is planned and executed, there would always be some emergent elements within that change. This highlights the important factor that to truly understand organisational change, one has to be aware that it is a process that can be facilitated by perceptive and insightful planning and analysis and well crafted, sensitive implementation phases but acknowledgement should be made of the fact that it can never be fully isolated from the effects of serendipity, uncertainty and chance (84). The important message is that organisation level change is not fixed but contains an important emergent element (84).

Episodic versus continuous change

Another distinction that can be made is between episodic and continuous change. Episodic change sometimes referred to as ‘second order’ change is infrequent, discontinuous and intentional and often involves replacement of one strategy or programme with another (85). In contrast, continuous change, sometimes referred to as ‘first order’ change, is ongoing, evolving and cumulative (86). It is characterised by people constantly adapting and editing ideas they acquire from different sources. An organisation can help clarify its thinking with regards to its future development by making the distinction between episodic and continuous change. However, very few organisations within the NHS are able to adopt an exclusively continuous change approach due to the seemingly constant changes in the local and national political landscape (86).

Developmental, transitional and transformational change

Ackerman distinguished between three types of change related to the extent and scope of change: developmental, transitional and transformational (87):

- Developmental change can be either planned or emergent. This type of change can enhance or correct existing aspects of an organisation with its main focus often being on the improvement of the skill or process.
- Transitional change is episodic, planned and second-order. The aim of transitional change is to achieve a desired state that is different from the existing one. Transitional change is the basis of much of the organisational change literature from the 1980s (88–90). The origin of transitional change is based around the work of Lewin who conceptualised change in a three-stage process involving (91) :
    - **Unfreezing** the existing organisational equilibrium
    - **Moving** to a new position
    - **Refreezing** in a new equilibrium position

Transformational change, second order in nature, requires a shift in the assumptions made by the organisation and its members, resulting in an organisation that will differ significantly in terms of structure, processes, culture and strategy (84).

The literature suggests that the process of change within an organisation can be classified easily. For example, the Burke-Litwin model (80) suggests that environmental factors are the most important driver for change. Other important elements of organisational success are, mission and strategy, leadership and organisational culture that are often impacted by changes that originate outside the organisation. When change is required it is the job of the team or individual to understand what these external factors are and identify the implications of them. However, all of the approaches mentioned above give the impression that change is a rational, controlled, and orderly process (84). In real world terms, however, organisational change, especially within the NHS, is chaotic. It often involves shifting goals, discontinuous activities, unexpected events, changes and outcomes and unintended consequences (85,92). Change within the NHS is never likely to be linear and the ambitious goals that are currently being set for the NHS in times of austerity will require the organisation to be able to embrace continuous and emergent change. Attempting to meet these goals will involve working with (84):

- Changing pressures in the environment
- Multiple stakeholders within and outside the organisation
- Changing technologies available to those stakeholders
- Complex organisations in which individuals and teams are interdependent
- People who have experience of change interventions which have had unforeseen or unintended consequences.

By viewing the NHS as a complex, non-linear system, a greater focus is placed upon the connections between the individual components that make up the system. The interactions between the individual components can lead to emergence of novel, unpredictable outcomes and the element of ‘attractor patterns’ (82) where individuals within the system may default to a certain group of behaviours which could be perceived, potentially incorrectly, to be resistance to change (76). At this point, an effective leader would place a greater emphasis on identifying how services interact and influence each other, whilst engaging with staff within the organisation to introduce new ‘attractors’ in order to influence behaviour and attitudes (76,82,83). From a complexity theory perspective it is important to understand that meaningful change is more likely to occur if it is allowed to emerge spontaneously, rather than being imposed from a traditional top down approach (76). According to Greenhalgh (82), this has to be guided and may be achieved by the use of ‘minimum specifications’. This is a management strategy where the emphasis is placed upon ‘direction pointing’, setting ‘boundaries’ and ‘resources’, and then giving ‘permission’ for the system to generate its own solutions (76,82). Effective feedback mechanisms must also be in place to allow solution sharing throughout the organisation (82). As an example, an individual may have highlighted a high number of drug errors within the emergency department. The question for that individual or leader is what the best approach to reducing emergency department drug errors is. An organisation could disseminate top-down warnings to promote and create a greater awareness of the issue or alternatively, it could engage with emergency department members to discover if there are any recurrent themes (or attractors) in these errors, suggest options for how to minimize these in the future (direction pointing) but also encourage staff to take ownership of the problem themselves to ideally find their own solutions (permission). The solutions generated could then be used elsewhere within the organisation to attempt to reduce the problem in other departments. In contrast to this approach is the consideration of “champions of change”, a top down approach to change. The “champions of change” need to be the top management players within the organisation who keep the change process moving whilst maintaining the operational integrity of the organisation (93). Conger et al (94), identified steps that were needed to transform an organisation:

- Establishing a sense of urgency

- Forming a powerful guiding coalition
- Creating a vision
- Communicating the vision
- Empowering others to act on the vision
- Planning for and creating short-term wins
- Consolidating improvements and producing further change
- Institutionalising new approaches

Across the United Kingdom, in each region, and within organisations, the process for raising ideas and delivering change will differ, adding further complexity and non-linearity to the systems. According to a report from the British Medical Association however, the principles behind how to influence change are the same. This report sets out six themes which doctors will want to consider as they look to influence change in their organisation (95):

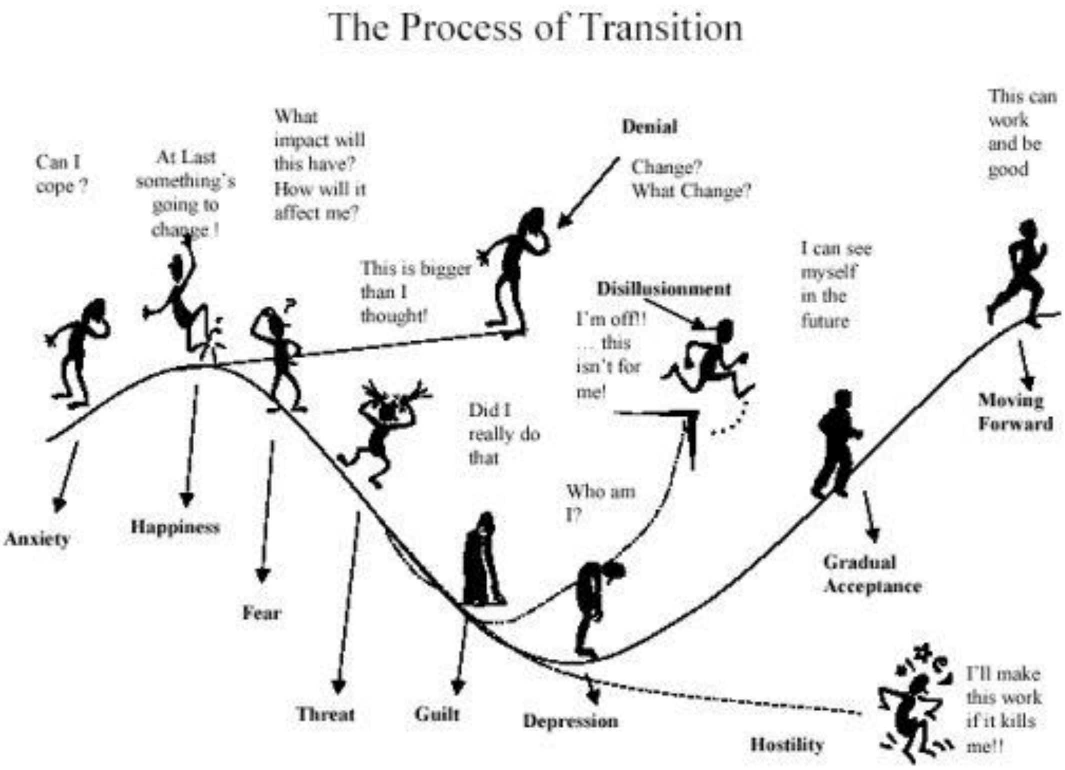
- Understand the process for change in your organisation
- Be clear about what you are proposing and why
- Use evidence to demonstrate the case for change
- Engage with stakeholders
- Understand the risks
- Monitor and evaluate progress

This report and the six themes have all the hallmarks of the substantial change management literature, originally from the business sector, which suggests change is linear. As has been discussed previously, the NHS and change within the NHS is certainly not linear in nature, however people are still attempting to work in this linear nature causing further inefficiencies within an already complex and inefficient system (82,84).

So far, the theories behind change in the NHS, linear and non-linear systems and complexity theory have been discussed. One element that is essential to consider is how people respond to change. Fisher's process of transition model (96) identified eight stages that people follow in succession through a change process (figure 1). The eight stages are:

1. Anxiety and denial
2. Happiness
3. Fear
4. Threat
5. Guilt and disillusionment
6. Depression and hostility
7. Gradual acceptance
8. Moving forward

Figure 1: Fisher's Process of Transition Model (96)



Different people will move through the stages at different speeds depending on their temperament, life experiences and degree of control (96). Depending upon the situation people may also regress to earlier stages. A good change leader should be able to identify where people are on the transition curve and therefore respond appropriately (96). This model identifies that people will generally react in a negative way to change in the initial period. They will be anxious and in shock, but this will be followed by a degree of happiness about the situation. The change leader may be able to reduce the amount of fear that is apparent at stage three if there has been open and honest communication at the happiness stage, but fear will always be present (96). Where fears are present these need to be addressed as quickly as possible as in times of significant change rational thought tends to go out of the window. When leading change, one has to be aware that there will be resistance to change, as it may be seen as a threat evoking the emotions of guilt, depression and hostility before accepting and moving forward (96). This resistance to change must be accepted as a perfectly normal reaction and not as a deterrent to continue the change process. People will move through the process of transition at different speeds and therefore change facilitators should be wary of which stage people are in when communicating with them as it can cause problems if people are pushed too far too quickly (96). If a change is attempted to be forced through before the majority of people are ready then in the long term the change will not be as effective as anticipated (96).

Although participation of all players is necessary, the role of a clear leader in the change process is crucial (93). In terms of the role of a leader within an organisation, it is essential that they are responsible for the creation, design and maintenance of a climate for change within the organisation, in this case the NHS (93). However, change within the NHS is often disruptive and complicated with events rarely occurring exactly as people predict.

Leadership

High-quality leadership and management at all levels is a prerequisite for a NHS that delivers both the highest possible quality of care to patients and the best possible deal for the tax payer (97). In 2015, a review conducted by the Faculty of Medical Leadership and Management (FMLM), The King's Fund and the Centre for Creative Leadership (CCL) showed the importance of leadership in the health service (98). The review concluded that 'there is clear evidence of the link between leadership and a range of important outcomes within health services, including patient satisfaction, patient mortality, organisational financial performance, staff well-being, engagement, turnover and absenteeism, and overall quality of care'(98). It follows that if we are able to develop leaders and improve leadership behaviours and skills then that will lead to better patient care, experience and outcomes. Before looking at leadership and how leaders are developed within the NHS itself though, we need to consider what leadership is and the theory behind leadership and its various styles.

A definition for leadership upon which everyone agrees is extremely difficult to identify, with different disciplines, such as business and education, having diverging definitions. According to Bass and his work on transformational leadership, a leader should (99):

- Be a model of integrity and fairness.
- Set clear goals.
- Have high expectations.
- Encourage others.
- Provide support and recognition.
- Stir the emotions of people.
- Get people to look beyond their self-interest.
- Inspire people to reach for the improbable.

More than 25 years after Bass's work was published, transformational leadership is often argued to be one of the most important ideas in business leadership (99). As healthcare systems both locally and internationally are confronted by multiple new challenges, including workforce deficits, increased patient expectations or demands and financial constraints, effective leadership and management of hospitals have become crucial. The literature relating to business leadership and management has largely been translated to the healthcare setting, as it provides both clinical and managerial professionals with existing frameworks or models that can be applied to elements such as change management and governance(97,98,100,101) .

Several core theories regarding leadership have emerged over the course of time. On the whole, these theories can be placed into four categories (102):

1. Trait theories
2. Behavioural theories
3. Contingency theories
4. Power and influence theories

All of these categories have been debated within the literature for two or three decades (101–103). For example, trait theories are of the opinion that effective leaders will share common personality characteristics. The trait theory of leadership suggests that leaders are born and not made, in so far as personality traits are what influence leader emergence and effectiveness (104). Fleenor (105) suggested that characteristics such as integrity, empathy, assertiveness may well be common amongst leaders but this has more recently been challenged by Northouse who argued that this does not guarantee a person to be a good leader, as a situational component needs to be taken into account (106). In contrast the behaviour theories focus on how leaders behave. One behavioural theory developed by Lewin in the 1930s (107) described three types of leaders: autocratic, democratic and laissez-faire. What is clear to see though is that there is no one single answer, as to what makes a good leader.

As there is no universally agreed upon leadership definition or theory, focusing on different leadership styles is helpful in learning the elements of what makes a good leader. In 2001, Goleman (108) identified six different leadership styles, arguing that good leaders will adopt one of these six styles to meet the needs of different situations. Goleman (108) links these leadership styles to their effect upon organisational climate and describes ways in which the various styles can be effective or ineffective in different situations. Key to Goleman's argument is that good leaders must be emotionally intelligent or sufficiently sensitive and interpersonally aware to know which styles to adopt in different situations. The six styles have been split into two groups where four of the styles are thought to encourage team harmony and inclusion whilst the other two styles can potentially create dissonances and discord. The four styles encouraging team harmony are called visionary (moves people towards shared dreams, creates a sense of direction, encourages change), coaching (helps individuals improve their performance and align employee goals with those of the organisation), affiliative (builds relationships and teams, and helps to deal with problems/situations between teams), and democratic (helps to create buying all consensus by involving people and valuing their input) (108).

The other two leadership styles are more directional and focus on the setting down of expectations: pacesetting (sets challenges that highly performing team members can achieve and this can leave less competent people falling behind and obviously potentially uncomfortable and dissatisfied), and commanding (gives direction when problems arise or calms things down a crisis) (108).

Each of these styles demands different characteristics from the leader. Characteristics needed for the visionary style include being able to inspire and believing in one's own vision and spreading the passion for that vision. In comparison, the coaching style requires a leader to build, nurture and empower their team and treat them as individuals. The affiliative leadership style requires diplomacy, encouragement and the ability to discourage conflict, whereas a democratic leadership style needs the characteristics of collaboration, influence and the ability to listen. When considering the two more directional leadership styles, characteristics needed for the pacesetting style include being a high achiever with high standards and being impatient or unsympathetic. The commanding leadership style requires the leader to be coercive, in control and often they employ a divide and rule ethos (108). All of these styles will have different effects and impacts upon individuals depending upon when they are used. Characteristics that have not been mentioned yet, but are essential, are flexibility and the ability to adapt to the situation the leader faces. Without these two characteristics switching between the leadership styles would be difficult and therefore the quality of leadership would be compromised (108). Alongside this, the ability to learn new and potentially better ways to deal with problems would also be lacking, demonstrating not only a lack of flexibility and adaptation but also potentially insight (108).

Goleman's work on emotional intelligence highlights that we must have an awareness of being able to manage ourselves in order to be an effective leader (108,109) Awareness of an individual's personal qualities like self-awareness, self- confidence, self-control, self-knowledge, personal reflection, resilience and determination is vital for a leader and these characteristics are the foundations of how we behave (109). An individual being aware of their strengths and limitations in these areas allows for the development of their own leadership skills.

The next focus is on how the NHS develops their leaders. It has already been discussed that the FMLM, King's Fund and the CCL produced a review that demonstrated a clear link between the leadership within an organisation and better patient and organisational outcomes (98). In 2013 the NHS Leadership Academy commissioned a study which looked into a leadership model that could be used by the NHS (110). In its foreword, the study states that ‘technical competence, professional skills, managerial excellence all contribute to good leadership, but the real test of what separates those people, in an organisation such as the NHS, is the care, compassion and genuine investment in staff that great leaders recognise as being the key difference between adequate technical clinical care and a great healthcare service’(110).

The review came up with a proposal which categorised three behaviours of leadership (110):

- provide and justify a clear sense of purpose and contribution
- motivate teams and individuals to work effectively
- focus on improving system performance.

Following this review, the healthcare leadership model (109) was developed to help those who work in healthcare to become better leaders. This model aimed to help healthcare professionals understand how their leadership behaviours affect the culture and climate in which they and their teams work. This model is made up of nine ‘leadership dimensions’ (109):

1. Inspiring shared purpose
2. Leading with care
3. Evaluating information
4. Connecting our service
5. Sharing the vision
6. Engaging the team

7. Holding to account
8. Developing capability
9. Influencing for results

For each dimension, leadership behaviours are detailed on a four-part scale that ranges from essential to exemplary. According to the healthcare leadership model (109), all nine dimensions are important for an individual's leadership role. However, the type of job, the needs of the people within the team and the context of the leader’s role within the organisation will affect which dimension is most important to use and develop. One of the leadership dimensions is shared purpose, which will be described next as one of the key components of this study.

Shared purpose

Shared purpose is the ‘alignment of the belief systems or values of a group of individuals with a clear challenge, vision for the goal’ (111). The NHS change model (111) was created to support the NHS in adopting a shared approach to leading change and transformation. There are eight components in the model of which shared purpose is the central concept. To truly understand the phrase, shared purpose, a definition of purpose is required. Purpose is the why, not the what or the how of our working lives (111). It encompasses or touches upon a number of other concepts such as vision; values; goals; organisational culture and engagement but sits above all these(112). Purpose becomes shared when three things happen. Firstly, listening to and understanding others’ perspectives, the second stage is the discovery of these perspectives overlapping with our own. The third step is when an agreement is reached on how to translate these shared perspectives into action towards a common goal. Strong shared purpose is a common thread in successful change programmes (112–114).

Leaders can be reluctant to spend the necessary time establishing a shared understanding and listening to the stories and perspectives of those whom the change will affect (112). A pacesetting leadership style is prevalent in the NHS, which is not often compatible with the collaborative approach that is most likely to deliver successful and sustainable change (111). Engaging health care staff in any change process is essential as the quality of care that patients receive depends on the skill and dedication of this group of people (115). Highly engaged staff or individuals who are committed to their organisations and highly involved in their roles are more likely to commit to their work, to take the initiative, to ‘go the extra mile’ and to collaborate effectively with others (115). Following the much publicised Mid Staffordshire inquiry, the Department of Health and Social Care published a recommendation in relation to staff commitment to the values and constitution of the NHS (116):

> ‘All NHS staff should be required to enter into an express commitment to abide by the NHS values and the Constitution, both of which should be incorporated into the contracts of employment.’

This was intended to send a clear message that patients and their safety come first (116). This is without doubt a key finding of the Francis report (116), and reviewing the evidence surrounding staff engagement and commitment confirms that positive staff engagement has been linked to reduced staff turnover, lower sickness absence and improved patient experience (117–119), which demonstrates the value of investing in staff engagement and commitment. The King’s Fund produced a document that described six building blocks for harnessing staff engagement (115):

- Develop a compelling, shared strategic direction
- Build collective and distributed leadership
- Adopt supportive and inclusive leadership styles
- Give staff the tools to lead service transformation
- Establish a culture based on integrity and trust
- Place staff engagement firmly on the board agenda

These building blocks were created because, despite the growing evidence of improved outcomes from good staff engagement, how to create an engaged workforce is seemingly a struggle. The first building block - ‘develop a compelling, shared strategic direction’ - brings the concept of shared purpose to the forefront. Three steps have been identified by Manley et al, (112) to facilitate the creation of shared purpose: create a safe space, look for commonalities and design the service together (112). Providing a safe space in which people feel able to express themselves free from hierarchical influence is a key component to building shared purpose. Following this, encouraging each individual to talk about their own values and stories will help to unite the group with similar values, ambitions and goals. The third step, designing the service together, suggests that involving those at the coalface of change in its design as well as its implementation is likely to create a sense of shared purpose. Once shared purpose is created it can be used at different points during the change process, to ensure the change process keeps on track and also if the change process needs to be re-energised (112). By returning regularly to the original purpose for the change the leader can guide decisions and prevent the process from going off track, simply by asking the question 'how does this support our shared purpose?' In any change process there is often at least one point where it plateaus, which can ultimately lead to failure (96). Again, revisiting the purpose and vision is one of the best ways of reviving the process. The Health Foundation report a number of areas within healthcare whereby corporate and clinical teams have worked together to enhance patient care (114). Their report identifies that if a shared sense of purpose and teamwork are aligned then successful change can occur.

Teamwork

The benefits of high-quality teamwork in healthcare are well recognised. A reduction in medical errors (120), an increase in patient safety (121) and improved patient mortality rates (122) have been proven by teams who work effectively together. Alongside these patient outcomes there are also improved outcomes in relation to reduced stress and improved job satisfaction for health care workers. The Royal College of Physicians has produced a collection of reports aiming to promote high-functioning team working in the medical setting (123). Key to the improvement and maintenance of professional satisfaction and engagement (117), organisational performance (124), productivity (125) and patient satisfaction and outcomes (126) is a team that works together effectively but also with high quality individuals within that team. Working in well-structured teams is a prognosticator for patient mortality as well as staff absenteeism and turnover (117). Teamwork is reported to be a key predictor of organisational success (124) with further research confirming those findings (125), in relation to people management and organisational performance.

In relation to the implementation of organisational change, working as part of the team is a critical success factor. During times of change the strength of the team will be tested and being able to maintain the strong bond of the team during periods of uncertainty could be the difference between success and failure. Within the literature there is a broad consensus on what constitutes a team. Katzenbach and Smith (127) stated that "... a team is a small number of people with complementary skills who are committed to a common purpose, performance goals, and approach for which they hold themselves mutually accountable". In addition, regular communication, coordination, distinctive roles, interdependent tasks and shared norms are important features (128,129).

Teams are often viewed as a three-stage system where they utilise resources (input), maintain internal processes (throughput) and produce specific products (output) (130). Within this model the characteristics of an effective team are based on the antecedent conditions together with the processes of maintaining a team, with the outcomes being used to evaluate the team's effectiveness (130). Many theorists offer recommendations about the structural characteristics of teamwork, by referring to relatively stable procedures of coordination and control. The most commonly described structural characteristics are: clear purpose, appropriate culture, specified task, distinct roles, suitable leadership, relevant members and adequate resources, all of which were identified within this study (130). The characteristic of 'clear purpose' is described by organisations having a clear vision that encompasses their underlying value (131), and agreeing upon goals often being achieved through a common commitment to patients' needs (132,133). One could argue that this is a similar concept to shared purpose. With regards to 'appropriate culture', teams should be recognised and integrated within their organisations (134), whilst organisational culture must transform shared values into behavioural norms (135,136). If a team is given a 'specified task' then that task needs to make a tangible contribution to the organisation and be consistent with the team's purpose, abilities and attitudes. The tasks also need to be sufficiently motivating for team members to share responsibility and accountability for achievement (137). Healthcare teams need to clearly define the specific aspect of complex and inter-related patient care which they address (138). Within a team, 'distinct roles' need to be clarified and understood by all. However, role construction can be influenced by personal expectations, and by organisational and interpersonal factors (139). Therefore, roles need to be flexible enough to accommodate individual differences, personal development needs and membership changes (135). Roles were already in place prior to commencement of this study and did not change throughout, although personnel did change. The more complex and dynamic the team's task, the more a leader is needed. 'Suitable leadership' should reflect the team's stage of development. Leaders need to maintain a strategic focus to support the organisation's vision, facilitate goal setting, educate, and evaluate achievements (140). When leaders delegate responsibility appropriately, team members become more confident and autonomous in their work (130). Teams require the right number of members with the appropriate mix and diversity of task and interpersonal skills- 'relevant members'. A balance between homogeneity and heterogeneity of members' skills, interests and backgrounds is preferred (141). West (131) emphasised that organisations need to provide teams with adequate financial resources, administrative and technical support and professional education, described as the 'adequate resources' characteristic. In healthcare environments, there may be conflict between clinical responsibilities and training needs, and over issues of patient risk and privacy (141).

The above characteristics describe the elements that are needed for successful teamwork but what about the reasons why teams fail? Lencioni describes five dysfunctions of a team that can cause failure (142). These include:

1. Lack of trust
- Unwilling to be vulnerable within the group
2. Fear of conflict
- Seeking artificial harmony over constructive passionate debate
3. Lack of commitment
- Feigning buy-in for group decisions creates ambiguity throughout the organisation
4. Little or no accountability
- Ducking the responsibility to call peers on counterproductive behavior which sets low standards
5. Failure to focus on results
- Focusing on personal success, status and ego before team success

This model helps to explore the ‘dark side’ of individual and collective behaviours and can help unpick why individual positive intent is not sufficient to create effective teams (143).One theme that has run throughout the shared purpose, teamwork and leadership aspects is that of commitment. It is evident that without commitment the process of change or success within a team environment would not be possible.

The next two topics in this literature review are based around the more tangible and measurable elements of capacity and clinical outcomes. The importance of both of these elements is discussed.

Capacity

Managing demand and capacity within the NHS where budgets are stretched has become increasingly difficult. Meeting targets, such as the 2-week wait for cancer referrals and the 4-hour emergency department target, has become a primary focus and goal that is rarely achieved in individual hospital trusts (144,145). Waiting lists and times are often spoken about within the NHS and there has been a great deal of analysis which has indicated that most waiting lists are actually relatively stable, suggesting that the variation in waiting lists is due to changes in capacity and demand (146,147). Capacity is defined as the resources available to do work, for example number of pieces of equipment available multiplied by the hours of staff time available to run it (146). Demand is defined as all the request/referrals coming in from all sources and how many resources they need to be dealt with (146,147). Variation in capacity and demand is one of the main reasons why waiting lists develop and waiting times increase. When aiming to identify patient flow through a healthcare system, it is necessary to address the entire patient process, allowing identification of where the delays for patients are and how these can be resolved (146).

Without doubt the aim of all NHS trusts and healthcare providers is to deliver high quality care consistently. The NHS improvement team have developed demand and capacity models to assist trusts with attempting to delineate their requirements in elective settings (146). Whilst the NHS has developed a national model to identify issues with demand and capacity, healthcare services around the world have adopted process improvement methodologies from the manufacturing sector in an attempt to improve operational efficiency, such as Lean

Production- a business concept used to drive the elimination of waste and streamline processes within a business (148,149). Radnor et al described how the application of these process improvement methodologies tend to produce small-scale, localised gains but not necessarily on a system-wide approach (148). This paper also suggested that healthcare is predominantly designed to be capacity-led and there is limited ability to influence demand or make full use of available resources (148). Interestingly, another paper suggests that a lack of capacity is typically not the major issue (150). It suggests that the primary reason why there are long waiting times in the NHS is due to the mismatch between demand and capacity, i.e. demand and capacity variation (150). As a result, elements of the NHS are investing in additional capacity that will not necessarily increase the overall output from the service or may even make the situation worse (150). A number of elements can have an influence on demand and capacity, particularly in outpatient clinics, mainly based around the fact that a variability in capacity has a greater influence than variability in demand (151). The subsequent development of the NHS demand and capacity models should help to limit the variation between demand and capacity in local organisations and potentially throughout the country (146). Once an organisation has managed its capacity and demand, the focus shifts to outcome measures, with the next part of this literature review focusing specifically on clinical outcomes.

Clinical outcomes

Clinical outcomes are broadly agreed, measurable changes in health or quality of life that result from care given by healthcare providers (152,153). Primarily, they are measures of treatment effectiveness, however they may also be used to identify other elements that can impact treatment effectiveness, such as safety and efficiency(152,153). Clinical outcome data can be captured in a number of different ways but is usually captured by healthcare professionals (154).

Patient Reported Outcome Measures (PROMs) are used so that there is a measurement of clinical outcome from the patient's perspective (155). They are standardised, validated questionnaires, completed by patients to ascertain perceptions of their health status, perceived level of impairment, disability, and health-related quality of life (156,157). Pre and post-treatment questionnaires are completed to allow comparison of outcomes (158). PROMs are not just used for the effectiveness of interventions but they can be used to measure a patient's perception of their general health or their health in relation to a specific disease (159). PROMs used for general health measure a variety of aspects that allow evaluation of care, quality of life and cost effectiveness of interventions (159). Alternatively disease specific PROMS allow specific aspects of a condition and their impact on outcome to be examined (157). In clinical practice a combination of the two types of PROMs is used (156).

There is a significant body of evidence that suggests the systematic use of PROMs leads to better communication and decision making between doctors and patients and ultimately improves patient satisfaction with care (160–164). Despite this, the attempt at embedding PROMs into routine practice has been difficult due to many technical, social, cultural, legal and logistical barriers (155,165,166). One of these barriers is based around clinician fear that using PROMs will add to their workload instead of making them more efficient or effective (155). In contrast, patients welcome systems that routinely use PROMs whereas some clinicians feel that they already understand their patients’ problems and do not require the information that using PROMs would afford them (155).

PROMs data can be used in research, quality improvement projects, audit, and for economic evaluation. The data obtained from PROMs helps to improve and focus patient-centred clinical management but also provides vital feedback to healthcare providers to allow comparisons in clinical care (156). However, care must be taken when healthcare providers implement these tools, as there are limitations to using PROMs. Use of the correct measuring instrument, how the data is collected and cost are all key factors that need to be taken into account when considering using PROMs (156,167). In particular, education programmes may be needed to allow healthcare providers to use the tools effectively, at the cost of time and money (167). Awareness of the fact that patient outcome data is an indicator of quality, but not a direct measure of it is key when any disparities occur between patient experience data and clinical effectiveness or safety data (156,167).

For the purposes of this study, the change involves the implementation of an innovative ICP for FI. Implementing and integrating a healthcare innovation such as this ICP is a complex process, that will be dependent upon all of the topics previously discussed. This complex process can be explained on a sociological basis by normalization process theory (NPT) (37).

Normalization Process Theory

The normalization process theory (37) and its predecessor, the normalization process model (168,169) identify factors that promote and inhibit the routine incorporation of complex healthcare interventions and technological or organisational innovations into everyday practice. This theory also explains how these interventions work, not only looking at early implementation but beyond this to the point where an intervention becomes so embedded into routine practice that it becomes “normalized” (170). To be “normalized” a classification, artifact, technique or organisational practice becomes routinely embedded in everyday life (171).

By providing a framework that aids in the identification of facilitators and barriers to the implementation of healthcare innovations, NPT can be viewed as an adjunct to the theories of change management. NPT will help to identify some of the elements detailed in the change management models discussed previously, allowing those involved in managing change to apply practice to the theory e.g. step 5 of Kotter’s 8-step change model (81), removing obstacles- using NPT obstacles can be identified, allowing the change leader to be aware and resolve the obstacle. However, it must be noted that NPT focuses on the implementation and integration of interventions with reference to the work that people do and therefore is limited in this regard as it will not cover all aspects of change management theory (171).

NPT is concerned with the generative processes that underpin three core problems (37,168,169,172,173) :

- Implementation- bringing a practice or practices into action;
- Embedding-when a practice or practices may be routinely incorporated into the everyday work of individuals and groups;
- Integration-where practice or practices are reproduced and sustained in the social matrices of an organisation or institution

There are three core propositions of NPT starting with (171):

(a) Complex interventions become routinely embedded in their organisational and

professional contexts as the results of people working, individually and collectively, to implement them

This is important as it states the routine embedding of a complex intervention is the product of action or what people do, not necessarily due to people's attitudes, or intentions. Explaining implementation and integration is about explaining action. So, to understand the embedding of a complex intervention it is imperative to look at what people actually do and how they work. This leads to the second core proposition:

(b) The work of implementation is operationalised through four constructs:

- *Coherence*-sense making that promotes or inhibits the coherence of a complex intervention to its users. These processes are driven by investments in **meaning** made by participants.
- *Cognitive participation*- promotes or inhibits user’s enrolment and legitimisation of a complex intervention. These processes are driven by investments of **commitment** made by participants.
- *Collective action*- promotes or inhibits the enacting of a complex intervention by its users. These processes are energised by investments of **effort** made by participants.
- *Reflexive monitoring*- promotes or inhibits users comprehension of the effects of a complex intervention. These processes are driven by investments in **appraisal** made by participants.

NPT is concerned with identifying and understanding the ways that people make sense of the work of implementing and integrating a complex intervention- coherence; how they engage with it- cognitive participation; enact it- collective action; and appraise its effects- reflexive monitoring (171). Each of the four constructs has four components within them (171):

Table 5: The four components of each of the four constructs within NPT

Component	Description
Meaning *(Coherence)*	Understanding what is different about a proposed change and discussing this with everyone affected so that it makes sense and seems attractive to everyone. Individuals will need to consider the effect of the change on their role and responsibilities. If individuals fail to see the importance and benefit of the proposed change it is unlikely to succeed.
Commitment *(Cognitive participation)*	Following the introduction of a complex intervention it is essential that key participants organise themselves and others to drive the implementation process forward. If participants are to do this and make valuable contributions to sustaining the intervention, the participants must believe in the intervention and be aware of the actions needed to sustain the intervention.

Effort (*Collective action)*	Understanding the interaction between participants and other elements of the intervention during the process of implementation, therefore, allowing the participants to gain confidence in the intervention when using it. Thought should be given to the skill set and resources available within the team. Appropriate allocation of work to the participants may help to build accountability for the intervention.
Appraisal (*Reflexive monitoring)*	Participants will collect information so that they can define how successful the intervention has been personally and its general or collective worth. Different types of information may be used to evaluate this, but once the information has been collected the participant will decide upon their personal view with regards to the intervention. Once the participant has got to this point, any changes or modifications to the intervention may be considered.

The third core proposition is that:

(c) *The work of integration of a complex intervention requires continuous investment by people in an ongoing collective action that carries forward in time and space.*

This third proposition suggests that there is a need to continue investing time and effort to ensure that the complex intervention continues to develop. By continually investing in the sense making, commitment, effort, and appraisal of a complex intervention it ceases to be a ‘complex intervention’ at all and instead disappears into the everyday normal activities and therefore becomes normalized (171). Although NPT is a relatively new theory (described within the last five years), it has already been developed, tested, and refined in studies conducted across diverse settings including:

- Informing the development and evaluation of complex clinical and organisational interventions mental health care (174–176)
- Examining the work processes entailed in implementing treatment regimens into patients’ routines (177)
- Informing evaluations of treatment modalities in cancer (178), and diabetes (179)
- Aiding the understanding of the findings of randomised controlled trials for chronic constipation (180) and collaborative care for depression (181).

The majority of the work that has been published has been based on ensuring that the core constructs of NPT can be operationalised in a stable and consistent way in multiple diverse areas. This has involved qualitative studies that interrogate very different social contexts, which is of particular value for this study. Qualitative research is a key tool in identifying, describing and understanding implementation processes, as it is often difficult to precisely measure these. NPT can play a key role in a qualitative research project in four main ways: helping to inform, guide or structure the initial research focus and questions; initial research design, sampling and data collection; the way data is coded and analyse the emerging interpretations, conclusions and recommendations (171). In this study NPT will help to inform, guide and structure the emerging interpretations, conclusions and recommendations from both the qualitative and quantitative elements.

The next chapter will describe in detail the methodology and methods used in the study.

CHAPTER 3: METHODOLOGY AND METHODS

This chapter describes the methodology used within the study. The chapter commences with a discussion regarding the different methodological approaches that can be used, followed by the methods used within this study.

Methodological Approaches

The term ‘methodology’ refers to the philosophical principles, paradigms and underlying assumptions on which the research is based (182). The methodology of a piece of research is based on a particular paradigm, a patterned set of assumptions concerning reality (ontology) and knowledge of that reality (epistemology) (183).

To select an appropriate methodological approach, the researcher had to consider both the quantitative and qualitative research paradigms, to ensure that the data obtained would be able to answer the research questions comprehensively. A paradigm is a perspective based on a set of assumptions, concepts, and values that are held by a community or researchers (184). The two paradigms differ in their ontological and epistemological positions. The quantitative paradigm is generally based on positivism, with the ontological position being that there is only one truth, an objective reality that different observers agree on. Epistemologically, the investigator is capable of studying a phenomenon without influencing it or being influenced by it, “inquiry takes place as through a one way mirror” (182). The purpose of quantitative research is to test hypotheses, look at cause and effect and make predictions based on the analysis of statistical data, (numbers) which will aim to identify statistical relationships. Within the quantitative paradigm the researcher tests the hypothesis and theory with the data, therefore using a deductive, confirmatory or top down scientific method (184,185).

In contrast, the qualitative paradigm is based on interpretivism (186,187) and constructivism (182), with the ontological position being that there are multiple realities, which are subjective in nature. The fact that there is subjectivity in one's construction of reality means that reality is constantly changing within the qualitative paradigm. This is more easily explained as when a person is attempting to identify what is happening in a certain situation, their judgment will be shaped by their personal feelings or opinions, therefore as the situation evolves so will the persons view of that situation. Alongside this, the same situation could be viewed by a different person and elicit a different ‘reality’, due to their opinions being different. The purpose of qualitative research is to understand and interpret social interactions, whereby patterns or themes are identified from qualitative data such as words, images or physical objects. In contrast to the quantitative paradigm, the researcher generates a new hypothesis and theory from the data collected, therefore using an inductive, exploratory or bottom-up approach (184,185).

Clearly the two paradigms do not only differ in their ontological and epistemological assumptions. Qualitative research focuses on examining the breadth and depth of phenomena to enable researchers to learn more about them using a wide-angle and “deep angle” lens (184,185). In contrast quantitative research uses a very narrow angle lens, focusing on testing specific hypotheses. When comparing the view of human behaviour between the two paradigms qualitative research assumes that behaviour is fluid, dynamic, situational, social and personal, whereas quantitative research assumes that behaviour is regular and predictable (184,188). This is one reason why when comparing results of the two paradigms, the qualitative research findings are less generalisable, whereas quantitative research findings are deemed to be generalisable and can be applied to other populations (184,188). Both paradigms have advantages and disadvantages. Since the 1970s the debate with regards to the quantitative–qualitative paradigms has continued unabated, leading to research studies being performed that combine qualitative and quantitative methods or paradigm characteristics, labelled mixed methods research (182,184). A definition of core characteristics of mixed methods research has been formulated (189), that include (188):

- Collecting and analysing persuasively and rigorously both qualitative and quantitative data;
- Mixing the two forms of data concurrently by combining them, sequentially by having one build on the other, or embedding one within the other;
- Giving priority to one or to both forms of data (in terms of what the research emphasises);
- Using these procedures in a single study or in multiple phases of a programme of study;
- Framing these procedures within philosophical worldviews and theoretical lenses; and
- Combining the procedures into specific research designs that direct the plan for conducting the study.

Since the 1990s a number of descriptions on how to perform mixed methods studies have been published (189–192). Despite mixed methods now being used widely within the research arena, there are still differing views held with regards to the advantages and disadvantages of using mixed methods. Both quantitative and qualitative research paradigms have their own strengths and weaknesses as general approaches when conducting social research. Table 6 shows the particular emphases of quantitative, mixed and qualitative research paradigms (184,185).

Table 6: An Overview of the Emphases of Quantitative, Mixed and Qualitative Paradigms (184,185).

	Quantitative Research	**Mixed Research**	**Qualitative Research**
Scientific method	Deductive or "top-down" The researcher tests hypotheses and theories with data	Deductive and inductive	Inductive or "bottom up" The researcher generates new hypotheses and grounded theory from data collected during fieldwork
View of human behaviour	Behaviour is regular unpredictable	Behaviour is somewhat predictable	Behaviour is fluid, dynamic, situation, social, contextual, and personal
Most common research objectives	Description, explanation, and prediction	Multiple objectives	Description, exploration, discovery and theory development

Focus	Narrow-angle lens, testing specific hypotheses	Multi-lens focus	Wide angle and “deep-angle” lens, examining the breadth and depth of phenomena to learn more about them
Nature of observation	Attempt to study behaviour under controlled conditions	Study behaviour in more than one context or condition	Study behaviour in natural environments. Study the context in which behaviour occurs
Nature of reality	Objective (different observers agree on what is observed)	Common sense, realism and pragmatic view of world	Subjective, personal, and socially constructed
Form of data collected	Collect quantitative data based on precise measurement using	Multiple forms	Collect qualitative data (e.g., in-depth interviews, participant

	structured and validated data collection instruments		observation) The researcher is the primary data collection instrument
Nature of data	Variables	Mixture of variables, words, and images	Words, images, categories
Data analysis	Identify statistical relationships	Quantitative and qualitative	Search patterns, themes, and holistic features
Results	Generalisable findings	Corroborated findings may be generalisable	Particularistic findings Present multiple perspectives Representation of insider viewpoint Theoretical insights may be

			generalisable.
Form of final report	Statistical report	Eclectic and pragmatic	Narrative report with contextual description and direct quotations from research participants

Can the quantitative-qualitative paradigms realistically be combined in research?

Given that some of the basic paradigmatic assumptions of the qualitative–qualitative debate have been discussed, the arguments as to why mixed method research can be used in a single healthcare study can be addressed.

There are a number of viewpoints as to why mixed methods research is deemed acceptable. Firstly, as the two paradigms (quantitative-qualitative) share the same goal of understanding the world in which we live (193), whilst also sharing a unified logic with the same rules of inference (194), it is felt to be acceptable for them to be combined (194). Secondly, both research paradigms are united by a shared commitment to gaining knowledge to help to improve the human condition, proceeding to disseminate this knowledge for practical use and an overarching shared commitment for a rigorous research process (195). It has been argued that researchers should view qualitative and quantitative methods as part of a continuum of research, with the appropriate techniques selected from each paradigm based on the research question or objective (190). Combining research methods is especially useful in certain areas of research, such as healthcare research, as the complexity of the phenomena studied will often require data from a large number of perspectives (196). Studying a public health problem or social intervention, such as health education and health promotion programmes will often require the use of both qualitative and quantitative methods to perform an appropriate and adequate research study (197,198). Combining qualitative and quantitative methods within a single study is now a widely practiced and accepted form of methodology used in healthcare research. Given that this is the case, it can be argued that quantitative and qualitative techniques are merely tools (199), whereby the integration of these tools enables researchers to answer questions of substantial importance.

For combining qualitative and quantitative paradigms two reasons prevalent within the literature are the ideas of cross validation or triangulation and complementarity. Firstly, cross validation or triangulation is the combination of two or more theories or sources of data to study the same phenomenon in order to gain a more complete understanding of it (200). The second reason for combining the two paradigms is to achieve complementary results by using the strengths of one method to enhance the other (201). Triangulation maintains that research methods are interdependent, whereas the complementary theory suggests that they are independent (202). Bryman (203) detailed a number of different ways in which quantitative and qualitative research can be combined in the research setting. Table 7 is a summary of the eleven approaches that were postulated.

Table 7: A summary of Bryman's approaches to combining qualitative and quantitative research (203)

Approach	**Description**
"Logic of 'triangulation'"	The findings from one type of study can be checked against the findings deriving from the other type. For example, the results of a qualitative investigation might be checked against a quantitative study. The aim is generally to enhance the validity of findings.
"Qualitative research facilitates quantitative research"	Qualitative research may help provide background information on context and subjects, act as a source of hypotheses and aid scale construction
"Quantitative research facilitates qualitative research"	Usually, this means quantitative research helping with the choice of subjects for a qualitative investigation.
"Quantitative and qualitative research are combined in order to provide a general picture"	Quantitative research may be employed to plug the gaps in a qualitative study that arise because, for example, the research cannot be in more than one place at any one time.

	Alternatively, it may be that not all issues are amenable solely to a quantitative investigation or solely to a qualitative one.
“Structure and process”	Quantitative research focuses on getting to the ‘structural’ features of social life, while qualitative studies are usually stronger on process aspects.
“Researchers’ and subjects’ perspectives”	Qualitative research is usually driven by the researcher’s concerns, whereas qualitative research takes subject’s perspective as the point of departure. These emphases may be brought together in a single study.
“The problem of generality”	The addition of some quantitative evidence may help to mitigate the fact that it is often not possible to generalise (in the statistical sense) the findings deriving from qualitative research.
“Qualitative research may facilitate the interpretation of relationships between	Quantitative research readily allows the researcher to establish relationships among

variables"	variables but is often weak when it comes to exploring the reasons for those relationships. A qualitative study can be used to help explain the factors underlying how broad relationships are established.
"The relationship between 'macro' and 'micro' levels"	Employing both quantitative and qualitative research provides a means of bridging the macro–micro gulf. Quantitative research can often tap into large scale, structural features of social life, while qualitative research tends to address small-scale, behavioural aspects. When research seeks to explore both levels, integrating quantitative and qualitative research may be necessary.
"Stages in the research process"	Quantitative and qualitative research may be appropriate to different stages of a longitudinal study.
"Hybrids"	When qualitative research is conducted within a quasi-experimental, quantitative research study design.

This table cannot be considered to be exhaustive nor should it be considered to be prescriptive. However, it is clear that any piece of mixed methods research can exhibit more than one of these approaches.

Strengths and Weaknesses of Mixed Methods Research

Awareness of the strengths and weaknesses that mixed methods research has is essential. Historically, a key argument for the use of mixed methods research has been the ability of the methodology to offset the individual weaknesses of both quantitative and qualitative research (203). It can also provide more evidence when studying a research problem than either individual paradigm alone (203). Within this point also lies the fact that mixed methods research can be deemed as being ‘practical’ in the sense that it is free to use all methods possible to address a particular research problem. Another strength leading on from this is that mixed methods research can help answer questions that would not ordinarily be able to be answered by either quantitative or qualitative research methods alone (203,204). Perhaps most importantly, researchers who conduct mixed methods research may be more likely to select the appropriate methods with respect to their underlying research questions rather than have to be ‘constrained’ by a singular research paradigm which could lead to bias within the study (203).

Despite all of the potential benefits when using mixed methods research, it is important to understand that mixed methods research designs are not always the appropriate choice for all research studies (204). The most important aspect is that the research question should inform which methodological approach is best suited to the study. Carrying out mixed methods research can be challenging, especially for researchers working in isolation, as two or more approaches are to be performed either concurrently or in succession. This highlights two issues, firstly the fact that to perform both a quantitative and qualitative study is time intensive and secondly, that the researcher has to be familiar with both qualitative and quantitative research paradigms whilst also knowing how to combine them appropriately (205). This means that researchers should ideally have gained experience with both quantitative and qualitative research separately before beginning to undertake a mixed methods study. Extending further on the time issue, researchers need to be aware that mixed methods studies not only require extensive time commitment, but they also will require extensive resources and effort on the researcher's part (204). This raises the issue of feasibility and researchers should consider the following questions early in the planning stage of their study (205):

- Is there sufficient time to collect and analyse two different types of data?
- Are the skills and personnel available to complete the study?

As with any study, a mixed methods study must be planned carefully, with the ability for the researcher to define a clear rationale that is defensible, which is part of the reason that this methodology is so time consuming (206). Mixed methods research demands flexibility from the researcher to be adaptive to the needs of the problem being studied (206). These are two of the key weakness of mixed methods research, but other strengths and weaknesses are described in table 8.

Table 8: An Overview of the Strengths and Weaknesses of Mixed Method Research

(205)

Strengths	Weaknesses
Words, pictures, and narrative can be used to add meanings to numbers.	It can be difficult for a single researcher to carry out both qualitative and quantitative research, especially if two or more approaches are to be used concurrently (i.e., it might require a research team).
Numbers can be used to add precision to words, pictures, and narrative.	The researcher has to learn about multiple methods and approaches and understand how to appropriately mix them.
Can provide quantitative and qualitative research strengths.	Methodological purists contend that one should always work within either qualitative or quantitative paradigms.
Researcher can generate and test a grounded theory.	It is more expensive.
Can answer a broader and more complete range of research questions because the researcher is not confined to a single	It is more time-consuming.

method or approach.	
A researcher can use the strengths of an additional method to overcome the weaknesses in another method by using both in a research study (this is the principle of complementarity).	Some of the details of mixed research remain to be fully worked out by research methodologies (for example, problems of paradigm mixing, how to interpret conflicting results).
Can provide stronger evidence for a conclusion through convergence and corroboration of findings (this is the principle of triangulation).	
Can add insights and understanding that might be missed when only a single method is used.	
Can be used to increase the generalisability of the results.	
Qualitative and quantitative research used together produces more complete knowledge necessary to inform theory and practice.	

When comparing quantitative, qualitative and mixed methods research paradigms the benefits of mixed methods research are clear to see. On the whole, this is due to the fact that mixed methods research is not limited by epistemological and ontological assumptions that limit mono-method research. However, some researchers believe that the quantitative and qualitative paradigms are so distinct from each other, epistemologically and ontologically, that they cannot be combined (207,208), whereas other researchers argue that there are definite similarities between the research paradigms (205).

Mixed methods research seems to be both practical and intuitively attractive in that it helps to offer multiple ways of viewing problems–something that is found in the real world. However it is not a methodological panacea, but it certainly offers researchers another method within which attempts can be made to explore as well as explain a specific research problem.

Study Methods

Evaluating the implementation of an ICP is a complex process. The methodology chosen for the study reflects this. By using a mixed methods approach, a study was performed, whereby conclusions could be drawn about both quantitative and qualitative aspects of the new service. This allowed the researcher to explore and explain the barriers and facilitators with regards to the implementation of an ICP for FI. To be able to answer the research questions posed within this study, a mixed methods approach was essential. To capture referral and clinical outcome data requires the use of quantitative methodology, whereas attempting to identify facilitators and barriers to the implementation process alongside how this affects the key stakeholders involved in the process requires qualitative methodology, as this element is not amenable to a quantitative approach.

For the purpose of clarity, the study period was split into three main phases: baseline, implementation and final, to enable description of the methodology in a narrative form. The different elements of the mixed methods approach that were used throughout these phases will now be detailed, firstly in a tabulated form with a brief overview of each phase (table 9), followed by a graphic timeline of methodology (figure 2) and subsequently, a more detailed description of each phase. Within the descriptive element of each phase, there will be details on the justification for the use of methodology within the study.

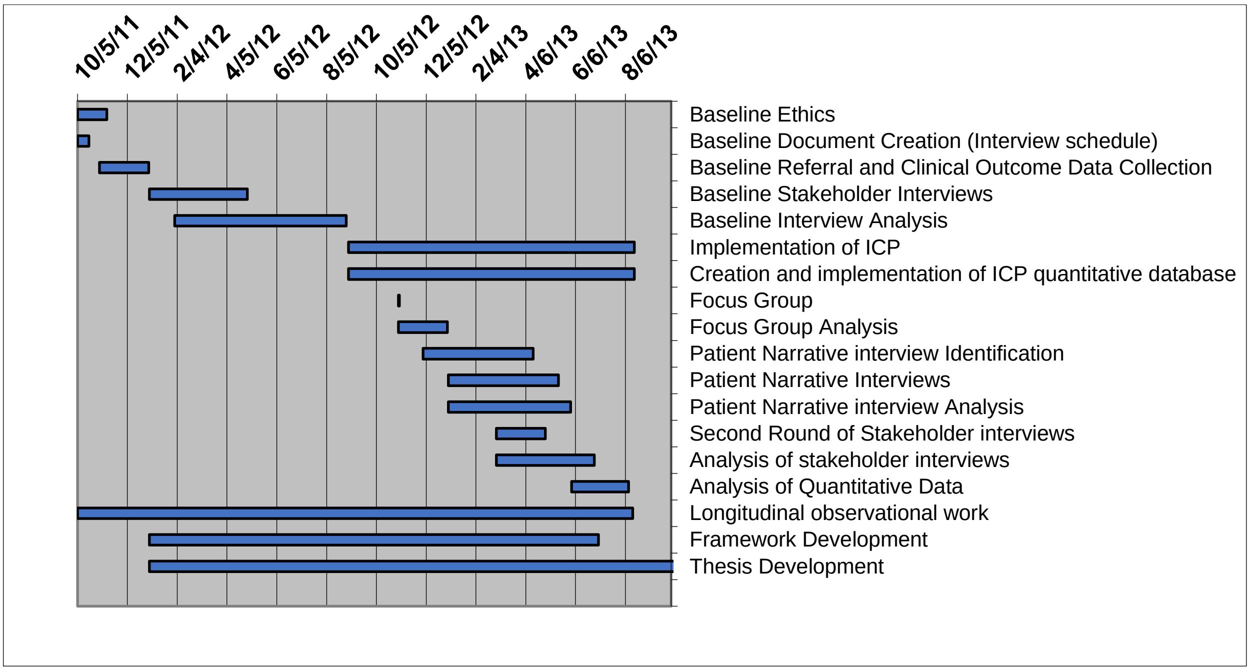
Table 9: Overview of the Research Phases

Research Phase	Research Activity	Stakeholder and/or patient involvement	Time duration
Baseline	University ethical approval Hospital trust governance approval Development of interview schedule First round of semi-structured interviews Baseline interview analysis Longitudinal	Stakeholders	October 2011- June 2012

	observational work at service related meetings Quantitative data collection of referral rates and clinical outcomes of original service		
Implementation	Longitudinal observational work at service related meetings Creation of ICP database for prospective quantitative data collection Focus group	Patient	June 2012-January 2013
Final	Second round of semi-structured interviews	Stakeholders	January 2013-October 2013

	Narrative patient interviews Longitudinal observational work at service related meetings Interview analysis Quantitative data analysis	Patient	

<u>Figure 2: Gantt Chart: graphic timeline of methods</u>



Baseline Phase: October 2011- June 2012

Upon commencement of the study period in October 2011, the proposed date for implementation of the ICP was February 2012. Therefore it was imperative that a timely start was made with the research study. At this point, the research study was to be focused around the implementation of the ICP for FI but during the first month of the research period, following a review of relevant literature around ICPs and FI, the specific aim of the study was decided upon with it being based around the barriers and facilitators for the implementation of the ICP for FI at SWBHT. This aim would be subsequently focused to form the researcher's specific research questions, which have been described earlier (pp20).

Ethical Approval

Ethical approval was sought for the study, following consultation with the University of Birmingham ethical review committee and SWBHT's research and development office. This consultation process determined that national ethical approval was not required as the study was deemed to be a service evaluation; therefore University of Birmingham ethical approval would be sufficient. As part of the ethical approval process and preparation for the baseline phase of the study, participant interview schedules and information sheets were drafted. The questions within the semi-structured interview schedule were based upon trying to identify how the current service works, who is involved in delivering the service, issues with the current service and plans for the service in the future. Both the semi-structured interview schedule (appendix 1) and information sheets (appendices 2 and 3) were revised on three occasions following review by the researcher. The semi-structured interview schedule and information sheets were submitted to the University ethics department for approval, which was subsequently obtained without any issue, ERN_12-0486 12/12/2011.

Semi-structured interviews

Three main types of qualitative interview have been identified: structured, semi-structured, and narrative (209). All three types of interview have their advantages and disadvantages. Structured interviews tend to consist of interviewers asking questions in a rigid, standardised manner according to a strict interview schedule or by administering structured questionnaires. This is advantageous if a limited number of responses are required to a question but the opportunity to explore emergent findings may be missed. Semi-structured interviews consist of an interview schedule that has open-ended questions that are based around a loose structure (209). The open-ended questions define the area that is to be explored and act more as a guide, allowing the interviewer to pursue comments made by interviewees in more detail if they feel this is necessary. Semi-structured interviews were deemed more appropriate by the researcher, for the stakeholder interviews, as this allowed the exploration of any ideas outside of the questions that needed to be asked. This allowed the researcher to gain similar information from all stakeholders but allowed flexibility within the process so that any emerging issues from their personal perspectives could be taken on board. Narrative or in-depth interviews are less structured than the previous two interview techniques. They will only cover one or two issues but generally in much greater detail (209). This type of interview was used for the patient interviews as the researcher felt it would give them a greater insight into their feelings on their condition and the pathway of care within which they were managed. Unstructured narrative interviews are particularly useful when researchers are uncertain which topics are most important to participants (209).

A key element in any qualitative research interview is discovering the interviewee’s own framework of meanings whilst trying to avoid the imposition of the researcher's assumptions as much as is possible (209). As a researcher it is key that when performing an interview, especially with semi-structured interviews, that one remains open to the possibility of emerging concepts that one may not have predicted at the beginning (209). Certainly as a novice qualitative researcher this was one of the thoughts that stayed at the forefront throughout the interview and analysis process. For this reason, structured interview techniques were not used.

When considering which type of interview to use for the stakeholder interviews, one of the key considerations was ensuring that a core amount of information was captured, whilst not being too restricted by this. Therefore semi-structured interviews seem to be most appropriate as they provide a clear set of instructions or questions, for interviewers, which will help to provide reliable, comparable qualitative data, whilst also allowing interviewers to deviate from the interview schedule to follow any relevant topics mentioned by the interviewee. Another benefit, certainly for a novice qualitative researcher, is that questions used in semi-structured interviews can be prepared ahead of time, allowing the interviewer to be adequately prepared during the interview (209).

This preparation involves developing the interview guide or schedule; this is a document that contains the questions that will need to be asked within the interview with specific prompts underneath them. Whichever type of interview is being performed, the questions that are going to be asked should take into consideration the following points (210):

- "The focus of the enquiry" (research question)
- "What the interviewer wants to learn from the person they are speaking with"
- "How much time the researcher has and the kind of access they have"

- "How much the researcher already knows about their question, and how to manage this knowledge"

Patton (211) reported that good questions in qualitative interviews should be open-ended, neutral, sensitive, and clear to the interviewee. The researcher made efforts to achieve this with their interview questions.

All interview guides or schedules should be developed iteratively (210). This was certainly the case with the interview schedule developed by the researcher in this study, as after each interview was performed the interviews were transcribed to try to identify any key points that could be included in subsequent interview schedules. With regard to semi-structured interviews specifically, the researcher developed a schedule that had general questions, which attempted to explore the topic. The order in which the questions from the interview schedule were asked varied as the researcher needed to remain flexible dependent upon where the topic of conversation was heading. There were a number of readily prepared probes available for the researcher to elicit the information that they needed. However, an interviewer (or researcher) can only probe if they are aware of when to probe. This highlights another important point about interviewing. The researcher's day-to-day job involved interviewing patients in a clinical setting that, although some elements overlap, on the whole is different from qualitative interviewing. Bearing this in mind the researcher underwent a period of training prior to commencing the semi-structured interviews. This consisted of observing a qualitative researcher perform four semi-structured interviews, the researcher performing two semi-structured interviews whilst being observed, with the first two semi-structured interviews of the study being performed by the researcher but observed by an experienced qualitative researcher. The observer, following each interview, gave feedback to the researcher that was acted upon where necessary. This training was vital, as qualitative interviews require considerable skill from the interviewer. The key elements that a novice qualitative interview needs to be aware of are (212):

- Whether leading questions are being asked
- Whether verbal or non-verbal cues are being picked up
- How directive they are being
- Whether interviewees are given enough time to explain what they mean

Whyte (212) devised a six-point directiveness scale to help novice researchers analyse their own interviewing technique. The researcher used this six-point directiveness scale to analyse each of the interviews performed whilst transcribing them. This allowed reflection upon the researcher’s interview technique as well as the key elements that have been mentioned above.

Staff Interviews

Semi-structured interviews were begun from January 2012. They were recorded using a digital recorder. The researcher decided that recording the interviews was the most appropriate method to use, as semi-structured interviews, contain open-ended questions and discussions may well deviate away from the interview schedule, therefore making it difficult to make comprehensive and reliable written notes (209,210). Another advantage of recording the interview was that the researcher was able to develop rapport with the interviewee rather than hurriedly writing notes.

Identifying participants, however, was not an entirely straightforward process. Gaining access to the members of the secondary care pelvic floor dysfunction service (Lead Consultant, Second Consultant, bowel function nurse specialist and anorectal physiologist) and the

Sandwell and West Birmingham community continence team lead nurses was straightforward as these team members were aware of the study being commenced and were keen to be involved. The difficulties arose when trying to identify external stakeholders such as general practitioners (GPs). Numerous strategies were used to try to recruit these external stakeholders, including e-mail contact to individual GPs/practice managers, sending letters to individual GPs/practice managers and telephone calls to GP surgeries aiming to make contact with either GPs or practice managers in the Sandwell and West Birmingham area. Fourty-two GP practices were contacted in total. Despite all the strategies used there was a distinct lack of uptake from the GPs and GP practices within the area. The researcher managed to recruit four GPs, three from the Sandwell area and one from the West Birmingham area with the other interviewee job roles described below. A total of eleven stakeholder interviews were performed.

- Two Consultant Colorectal Surgeons with specialist interest in pelvic floor dysfunction, one of whom is the clinical director for surgery
- Bowel function nurse specialist
- Anorectal physiologist
- Deputy divisional manager for surgery
- Community continence team lead nurses for both the Sandwell and West Birmingham areas.
- Four GPs, including a senior member of the Sandwell clinical commissioning group (CCG).

The interviews took place over a two-month period with all participants being asked similar questions. All participants received a participant information sheet and an adequate amount of time as per Good Clinical Practice guidelines (213) to consider whether they would like to take part, with informed consent (appendix 4) obtained prior to commencement of the interview. The interview schedule had a fluid element insofar as following each interview, when reviewing the recording or subsequent transcript, if there were any potentially key or surprising points raised then these could be included at the next interview. On each individual interview schedule there was space within which the researcher could describe a minimum of three initial thoughts about the content of the interview. This allowed the researcher to compare their initial thoughts following the interview with thoughts they had following analysis of the interview at a subsequent date. This would highlight whether the initial thoughts of the researcher were consistent with the thoughts post-analysis and if they were not, allow the researcher to identify why not (214). Following this each interview was transcribed as close to the time of interview as possible, which allowed the researcher to prepare for subsequent interviews thoroughly (214). Analysis of these interviews was performed using thematic analysis (215) with the Framework Method (216) being used to manage the data.

There are a number of things to take into account when considering the interviews and analytical process in relation to the researcher’s characteristics. As stated in the opening chapter, the researcher is medically trained (with links to the service) and a novice in qualitative research. This potentially could have an influence on the interviews and also the perspective from which the analysis is performed. From an interview perspective, the researcher may not have had a direct influence but an indirect influence due to being known to most stakeholders within the service prior to commencement of the interview process. These elements were considered by the researcher throughout the study and accounted for where possible.

Analysis

As a novice qualitative researcher, a strong emphasis was placed on maintaining a rigorous approach throughout the duration of the study. At no point was this more critical than at the initial stages of analysis of the baseline qualitative data (semi-structured interviews). Given the researcher's inexperience with qualitative research help was enlisted from a number of experienced qualitative researchers who could give advice on aspects of qualitative analysis as well as throughout the process. The experienced researchers provided support in relation to the coding process of the transcripts and also the initial process of charting the qualitative data. One aspect that is central to providing rigour in qualitative research is the element of critical reflection throughout the research process: on the design of the study, collection of data and the analysis (210). This allows new ideas or insights from participants to inform further lines of enquiry for the researcher. Being a novice qualitative researcher, this was a key element throughout the whole process. The researcher attempted to remain flexible and adaptive throughout the research, which allowed the data to be analysed in a rigorous and reflexive way, to ensure that the richest findings possible were obtained.

Thematic analysis is one of the most commonly used methods of qualitative analysis, possibly due to the fact that it is not as dependent on specialised theory as some of the other qualitative techniques such as discourse analysis or conversation analysis (215). Bearing this in mind, this form of analysis is more accessible to novice qualitative researchers (215). Thematic analysis involves reviewing data to identify any recurrent patterns, which allows the researcher to identify a number of themes that adequately reflect the textual data (215). It helps the researcher to identify commonalities and differences in qualitative data, before focusing on relationships between different parts of the data, thereby seeking to draw descriptive and/or explanatory conclusions. The researcher lacking any detailed prior knowledge of the research topic can enhance the value of thematic analysis, as this means they will not be guided by any preconceptions. This is certainly the case in this research study as the researcher had very little knowledge of ICPs and the process of organisational change. The researcher did have some limited prior knowledge of FI but certainly not enough to have developed any preconceptions about the subject.

The Framework Method sits within the broad confines of thematic analysis (215). Researchers from the Qualitative Research Unit at the National Centre for Social Research developed the Framework Method in the late 1980s (216). It was developed as a tool for supporting qualitative data analysis as it provides a systematic model for managing the data. The unique feature of Framework Method is the matrix output that allows the researcher to structure then analyse data by case and by theme (217). The Framework method is most suitable for analysis of interview data (often, but not restricted to, semi-structured interview transcripts), where the researcher would like to compare themes that emerge from the interviews within and between cases (217). This method allows analysis of emerging themes to take place across the whole dataset by using the matrix, but also retains the context of each research participant’s experience by connecting their views to other aspects of their account (216,217). An important limiting factor is that the Framework Method cannot accommodate highly heterogeneous data, meaning that data must cover similar topics so that it is possible to categorise into themes, even though the individual cases may have different opinions or experiences (217). These differing opinions or experiences can then be compared in a systematic manner. In this study, heterogeneous data was not going to be an issue as only one service was being evaluated. The fact that the Framework Method has flexibility during the analysis process allowed the researcher to start to perform data analysis whilst continuing to collect data. This was vital for the study, as it allowed exploration of findings in a timely and reflective manner, therefore informing future data collection.

The various stages of the researcher's baseline interview analysis will now be detailed, using the methods described above in table 10:

Table 10: Baseline interview analysis

Process	Description
Transcription	All interview transcripts were transcribed using Microsoft Word and were transcribed in a standard format with line numbers, adequate line spacing and large margins which all helped with the process of coding.
Familiarisation	As with all qualitative analysis, it is vital that the researcher becomes familiar with their data if their analysis is to be insightful. The researcher needs to immerse themselves in the data by listening to recordings or reading the transcripts so that they become aware of any key ideas or themes that are emerging (211,212). Throughout the study only the main researcher was involved, therefore being the only interviewer and transcriber enabled the researcher to familiarise themselves with the data quickly. The fact that the interviews were transcribed quickly following each interview meant that this familiarisation process started promptly and could be maintained with subsequent review of the transcripts. At this point the transcripts were printed off so that the next stage of analysis, coding, could begin.

Coding	Coding has been described as the “critical link” between data collection and their explanation of meaning (218). “A code is most often a word or short phrase that symbolically assigns a summit, salient, essence–capturing, and/or evocative attribute for a portion of language-based or visual data” (219). The overall aim of coding is to identify important or recurring themes within the textual data. How this is achieved depends upon a number of things including the experience of the researcher, the type of qualitative data that is being analysed and also what the researcher is trying to achieve (219). There are numerous types of coding methods, which can be split into first cycle and second cycle coding processes (218). First cycle methods are processes that happen during the initial coding of data, with these methods tending to be fairly simple and direct. Second cycle methods however are more challenging because they require further analytic skills such as classifying, prioritising, synthesising, and theory building (219). For the first cycle method line-by-line initial coding was used. The goal of initial coding is “to remain open to all possible theoretical directions indicated by your readings of the data” (220). Taking this into account, following close examination of the transcript, codes were assigned to the data on a line-by-line basis. The researcher performed this by taking printed transcripts and placing codes in the wide margins that were set up when creating the transcripts. The purpose of

	performing the line-by-line coding was to help reduce the likelihood of missing important data, especially given the researcher's inexperience in the field of coding. Two experienced qualitative researchers (from within the CLAHRC team) and the main researcher independently coded three of the interview transcripts, using the initial coding method. Following the individual coding of these transcripts, a meeting was arranged where the researchers discussed their codes. This discussion led to an agreement upon a set of codes that could be applied to subsequent interview transcripts. During and after the initial coding process the researcher wrote analytic memos, allowing reflection upon the findings up to that point. After reviewing the first cycle codes, there were too many codes and the researcher undertook a process of refining these codes. At this point it was decided to employ focused coding, which is a second cycle coding method. The primary goal of second cycle coding is to develop a sense of categorical, thematic, conceptual, and/or theoretical organisation from the first cycle codes (219). Focused coding helped to categorise the data in a more streamlined and organised manner. An example of the coding process is displayed in table 11
Developing a working analytical	Following on from the detailed coding process, the development of an analytical framework began. At this point, the remaining codes

framework	(following first and second cycle coding) were analysed and brought together to identify all the key issues, concepts and themes, therefore producing a working analytical framework.
Testing the analytical framework	The researcher tested the original analytical framework by indexing the rest of the interview transcripts and comparing how this data fitted into the original themes. Indexing is a process where the researcher applies the analytical framework to the textual data by annotating the transcripts with numerical codes from the index (theme headings) (221). An ‘other’ code was used to accommodate any immediate data that did not fit within the original themes. This data could then be used to identify new themes if required. By performing this process, it continued to show a detailed approach to ensuring that rigour was constantly at the forefront of the researcher’s qualitative analysis, by ensuring that all available data was captured rather than being discarded, potentially inappropriately. Multiple versions of the analytical framework were produced during this phase due to new codes/themes emerging. The researcher was acutely aware that the analytical framework was never complete until the last transcript was indexed using it.
Charting data	Due to the large amount of data that can be created during a qualitative research project it is essential that the data be managed correctly.

	Summarising or reducing the data is a vital aspect of the analysis process. The researcher created a Framework matrix, which was a spreadsheet where the summarised qualitative data could be charted. Summarised data by theme from each transcript was then charted into the Framework matrix. The researcher attempted to balance reducing the data with retaining the original meanings of the interviewees' words as much as was possible. Striking this balance was a potential problem, therefore two experienced qualitative researchers (the same two researchers who were used during the coding element) were asked to chart a transcript each, to ensure that firstly, the researcher's original charting was correct and secondly, try to show reliability. The researcher met with both qualitative researchers individually to discuss the outcomes. Interesting or important quotations were identified and referenced within the matrix, so that they could be used and identified easily when the writing up process was to begin.
Interpretation of the data	During and following charting of the data, the final step of the process was to identify the similarities and differences between the data. This element was performed by taking each theme in isolation from the Framework matrix and comparing the views of each of the cases against each other. This allowed the researcher to explore the findings associated with the current management pathway, problematic areas of the current pathway, health professionals involved within the current service and the aspirations/plans for the future. Throughout this

	process a separate document was kept where any early impressions or ideas that the researcher was receiving from the data were noted.

Table 11: Example of coding process

Text	Initial Coding	Second cycle coding	Themes
"We can make the patient's journey a lot smoother really and they get to the right person because like I've already said if you're admitted and you've got a bowel problem and you tell somebody it all and then they say 'well, actually you need to go and see somebody else' – you know it can be devastating for the patient because they've just gone through it all with you and you know – so if they get to the right person at the right time hopefully we can make their quality of life a lot better then."	*Patient journey* *Right person* *Bowel problem* *See somebody else* *Communication* *Devastating for patient* *Right person* *Right time* *Quality of life*	*Improving patient journey* *Aim to improve quality of life* *Awareness of difficulties regarding patient pathway into service*	*Current patient pathway* *Targets for service* *Aspirational patient pathway* *Drivers for change*
"So hopefully it's the patient getting to see the right person at the right time and getting obviously the treatment that they need and therapies they need at that point."	*Patient* *Right person* *Right time* *Treatment* *Therapies* *Time*	*Aim to improve patient journey* *Patient management*	
"I think seeing a better	*Patient journey*		

patient journey. I think that would be a really positive outcome."	*Positive outcome*	*Visualising outcomes* *Improving patient journey*	

Observation

During this baseline period of the study, the researcher attended routine meetings, which were related to the pelvic floor service and the development/implementation of the ICP within the Trust. In the baseline phase this amounted to eight meetings. These were the only meetings held with relation to the development/implementation of the ICP during this phase. At these meetings non-participant observations were performed, detailing the contents of the meeting, attendees at the meeting, plus any interesting observations raised from those meetings. Non-participant observation is a data collection method where the researcher enters a social system to observe events, activities and interaction with the aim of gaining a direct understanding of a phenomenon in its natural context (217). All meetings were recorded on a standard proforma (appendix 5), developed at the beginning of the study, ensuring that observations were consistent and thorough throughout the process. Following each meeting observations were written up, using Microsoft Word, including any reflections upon the meetings and how the implementation of the ICP and also how the study was progressing. These observations were kept throughout the process, therefore allowing the researcher to compare and contrast the issues that were raised, and the actions implemented to solve these issues. The observation data was analysed by identifying themes within the meetings and following progress or lack of progress in those themes. Upon reflection of the non-participant observation, consideration has to be given to the potential for the introduction of bias into the study, as the presence of a person who the team knew was observing them may have led to different responses to what may have been given if the researcher was not present. This was unavoidable aside from attempting to provide an environment where people felt comfortable to speak as they saw fit despite the researcher's presence. This was attempted by ensuring that any comments would remain anonymous and also by the service lead developing an open and honest atmosphere.

Measurement

Quantitative data was collected relating to the service prior to the implementation of the ICP. The pelvic floor dysfunction team kept a prospective database of all patients who were seen within the service from its inception in 2008. The data fields within the database included patient identifiers, date of referral, referral source and who referred to, date of clinic appointment, patient outcome data (bowel diary, symptom severity scoring/ quality-of-life (QOL) outcome measures), and follow-up duration. The symptom severity score used in the service was the Wexner continence grading scale (222), with the QOL outcome measures used being Faecal Incontinence Quality of life index (FIQOL) (223) and SF-36 (224).The database was kept up-to-date by the bowel function nurse specialist and therefore was very much reliant on this person having the time available to ensure its accuracy. Alongside this database, the researcher contacted the health informatics department within SWBHT to see if the referral data could be verified. No data was available with regards to direct referrals to the bowel function nurse specialist, but referral data for the consultant clinics was obtained. Analysis of the referral data was performed in a systematic manner, allowing identification of the number of referrals into the service, any trends or frequent referrers and the average times for patients with FI to be seen in clinic.

With regards to patient outcome data, this consisted of bowel diary reporting, QOL outcome measures and a symptom severity score (as described previously). The data fields from within the bowel diaries include frequency of bowel opening per day, deferment time to defecation, the number of accidents, and the number of leakages. Analysis of all of the patient outcome data was performed using SPSS (225) to obtain mean and the standard error of the mean. Baseline (pre-treatment) versus post-treatment data was compared to assess any change in patient outcomes following the standard treatments. Despite including this information, the primary aim of this study was not to assess the effectiveness of the treatments (as these will not actually be changing during this process). This data was monitored to ensure that when the ICP is implemented comparisons could be made of the patient outcomes at that time and identify any trends that may occur.

Implementation: June 2012-January 2013

Following completion of the baseline interviews, the planned implementation of the ICP was to be commenced. Despite this being scheduled for February 2012, it did not actually happen until September 2012, for a number of reasons including lack of capacity to perform the work required to develop and introduce the elements of the ICP such as documentation, clinical governance procedures and lack of management input- all of which will be described in greater detail in the results chapter. Therefore, this period of time (including after the implementation of the ICP) was mainly spent on longitudinal observational work. The researcher attended all meetings in which the ICP, elements of the ICP or general issues regarding the pelvic floor dysfunction service were discussed. This allowed the researcher to observe and record the changes that occurred during this period of time, prior to and leading up to the implementation of the ICP. Identification of any drivers or barriers to the process of implementing the ICP and how the process of change was affecting multidisciplinary team members (within both the primary and secondary care sectors) was also aided by attendance at these meetings.

Whilst awaiting the implementation of the ICP a database was created, which could be completed prospectively with the following data fields:

- Patient Identifier (Patient hospital number for confidentiality purposes)
- Age
- Sex
- Date referred
- Referral source- GP/Consultant/Colorectal Nurse Specialist/ Tertiary centre
- Who/where triaged to?
- Date of clinic appointment
- Diagnosis
- Investigations performed
- Management
- Number of visits
- Date of discharge
- Patient outcome data
    - Number of times bowels opened- pre and post-treatment
    - Deferment time (the duration of time that patients can delay passing faeces without being incontinent)- pre and post-treatment
    - Number of accidents (incontinent episodes when patients feel the urge to defecate) per week- pre and post-treatment
    - Number of faecal leakages (leakage of faeces where patients do not feel the urge to defecate) per week- pre and post-treatment

- Wexner score (222) and QOL outcome measures (FIQOL/SF-36) (223,224)

The elements within this database were common elements already used within the service to identify basic patient demographics and patient outcomes. This database was reviewed by the researcher’s supervisors and also the pelvic floor dysfunction team who agreed that they would use it as their database for any patients referred into the service via the ICP.

Patient focus group

A focus group is a group of individuals selected and assembled by researchers to discuss and comment on, from personal experience, the topic that is the subject of the research (210). A focus group was conducted with the Sandwell community continence team’s service user group. This group was already in existence prior to the commencement of the study and was formed of a number of individuals who attended the meetings due to the fact they had either suffered or were suffering with faecal and/or urinary incontinence. The group met on a three-monthly basis and had done so for the previous six years (2007-2013). The researcher attended four meetings throughout the first year of the study period to ensure that integration within the group was achieved, therefore allowing the researcher to gain their trust and willingness to participate. All members of the group were clearly well motivated to continue attending and the ground rules and dynamics within the group were already clear to see on attending the meetings. The focus group was conducted after the group’s normal meeting content. All eight participants gave their informed consent having reviewed a participant information sheet, in accordance with Good Clinical Practice (213), to ensure ethical participation within the study. A focus group protocol (appendix 6) was drafted by the researcher and revised following review by the researcher’s supervisors prior to performing the focus group. This focus group was based on obtaining the group’s thoughts on the current pelvic floor dysfunction service and the potential effects the implementation of the ICP would have on patients. The discussion was recorded, with a set of notes recorded by a qualitative researcher from within the CLAHRC team (20). These notes mainly detailed key topics from the focus group, along with which members spoke and any significant data and/or dynamics noted within the group. For example, whether the more dominant members of the group were speaking positively or negatively regarding the service and ensuring the less dominant member's views were adequately represented. When noting which members were speaking they were all referred to as a letter of the alphabet (A-H), to ensure confidentiality. Transcription took place following the meeting and was analysed to identify any common themes or messages from the focus group. This analysis was based on reading through the transcript to identify key points made by the participants around the specific topics and analysing any differences between the participants' views (212,215).

Final Interviews:

Staff

Once the ICP had been in place for six months the second round of semi-structured interviews with key stakeholders was conducted. The researcher felt that that six months would be an adequate time period to have elapsed for the stakeholders to implement the ICP and experience how the pathways working and identify any changes that have occurred since the pathway was implemented. This decision was based on trying to balance the issues of ensuring enough time had elapsed since implementation and the time needed to perform both the interviews and analysis within the study period. As there has never been an ICP implemented for FI previously, there is no literature to support this time frame. From March 2013, the researcher conducted these semi-structured interviews, which were recorded using an audiotape. Identifying participants in the second phase was a much more straightforward process than in the initial phase.

Once again, gaining access to the members of the secondary care pelvic floor dysfunction service and the Sandwell and West Birmingham community continence team lead nurses was straightforward as these team members were aware of the ongoing nature of the study, as the majority had been interviewed previously. The difficulties that had arisen when trying to identify external stakeholders (GPs) in the initial interview process were negated this time, as the GPs who were interviewed in the initial phase were happy to be interviewed again. The researcher did however try to increase the numbers of external stakeholders using methods such as those alluded to in the initial phase of recruitment, but unfortunately no other external stakeholders were recruited. A total of twelve stakeholder interviews were performed (the extra interview being due to an increase in the number of bowel function nurse specialists within the team). This sample size was obtained by interviewing as many stakeholders as possible. All available key stakeholders within the acute and community setting were interviewed along with the GPs who agreed to take part.

- Two Consultant Colorectal Surgeons with specialist interest in pelvic floor dysfunction, one of whom is the clinical director for surgery
- Three bowel function nurse specialists
- Anorectal physiologist
- Deputy divisional manager for surgery
- Community continence team lead nurses for both the Sandwell and West Birmingham areas.
- Four GPs, including a senior member of the Sandwell clinical commissioning group

(CCG).

Informed consent was gained as previously described on page 100 (as per Good clinical practice guidelines (213)). The interviews took place over a two-month period with all participants being asked similar questions via a standard participant interview schedule (appendix 7). The interview schedule was based on the initial interview schedule, with questions having been altered slightly to focus on key findings from the baseline analysis. This interview schedule maintained a fluid element insofar as following each interview, when reviewing the recording or subsequent transcript, if there were any new key points raised then these could be included, for questioning, at the next interview. Aside from the differing interview schedule the recording, subsequent transcription and analysis was performed as per the initial interviews.

Patients

To obtain as complete a view of the new ICP as possible, five patients were recruited who had experience of the ICP clinic. This sample size was based on the fact that only this number of patients consented to be involved in the study. Recruiting the patients took considerable time and effort with the researcher’s attendance at ICP clinics being essential as the previous attempts at patient recruitment had been unsuccessful. Originally, patient information sheets were sent out with hospital letters, but this did not prove fruitful for recruitment. Patient information sheets were given out to patients when they attended clinic with the BFNS or Consultant without direct attendance of the researcher. This was an attempt to prevent any potential coercion from the researcher being present; however this also did not work. Once the researcher started attending the ICP clinics regularly, recruitment was more successful. Narrative interviews (209) (appendix 8) were performed based around their experience within the clinic. All patients received a patient information sheet and an adequate amount of time as per Good Clinical Practice guidelines (213) to consider whether they would like to take part, with informed consent obtained prior to commencement of the interview. The interviews took place in a separate room within the clinic. All interviews were recorded on a digital recorder and subsequently transcribed.

Purposive sampling of patients was used, which focuses on particular characteristics of a population that are of interest, which enables the researcher to answer the research question. The sample being studied is not representative of the population (210). The researcher attempted to recruit patients who would provide maximum variation in symptoms and demographics. Whilst this was not entirely possible, patients of both sexes, three different ethnic groups and patients with differing symptom severity were interviewed. All interviews were transcribed as promptly as possible with the analysis being performed using thematic analysis and the Framework method (as per the detailed description in the initial phase methods). Every patient attending the clinic also completed regular, standard clinic questionnaires and documentation, which form part of the quantitative data on patient outcomes (along with the quantitative data fields described in the implementation phase). With regards to the quantitative data the prospective database was continually updated and the cut-off date for final analysis was 1 June 2013. To analyse any potential changes in patient outcomes with relation to the implementation of the ICP, the quantitative data were extracted from the database and all referral, diagnosis, and management data was analysed for trends and compared with the initial phase quantitative data.

Observation

From a longitudinal observation point of view, the researcher continued to attend any meetings related to the ICP or the pelvic floor dysfunction service until 1 June 2013. This amounted to a further five meetings. Observations at these meetings allowed the researcher to compare and contrast the issues that were raised throughout the process and the actions used to solve these issues prior to, during, and after implementation of the ICP.

Further Analysis

NPT (37) was used to aid the structuring of the qualitative data. Following the completion of the study, the Framework matrix, observational, and focus group data was reviewed and the four core constructs were used to organise this data. The data was reviewed in accordance with each core construct (pp69-74) and then reported under the relevant construct. The aim of the study was to identify facilitators and barriers to the implementation of the ICP, which corresponds with the general aim of NPT. The data was placed under the core construct if relevant, however a great deal of attention was paid to ensuring that if there was any data that did not fit directly under a core construct, it would still be reported elsewhere in the results and did not remain unreported. The quantitative data is reported separately and not analysed in relation to NPT (37), using descriptive statistics.

In summary, a true mixed methodology approach was taken during the study. Both the quantitative and qualitative methods contributed to answering the research questions and achieving the study aims. A greater contribution to the study results was made from the qualitative data and this is due to the qualitative methods used- focus groups, interviews and non-participant observation. Each of the qualitative methods contributed to a differing degree to the results, but all were essential to being able to give a complete answer to the research questions posed (in combination with quantitative data). For example, five patient interviews alone provided some information, but this was augmented and strengthened by the patient focus group data. The stakeholder interviews and non-participant observations also complemented each other, allowing both individual methods to be validated and strengthened by each other.

CHAPTER 4: QUALITATIVE RESULTS

This chapter describes the qualitative results obtained from the study. The qualitative results chapter begins with two tables that indicate the characteristics of the stakeholder and patient interviewees, which allows the reader to understand and contextualise the quotes in the main body of the chapter. Following this there is a table describing how the themes produced from the qualitative data were allocated within the NPT model. To ensure that the qualitative results could be explained in a clear and coherent manner the four core constructs of normalization process theory: coherence, cognitive participation, collective action and reflexive monitoring, have been used (37). These core constructs were used to inform, guide and structure the emerging interpretations from all of the qualitative data (interviews, focus group and observational data), which allows this chapter to be structured in the same manner, with the four core constructs being broken down further into their four components (see table 14) (37).

Descriptive text applicable to each component within the four core constructs is followed by quotes, from the interviews undertaken, that are relevant to that particular text. The quotes are used to provide evidence for and consolidate the descriptive text above them. All quotes have a letter and number next to them e.g. S1 (stakeholder 1) or P1 (patient 1), denoting the interview participant number. The characteristics of the interview participants are described in tables 12 and 13. Alongside this, the quotes will also detail whether it was from the first or second round of interviews. This allows the reader to gain some context for the quote they are reading. There are some paragraphs of text whereby no quotes are included. The reason for this will be due to that particular data being observational and therefore will not have any direct quotes attributed to it. All data of a qualitative nature (interview, focus group and observational) will be described under the core constructs of NPT, with the quantitative data being reported separately.

Stakeholder Characteristics

Tables 12 and 13 describe the characteristics of the interviewees. Table 12 describes the stakeholder interviewees, including their job titles, which round of interviews they were interviewed in along with their primary function in the system as a manager, clinician or both. The table shows that all but one of the stakeholders took part in both rounds of interviews and there was a mix of job roles and clinical/management experience. Eight of the stakeholders had both a clinical and managerial element to their role, with only one being purely in a management role. Six stakeholders were based within the primary care sector, with the remaining six being secondary care based.

Table 12: Characteristics of Stakeholder Interviewees

Participant Number	Job Title	First/Second round of interviews or both	Clinical/Manager/Both
S1	Clinical Director of Surgery. Colorectal surgeon with an interest in functional bowel disease and colorectal cancer.	Both	Both

S2	[redacted] Continence Team Lead	Both	Both
S3	GP Partner and GP trainer.	Both	Both
S4	Salaried GP	Both	Clinical
S5	GP Partner	Both	Both
S6	Deputy divisional manager- General Surgery. Responsible for contractual service development side of the division for Upper GI, colorectal, general and emergency surgery which incorporates functional bowel	Both (change in personnel during study period)	Manager
S7	Surgical Care Practitioner	Both	Clinical
S8	Bowel Function Nurse Specialist Lead	Both (change in personnel during study period)	Both
S9	Pelvic floor Dysfunction Service	Both	Both

	Lead Consultant. Colorectal surgeon with an interest in functional bowel disease and colorectal cancer.		
S10	Bowel Function Nurse Specialist	Second round only	Clinical
S11	GP, Chair of [redacted] CCG, Chair of strategic commissioning redesign committee	Both	Both
S12	[redacted] Community Continence Lead	Both	Both

Table 13 shows the characteristics of the patient interviewees. Whilst the predominant gender was female, five males were included so there was a mix of gender, along with age (48-86 years) and ethnicity, giving a spread of patient demographics throughout this group. The youngest patient was only 48 and this has to be noted as a limitation within the study. Type of incontinence was also reasonably spread amongst the three differing types, again allowing a varied overall perspective.

Patient Characteristics

Table 13: Characteristics of Patient Interviewees

Participant Number	Gender	Age	Ethnicity	Type of Incontinence	Narrative Interview or Focus Group
P1	Male	74	Caucasian	Passive	Narrative
P2	Female	69	Afro-Caribbean	Mixed	Narrative
P3	Female	81	Caucasian	Urge	Narrative
P4	Male	58	Asian	Urge	Narrative
P5	Female	48	Asian	Passive	Narrative
P6	Female	71	Caucasian	Mixed	Focus
P7	Female	86	Caucasian	Mixed	Focus
P8	Male	60	Caucasian	Urge	Focus
P9	Male	72	Afro-Caribbean	Urge	Focus
P10	Female	76	Asian	Mixed	Focus
P11	Female	59	Afro-Caribbean	Passive	Focus
P12	Male	79	Caucasian	Urge	Focus
P13	Female	67	Caucasian	Mixed	Focus

Themes and NPT Constructs

Table 14 identifies how the themes identified from the interviews relate to each of the components within the core constructs, allowing some contextualisation of the themes and the four constructs.

Table 14: Relation of themes identified during the study to the constructs of the NPT model

Core Construct	Component within Core Construct	Themes Identified	Element of work from which themes identified
Coherence	Differentiation	**Initial service setup** (historical context of service, variation in similar services, current service challenges, location of service and referral pattern) **Aspirational service setup**	First round of stakeholder interviews. Observational data
	Communal Specification	**Purpose for intervention** (shared sense of purpose)	First and second rounds of stakeholder interviews.

		Drivers for introducing intervention	Observational data
	Individual Specification	**Challenges of current service** **Impact of challenges on the implementation**	First and second rounds of stakeholder interviews. Observational data
	Internalization	**Initial pathway patient/stakeholder benefits** **Aspirational pathway patient/stakeholder benefits** **Value to patients**	First and second rounds of stakeholder interviews Patient interviews and focus group
Cognitive Participation	Initiation	**Teamwork** **ICP document** **Information Technology**	Observational data
	Enrolment	**Stakeholder attitudes towards intervention**	Observational data

		Changes in stakeholder roles throughout the implementation **Patients attitudes towards the intervention**	
	Legitimation	**Stakeholder engagement**	First round of stakeholder interviews Observational data
	Activation	**Continuous development** **Amount of work required for different stakeholders during implementation** **Capacity** **Champions for the intervention**	Second round of stakeholder interviews Observational data
Collective Action	Interactional Workability	**Initial stakeholder roles** **Aspirational stakeholder roles (including changes**	First and second rounds of stakeholder interviews. Observational data

		in workload and capacity) **Final stakeholder roles (including changes in the way of working)** **Location of work** **Leadership**	
	Relational Integration	**Stakeholder commitment** **Effects on stakeholder consultations** **ICP document analysis and changes**	Second round of stakeholder interviews Observational data
	Skill Set Workability	**Training and education for stakeholders** **Capacity of key stakeholders (BFNS)**	First and second rounds of stakeholder interviews. Observational data
	Contextual	**Changes in stakeholders**	First and second rounds of

	Integration	**with most responsibility and/or power** **Integration of stakeholders** **Organisational integration and challenges**	stakeholder interviews. Observational data
Reflexive Monitoring	Systematization	**Stakeholder perception of the intervention (post-implementation)**	First and second rounds of stakeholder interviews.
	Communal Appraisal	**Perceived advantages of the intervention (to stakeholders and patients)**	Second round of stakeholder interviews.
	Individual Appraisal	**Stakeholder feedback** **Patient feedback**	Observational data
	Configuration	**Identification and resolution of challenges based on experience of the intervention** **Future ambition and targets**	Second round of stakeholder interviews. Observational data

Table 14 highlights the benefits of using mixed qualitative methodology. For example, if the researcher had not used observational methods and data, the themes within initiation, enrolment and individual appraisal would not have been identified. The observational data was extremely important as all of the core constructs had themes within whereby the observational element of the study had identified data relevant to that construct. The completion of two rounds of interviews with the stakeholders was also key as data was obtained from both rounds of stakeholder interviews for six components within the core constructs, four components using the second round of interviews and two components for the first round of interviews. Of greater importance is the fact that for the communal appraisal construct, no data would have been captured if the researcher had not performed the second round of interviews. The patient interviews and focus groups also elicited key information within the internalization component. Without all the different aspects of the qualitative work being undertaken in this study it is clear to see that potentially important findings could have been missed.

The chapter will now proceed with the qualitative results of the study being described via the four core constructs of NPT, starting with coherence (37).

Coherence

(The need for individuals to understand and make sense of what is different about the proposed intervention and the effect it will have on their roles and responsibilities)

Differentiation

(Is the intervention easy to describe and is it clearly distinct from other interventions?)

Prior to 2008, patients with FI did not have access to a service that could manage their condition at Sandwell and West Birmingham hospital trust. This changed with the appointment of a new consultant colorectal surgeon who specialised in bowel function disorders. With this appointment a pelvic floor service was developed that included the appointment of a bowel function nurse specialist (BFNS) and the development of a number of investigations needed for these patients. This process took place in 2008 and within six months of the consultant's appointment the BFNS had been appointed and within 18 months the service was deemed to be at a level of other similar services that were set up many years before.

> *"Our service has been up for 3 years. Eighteen months after it was up and running, I went to one of their conferences and a service that had been running 4 years was at the same level as we had been in 18 months." (S6, DDM, first round)*

The first nine to twelve months were spent training the BFNS. This included numerous training courses and shadowing in other similar services within the country. By October 2011 a service had been developed which, according to one of the consultants and the BFNS, was more complete than any other trust in the country**.**

> *"We had managed to develop a service that provided more diagnostic and management elements within it than any other trust in the country" (S1, Consultant, first round)*

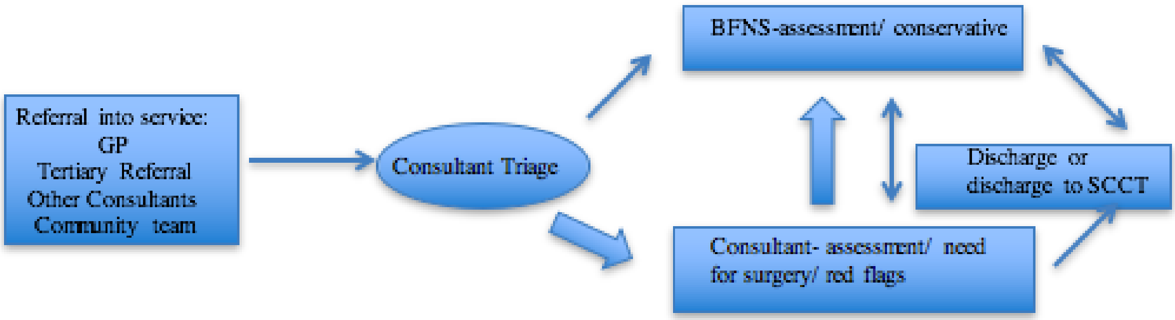
The service that was available at that point consisted of two pelvic floor consultants, a BFNS with a second BFNS in training, a surgical care practitioner (SCP) who performed physiology investigations (with an additional SCP who was trained in performing the same anorectal physiology investigations as a backup for sickness or other unforeseen circumstances), radiographers undertaking proctograms and the Sandwell community continence team (SCCT). The SCCT had been located within the Sandwell and West Birmingham hospital trust (SWBHT) since April of 2011 having previously had numerous organisational changes involving the acute trust and primary care trusts. At this point the setup of the service was based around the secondary care team running their own clinics twice a month in the hospital and the SCCT running their own clinics independently within the community. The patient pathway at this point consisted of a referral into the pelvic floor consultant, referrals were accepted from GPs, hospital consultants (within the same trust), other hospitals (tertiary referrals), and from the community continence team (see figure 3). The patient would then be assessed in clinic by the consultant before deciding whether to continue managing the patient themselves or handing the patient over to the BFNS for further conservative management, including pelvic floor muscle exercises, correct defecatory dynamics and biofeedback. The majority of patients see the BFNS for conservative management, with those patients failing conservative management being discussed in the multidisciplinary team meeting (MDT) for consideration of neurostimulation or consultant review.

"OK, at the moment the way the service runs is that a referrer will refer into the service and this can be tertiary referral, GP referrals, other colleague referrals and all the referrals at the moment are triaged by Consultant A and then she'll see them in pelvic floor clinic. I'll be present with her in clinic or with Consultant B who also does a pelvic floor clinic. So once a

> *month I'll sit in clinic with them and meet the patients for the first time and pick out really anybody that's going to be appropriate for me." (S8, lead BFNS, first round)*

The secondary care team performed all assessments; investigations and treatment of patients with FI within the secondary care setting. Upon completion of treatment patients will either be discharged completely from the service or referred to the SCCT.

Figure 3: Traditional SWBHT Pathway for Patients with FI



From a SCCT perspective there was an open referral basis whereby any health professional, patient or carer could refer into the service.

> *"We've got a self-referral, so anybody can ring in, the patient can ring in themselves, it can be a GP referral, it can be a consultant referral, social service – a lot of our referrals come from carer groups – if you've got an agency going in to look after somebody at home and*

they're incontinent they'll actually refer in, obviously with the permission of the patient. So, our referral is just open, we'll take it from anywhere." (S12, Lead SCCT, first round)

The SCCT would triage the referral on the basis of whether it was appropriate and where the location of the consultation should take place (home visit or in clinic). The SCCT provided patients with a bowel assessment and the commencement of conservative management strategies, similar to secondary care, including containment. No neurostimulation was available within the community setting at this point. Direct referral was available for the SCCT to the BFNS in secondary care for patients who required further assessment, investigation and management.

Although there was a well-developed service for patients with FI, the team wanted to continue to develop the service, including streamlining the patient pathway and increasing awareness of FI and the service for patients and GPs. Within the interviews with the staff it was felt that patients were either not being referred at all by their GPs, therefore being managed in community by the GPs, or they were being referred to varying different specialities based upon GP preference. Every member of the team felt that this variable referral route was unacceptable and needed to change, with the change being the implementation of the ICP.

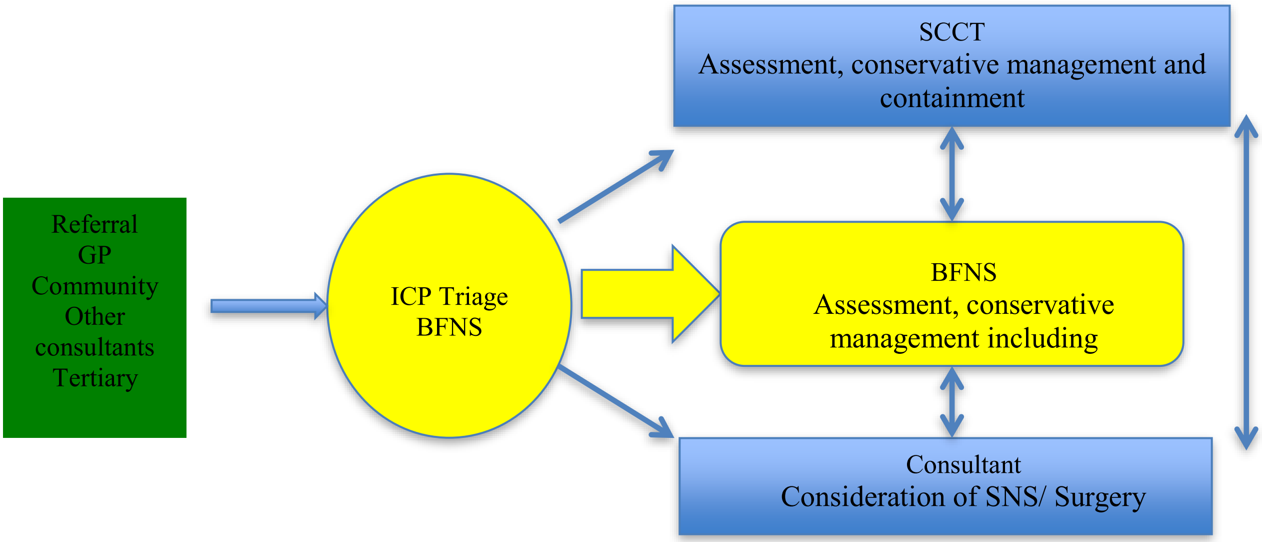
"We can make the patient's journey a lot smoother really and they get to the right person because like I've already said if you're admitted and you've got a bowel problem and you tell somebody it all and then they say 'well, actually you need to go and see somebody else' – you know it can be devastating for the patient because they've just gone through it all with you

and you know – so if they get to the right person at the right time hopefully we can make their quality of life a lot better then." (S12, SCCT, first round)

From the first round of interviews an intervention was described which would aim to solve these issues. This intervention was an ICP for FI. The aim of the staff at this point was to change the pathway for the patient so that the patient was referred in from the same origins as previously but would be triaged by the BFNS instead of the consultant. From the triage point there were three potential paths that patients could take: consultations with the BFNS, consultant or SCCT. One of the key elements of the introduction of this integrated care pathway lies at this point as not only was the triage process changing the pathway for patients, but the patients seen by the BFNS and SCCT would be seen in the community, within GP practices. Which path a patient would take would be based on the decision made at the triage stage. At the time of the first round of interviews, there were no plans to put guidelines in place for the triage; rather it would be left to the BFNS to decide based on their experience and knowledge. All patients would undergo the same assessment and management, except for those reviewed by the consultant as these patients' symptoms would either be deemed as too severe or require surgery. It was anticipated at the time that the majority of patients would be reviewed by the BFNS with a small number being reviewed by the SCCT and consultants (see figure 4). All assessments and treatment modalities were to remain the same. The integrated care pathway was attempting to streamline and improve the patient journey by ensuring that the patient was referred to the appropriate person at the appropriate time rather than modifying any assessment or treatments for the patient. Following treatment, once both patient and healthcare professional were happy with the improvement in symptoms, patients would be discharged (with the option for consultants or BFNS to refer to the SCCT if appropriate).

> *"I'm going to be the one that starts to triage and then dependent on a letter then I'll start triaging and saying 'OK, this one is for community, this one is for me – yeah OK, this one needs to be seen in consultants, but you know let's try and manage as many as we can' and then obviously if we don't manage them effectively we can take them to the consultant and say 'OK, we've done this, this, this and this, it's not worked, can we move onto to this or what do you think we can move onto?' So, it's just utilising the resources that we've got more effectively, and I think it's going to cut down on waiting times across the board to be fair."*
>
> *(S8, lead BFNS, first round)*

Figure 4: Integrated Care Pathway for Patients with FI



The ICP has been in use since October 2012. This included the development of the handheld ICP document, detailing everything that the patient could need whilst using the service. Demographic data, assessment tools and explanations of treatment modalities are all included within the document as well as a variance sheet if needed, for the benefit of the healthcare professional. The idea of a handheld document as well as an electronic document was raised in the first round of interviews but in a very brief manner, by a limited number of staff.

> *"The ICP is going to be a patient hand held document, so the patient takes it to and fro with their journey. So, it's the computer system that backs that up because if a patient doesn't turn up with the document you're kind of stuffed." (S8, lead BFNS, first round)*

Within the second round of interviews the handheld and electronic documents were mentioned on numerous occasions in positive terms.

> *"The document's brilliant actually. That's one good positive thing. I'd forgot about that till you said it, thank you very much. As in with it being hand held it's got all the information in there so we're not carrying a great deal of things round so from a personal point of view that's better. But also, because we're documenting their plan of care in there it's obviously a shared care thing, so you know it's there for everybody to see that needs to see it." (S8, lead BFNS, second round)*

The new ICP for FI in place within the trust is different to most other services for patients with FI in this country, as described by one of the consultants.

“Yes, it is going to be different and it’s something that no-one else is doing at the moment.”

(S9, Consultant, first round)

Whereas the original service was described as unique in the fact that all elements of the service were provided in one site or trust, these individual elements were not unique per se. The integrated care pathway for FI had been developed and introduced, but what impact did this have on all participants?

Communal Specification

(Does the ICP have a clear purpose for all participants? Do these participants have a shared sense of this purpose?)

Staff

From the first round of interviews there was a clear purpose as to why the staff from the service felt that the ICP should be implemented. This was based on streamlining and improving the patient journey. In the majority of the staff interviews, the patient journey was commented upon multiple times. The meaning of streamlining and improving the patient journey was that the patient was referred in to the appropriate person, reviewed by an appropriate person at the appropriate time. It was also clear that there was a shared sense of purpose surrounding the patient journey. This was evident in both first and second round interviews.

> *"So hopefully it's the patient getting to see the right person at the right time and getting obviously the treatment that they need and therapies they need at that point." (S9, Consultant, first round)*

> *"I think seeing a better patient journey. I think that would be a really positive outcome." (S1, Consultant, second round)*

Improving the patient journey could be described as having the patients referred in, then triaged by the BFNS-with the majority of patients being seen by the BFNS, with the other patients being triaged to either the consultant or the SCCT appropriately. Following the triage process patients would be assessed and managed by their relevant healthcare professional and followed up accordingly until discharge. The need to streamline the patient journey was as evident at the end of the study as it was the beginning. This was seen as the main driver for implementing the ICP. Another point at which there was a shared sense of purpose was the need to increase awareness of the service for patients and GPs so that access is improved. Improving access into the service was felt to be beneficial, as it would suggest that any potential barriers to patients coming forward or GPs referring had been broken down. Within the first round of interviews, despite multiple staff mentioning this need to increase awareness there were no formal ideas on how this would be achieved. From the observational work it was evident that this issue required a significant amount of work to be overcome.

However, from the observational work there was a distinct lack of attendance and input at meetings from the deputy divisional manager (DDM). This could be seen as a sign of the

DDM not giving any priority to the service or meetings involving the service. This feeling was shared by at least one of the other staff within the service.

> *"It's the middle management and higher structure within this organisation that's the biggest barrier." (S9, Consultant, first round)*

During the implementation phase of the study, the DDM changed. Therefore, there was a new DDM in post for the second round of interviews. The DDM was very honest about the fact that they had not been involved as much as they would like with the implementation of the ICP and that this was due to other organisational pressures.

> *"It was something I'd heard about. I've had, I've been kept engaged and informed…… I think I need to have more involvement from the business side." (S6, DDM, first round)*

Two of the other individuals involved within the service also stated that the lack of DDM involvement was due to other organisational pressures. This lack of involvement is a factor that could be one of the potential barriers for the implementation of the ICP.

> *"Again, I think it's about a bit of naivety in seeing how important the service is and time managing their time to say, 'Well, this actually requires this amount of time, so I'm going to carve out this amount of time in my diary for it.' I think there's been a lot of operational stuff in the trust going on, which swamps the general managers, and therefore a lot of stuff – not just the pelvic floor, but the whole strategy of the directorate, the governance of the directorate, gets binned. Inappropriately, I would say." (S1, Consultant, second round)*

"Everyone in the trust got down in winter because of bed crisis management. It's interesting how one part of the service can affect so many other different parts of the service. We're taking important people away from what they should be doing." (S1, Consultant, second round)

GPs

It was evident that the staff working within the service had a clear shared sense of purpose for implementing the ICP. All of the GPs that were interviewed felt that although the new pathway was very good in theory and would be of benefit to patients, it would only help a very limited number of their patient population. Every GP openly stated that they see very few cases of FI and did not enquire routinely about FI. These views were stated in both the first and second round of interviews by all GPs. Therefore, the GPs felt that it was a good pathway but as to how many patients they would refer in they felt this was likely to be in single figures per year.

"I might see a case or two a year, if that, probably one or two cases so the actual hit rate for an individual GP is small." (S3, GP, first round)

"I mean I can't remember the last time I had to refer anybody with faecal incontinence." (S11, GP, first round)

Individual Specification

(What are the challenges of the current service to the relevant participants? How the ICP would be expected to impact upon them?)

Before considering the benefits of the ICP, identification of the challenges that the service faced prior to the implementation of the ICP is essential. Firstly, consideration needs to be given to the demands placed upon the staff during the implementation of the ICP. During the first round of interviews it was commented by each member of the pelvic floor service, that the demand for the service had increased year-on-year and that waiting times at present were two months for a review by one of the BFNS and three months to see a consultant. At this point there were two pelvic floor consultants and one fully trained BFNS, with another BFNS commencing training. The main concern at this point was based around capacity, mainly from a BFNS point of view. Capacity of the nurse specialist was already stretched trying to fit in the clinical, organisational and educational work and there was a concern regarding the number of patients that may come into the service once the ICP is implemented and promoted, especially if the second BFNS is not fully trained.

"We've now just recruited another nurse to try and keep on top of the demand." (S9, Consultant, first round)

"The challenge at the moment obviously is time, there's only me that does the service at present and we've just currently recruited a new nurse which is hopefully going to start in the next month or two – she says" (S8, lead BFNS, first round)

However it was not only the secondary care team that had capacity issues, the SCCT also had staffing capacity problems. Due to a mixture of long-term illness and long-standing vacancies the SCCT were a number of staff members down and were unable to recruit. This impacted upon the involvement of the community continence team on the implementation of the ICP, meaning that they could not be as involved as they would like. From a waiting time point of view, the staffing issues within the SCCT meant that the times had slipped to longer than a month, but the expectation was that when fully staffed this waiting time would be reduced.

All of the staff within the service were aware that the implementation process would be demanding in terms of time and effort. From the second round of interviews it was clear that there was an underestimation of the exact amount needed. This statement must be tempered however by the fact that people were running this project in their own time (outside of regular clinical commitments) and therefore progress was dependent upon the key individuals' schedules and how much time they could dedicate to the project. This would certainly explain why there was an 'ebb and flow' element to the implementation based upon the key individual's availability.

> *"We've very much done this on a shoestring, very much done it in our own part time, with other clinical constraints and, again, it just demonstrates the importance of freeing up dedicated time and maybe – it's difficult to project-manage people when they're doing it in their own time, and I think, if you're going to do it, both the project management coming in but also dedicated PAs and time so people know if they've got this time, paid for, set aside to do this and we have to deliver it on this date." (S1, Consultant, second round)*

The amount of work that was needed in developing the pathway, document and to promote it far exceeded any member of the team's expectations. The team had regular meetings (at least once a month) to discuss the ICP and its implementation. These meetings were well attended from the clinical point of view with representatives from the hospital and community teams present. There was a notable lack of attendance from an organisational and managerial point of view. From a GP perspective, all of them did not feel at either the first or second round interviews that the ICP placed any demands upon them. All of the GPs interviewed felt that the ICP made their "job easier" as they now knew where to refer a patient with a condition that they all recognised as being difficult for the patient and the clinician.

When the ICP was implemented the BFNS felt that the content of their work would not change, rather the location where the work was carried out would. There would be no changes in the standard assessment and management that they gave beforehand, but the expectation was that they would see more patients with FI, if the ICP were successful. The workload of the consultants was hopefully going to change slightly as well. The aim was to have more appropriate patients being seen by consultants- which may or may not mean the consultants seeing less patients overall. The impact on the SCCT was unclear; the assumption was that they again would see more appropriate patients but as to whether numbers of patients overall would increase or not was not apparent.

Internalization

(What benefits will the ICP bring and to whom? Will these benefits be valued by the participants?)

Staff

At the first round of interviews, when staff were considering the benefits that the intervention would bring to the service it was clear that these benefits were different dependent upon the staff role.

- Consultant

From a consultant point of view the main benefit will be seeing more appropriate patients in their clinics rather than triaging the whole of the referral base through their clinic, which was something that was borne out by the second round of interviews.

> *"You could almost envisage the service of the future being modelled on nurse specialists running the service and consultants being referred patients when and if appropriate." (S1, Consultant, first round)*

> *"I'm not seeing any inappropriate patients in my out-patients, so… We get a steady throughput of quite a few appropriate patients, although more patients are coming into the service." (S1, Consultant, second round)*

This would not necessarily lead to fewer patients being seen by the consultants as more patients would be coming through the service in general, alongside the ICP, but it would allow the consultants to focus their efforts on managing the more complex patients. Therefore, logically, it should follow that patients would be managed promptly and effectively.

- Nursing Staff

From a nursing point of view, the BFNS thought that the implementation of the ICP would benefit them with regards to the fact that the increased dependence upon their input to the service would potentially mean job security and potential expansion of role and staffing numbers. With their extended roles they could also benefit from increasing knowledge through more training and education from varying sources. By the second round of interviews, it was difficult to determine whether the expansion of staffing numbers would remain following the return of the original lead BFNS from maternity leave. The BFNS were hopeful this would happen but was dependent upon the number of patients being referred to the pelvic floor service continuing to increase.

- SCCT

The SCCT were fairly peripheral figures in the traditional pathway, by introducing the ICP they were hoping to become more central to the pathway and in doing so become more integrated within the team. From the second round of interviews it was clear to see that the introduction of the ICP did improve the working relationship between the SCCT and the secondary care team, whilst also giving them the potential to increase their FI management skills by introducing neurostimulation in the future.

"And obviously like training for the staff – I mean I know Consultant A has got some training that she wants to do a workshop specifically for us and we've highlighted that we may be able to do things like the stimulation, we may be able to do that in the community so they're not having to go to acute." (S12, SCCT, first round)

The fact that the two teams were working more closely together would be of benefit to the service in general as any training related issues such as symptom severity scoring, or new management techniques could be addressed quickly and effectively due to this new working relationship.

- Deputy Divisional Manager (DDM)

Within the second round of interviews there was a distinct feeling from the DDM that the ICP would potentially lead to a financially sustainable service that becomes a complete necessity within the trust and for commissioners in the local region. This would be beneficial from an organisational point of view as to have a successful service that is financially sustainable would be a feather in the cap of the organisation.

> *"A complete necessity. Financially viable and sustainable, and completely embedded within the trust. Within the trust and with our commissioners." (S6, DDM, second round)*

- GPs

Overall, the GPs spoke positively about the introduction of an ICP in both the first and second round of interviews. All of the GPs mentioned that although they see very few patients with FI it is reassuring that they would have a service to which they can refer these difficult to manage patients. Again, this would only be of benefit to the patients as previously they would have been managed either in the GP setting or referred to varying different services, most of which would not be appropriate. GPs were unsure of the mechanism of referral and who to refer to, with only the community continence team being mentioned as a specific service they were aware of.

> *"Erm, I don't know anything about the faecal incontinence service. I've never heard of it." (S4, GP, first round)*

Patients

When discussing benefits to patients with both the staff involved in the service and GPs there was a consensus of opinion that the ICP would improve patient care. The staff within the service were focused on streamlining the patient pathway, aiming to get the patient to the right person at the right time. The main reason behind this was because of the fact that FI can be very distressing for patients and is also very embarrassing; therefore ensuring that patients are reviewed and commenced on management for their condition promptly will certainly be of benefit to the patients. Interestingly, although the GPs admitted to seeing very few cases of FI they were in agreement that FI could have a negative effect on patients. The fact that the location of care was moving from the acute hospital base into the community would also be of benefit for patients. There are multiple challenges for patients when they do attend acute hospitals mainly based around accessibility, cost of parking and also time pressures with clinics often overrunning. The move into the community had helped to solve some of these issues, ensuring that patients were more satisfied with the service (226).

> *"Sandwell [hospital] is a nightmare for parking, I get very frustrated. Luckily, here is better and it's free so that's a bonus too." (P5)*

Using the patient interviews and the focus group discussion, attempts were made to elicit the potential advantages and disadvantages of the ICP from a patient's perspective. Patients are key stakeholders in any new intervention and some common elements were identified based around the ICP and any previous experiences they had of continence services. Being able to describe the patient's experiences and perceptions was a key element within the research, as for the ICP to be considered a success much was dependent on what the patient's perceptions were. Common themes were grouped into three main categories: the experience of access to continence services, quality and provision of FI services and experience or opinions on the ICP. The demographics of the thirteen patient participants are described in table 15.

Experience of Access to Continence Services

Seeking Help

Ten of the thirteen patients had sought help for their FI prior to the interview. All patients eventually discussed their symptoms with their GP or practice nurse but did feel reluctant to do this openly due to embarrassment. Around half of the patients noted that there had been no direct enquiry from their GP regarding their FI symptoms (9).

> *"Well erm yes, I had tried to get help but you know it's an embarrassing thing really, it's not something that you want to discuss" (P4)*

Referral

The majority of patients had experienced a delay in being referred to the appropriate continence service, with some patients having to wait up to eighteen months before being referred appropriately. There was a strong sense that GPs were either unwilling to refer patients or that they were not aware of any services available. Some patients who were referred by their GPs mentioned that they were referred to various specialities within the hospital setting and not necessarily to the pelvic floor dysfunction service or the community continence team (9).

> *"I did go to see my GP, but I'm not sure he knew what to do with me really. It took a long time for me to be seen by someone who knew what they were going on about…. It probably took the best part of the year at least" (P2)*

Quality and Provision of FI services

Past Experience of Continence Services

Eight patients had been assessed and managed by continence services in the past. Three patients had been managed by community continence services with the remaining five having been managed by various different continence services. Interestingly, the patients mentioned some common themes in relation to all of the continence services. Firstly they felt that the continence services were almost "hidden" away. This was partly due to the fact that they presumed that the GPs did not know about the continence services and therefore could not refer. Lack of promotion or advertisement of services was postulated as a reason for this. The patients felt that once they were in the service then their assessment and management was positive on the whole. Around half of the patients who had accessed services previously, mentioned that the healthcare professionals involved were comforting and responsive to their needs. Some patients however did mention that they had been referred to what felt like a “pad service”. Overall, the majority of patients felt that their assessment was adequate whilst at the same time being appropriate in terms of enquiry into embarrassing topics (9).

> *“Yeah, I have been seen by a continence team and they certainly helped me, but it took me a while to get there and to be honest I feel I could have been referred earlier but whether the GP didn't know about the service, I don't know” (P5)*

> *“It was a few years ago now, but I was referred to a continence service but to be honest all they did was give me pads, I got no other treatment. I just accepted it as I didn't know there was anything else available” (P9)*

Management

From a management point of view, most patients were satisfied with how their symptoms were managed. Yet again, the notion of satisfaction with the management they received was tempered by the delay in getting to that stage. Around half of the patients felt that they were discharged from the services too early and decided against asking for another referral when their symptoms worsened due to their initial difficulties in accessing the service and the fact that there may be nothing that could be done for them aside from pad provision (9).

> *“Yes, I think overall I was happy with my treatment, but it didn't really last very long.” (P3)*

> *“Once I got to be seen by the nurse I felt it was very good but there's no getting away from the fact that it took too long for me to get there and I suffered in that time” (P7)*

Experience or Opinions on the ICP Pathway

Location of Care

The five patients who were interviewed that were on the ICP pathway spoke positively in relation to the fact that location of care was in the community setting. All five patients had been triaged to the bowel function nurse specialist clinics but were at different stages within their assessment and management. One key element was the ease of access for patients at getting to appointments. This includes ease of parking, not having to pay for parking and being closer to home than the hospital trust. The patients did mention that a potential issue could be for patients without their own modes of transport having to get to only two locations within a rather large geographical area. Alongside this, another potential issue is the fact that patients with FI will not feel comfortable travelling long distances without easy access to a lavatory (9).

> *"Yeah, yeah, it's erm it seems to be working well, this is my third visit and my incontinence is better. It's good as well that it's close to my house because I don't have to traipse up to the hospital it doesn't cost me any money." (P11)*

> *It's fine for me because I live nearby but if you live in Oldbury or Smethwick and you don't have a car, it could take you a while to get here. I wouldn't be so keen on that" (P13)*

Patient views of healthcare professionals

All patients mentioned that the healthcare professionals within the service whom they had been in contact with were knowledgeable and “put them at ease” by the fact that they seemed experienced when dealing with FI. All patients were happy to be seen by a nurse specialist rather than a consultant and did not see this as detrimental to their subsequent management. In fact, nine of the patients actually preferred to see a nurse specialist, as they were of the opinion that they could discuss their problems more openly with this individual. The focus group did not see any issues with being seen by a nurse initially as long as there is a “backup” readily available in the form of consultant review (9).

“To be honest, and this is no disrespecting yourself, I'd prefer to see a nurse as generally they have a bit more time on their hands and are used to dealing with these things more often” (P2)

“I have no issues seeing a nurse as long as if there are any problems I can get to see the doctor quickly” (P6)

Patient views on access to ICP

The five patients on the ICP were referred via their GP promptly following the presentation of their symptoms. They did not have to be reviewed by multiple services prior to being referred to the ICP for FI. All five patients had different GPs who were aware of the service. These patients did not wait longer than four weeks to be reviewed initially in the clinic.

Five of the individuals within the focus group did raise the potential issue of GPs being aware of the service and the potential need for promotion of the service throughout the Sandwell area to ensure that patients were referred appropriately and promptly to the service (9).

> *"Well I went to my GP and she just referred me straight in. She said she knew about this new service and that they'd see me at health centre one. I didn't have to wait long either which was a bonus, it was much quicker than when I was last referred" (P5)*

Management and Handheld Document

All five patients who were at varying stages on the ICP were happy with the improvement in their symptoms so far. These patients had only received conservative management modalities but these alone were enough to improve their symptoms significantly. They found that the ICP handheld document was very useful for reminding them how to perform some of their conservative management exercises such as pelvic floor muscle exercises and correct defecatory dynamics. The handheld document was also very useful for them in that it allowed them to see how much their symptoms had improved and also to liaise with their GP or practice nurse with regards to what treatments they are currently undergoing (9).

> *"So far my incontinence has got better. I can do things now that I couldn't do before coming to see the nurses." (P8)*

> *"The paperwork that I got sent was quite good actually, bit scary at first but the instructions on exercises turned out to be useful" (P4)*

Cognitive Participation

(The need for key participants to believe in the intervention and drive the implementation process forward by being aware of and making valuable contributions to sustaining the intervention)

Initiation

(How participants worked to initiate the ICP)

Over the course of the ICP implementation there was a growing sense of realisation as to how much work was needed. The key players involved in the ICP (Consultants, Lead BFNS and SCCT Lead) did the majority of this work. There were a number of key elements to getting the ICP implemented. The development of the patient pathway and the handheld document were a starting point for the team. All elements of the patient pathway were evidence-based practice that were identified and compiled by the lead consultant and the lead BFNS, with input from the SCCT lead. Given the complexity of the condition and the number of potential assessment tools, this was a process that took a long time with many discussions being held. These discussions involved deliberations with regards to the assessments that were to be used within the pathway and also the pathway of management. The majority of the decisions on management strategies were based upon the guidance from NICE and other government documents (6,11,33), alongside clinician experience and evidence-based medicine. With regards to assessment tools, more specifically symptom severity scoring and quality of life outcomes, this was a more difficult decision, as there were many different tools available. These tools have differing psychometric properties with no single measure having all the ideal properties. The decision to use the Wexner Incontinence symptom severity score (222) and the FIQOL/SF-36 (223,224) quality of life outcome measures were made based on the relevant psychometric properties of these measures. Consideration was given to previous clinical experience and familiarity with these outcome measures also. It should not be underestimated how much time was taken and also the importance attached to ensuring the patient pathway and outcome measures were correct. Once the patient pathway was decided upon, the next major element was the development of the ICP document (which would be in a handheld and electronic form). This document took a lot of the Consultants and BFNSs time, as it needed to be a comprehensive document that included everything that may have been needed within the management of a patient with FI via an ICP. The structure of the document included the following key elements:

- Patient demographics
- Patient history
- Patient examination
- Assessment tools- symptom severity scoring, quality of life measures
- Management advice and patient instructions, including pelvic floor muscle exercises, correct defecatory dynamics, biofeedback etc.
- Variance
- Space for written clinical notes

The inclusion of these elements was based on the need to ensure, as much information about the patients was available to the team for two purposes: patient care and audit. The document needed to contain a recording of patient symptoms and assessments at the first appointment and subsequent appointments to allow comparisons to be made and track patient progress through the pathway. Having this information also means that the process of auditing the ICP and patient outcomes is much easier as this information is readily available. The addition of the variance element is vital, as without this the team could not claim to have implemented an ICP, as this is an essential component of an ICP. The team did not use any other ICP as a guide, mainly due to the fact there had not been an ICP for faecal incontinence previously, especially one crossing care boundaries such as this one was attempting to do.

The development of this document was essential as without this there would be no ICP. The team produced many versions, making improvements to each one until they were happy with the end product. This process took place over a period of four months. Once the handheld document was produced, it needed to be placed on to a computer system called System One. During the initial period of the implementation the team had identified that the majority of GPs in Sandwell were using System One as their IT (Information Technology) system within their practices. Not only this, but the SCCT were also already using System One, therefore the decision was taken to put the ICP onto System One. This was achieved by meeting with the Trust IT department who placed the elements of the document described above onto System One in a format that was easy for the clinical team to navigate. Once this was done, the IT department granted special access so that the secondary care team were able to access System One and training was given to enable them to use System One and the ICP document effectively. This part of the process was performed in a timely manner, allowing the team not to experience any further delays to the implementation. These two elements-the handheld document and the IT document were key to the implementation- without them there would be no ICP to implement. In the background of these two elements was the process of gaining governance approval for both the ICP itself and the documentation. Approval from the hospital and community trust governance boards was needed as without this approval the pathway could not be implemented. Once again, this meant work for the leads within the service in the form of ensuring that all documentation for either the acute Trust or community governance board was completed to a level that would gain approval. Governance approval was granted in a straightforward manner once the applications had gone in, but again this was a time consuming process for both the secondary care and community team. Due to the fact that the team had been prepared and were planning to seek approval as soon as the ICP document was finalised, this did not lead to a significant delay in implementation. The researcher cannot comment on the managerial aspect at this point in the process, as they were not aware that any input was being made.

Once the pathway, document and governance were in place, the decision was made to implement the ICP. To do this, the BFNS needed somewhere to run clinics from in the community. The SCCT had already identified one large local health centre (health centre one), which could be used and pre-emptively had booked two sessions a month in this centre for the BFNS. However, the anticipated increase in referrals meant that the team were looking for other premises as well. The BFNS managed to arrange a clinic space at another large health centre (health centre two), based in a geographical area that was distinct from health centre one. This meant that the BFNS now had the capacity to run one clinic per week from two different sites. This was an important breakthrough for the team. The first clinic was commenced in October 2012. These sites were used by the team as they were thought to be ideal locations with them both being large health centres that had available space to run clinics from. They were both in differing geographical areas within the Sandwell region, allowing a good initial coverage of the region to begin the implementation. Both health centres were approached by team members and were keen for the team to run the ICP from their clinic rooms. No financial issues were raised and the ICP was implemented in both health centres promptly.

Enrolment

(Are target user groups likely to think the intervention is a good idea?)

All clinical staff involved within either the pelvic floor service (Consultants/BFNS) or the Sandwell community continence team played active roles in the implementation of the ICP. From the first and second round interviews there is a clear emphasis on the need for clinical staff to be heavily involved with the implementation process, but once the ICP was implemented, did this involvement continue? Yes, staff members who were involved in the implementation process continued to be involved when the ICP was setup. The key players became the BFNS who, as per the pathway, triaged patients and as will be discussed later, started to have first contact with the majority of referrals, with a smaller proportion being seen by the SCCT. From a consultant point of view, they were still heavily involved but via a different route- the MDT. At this meeting complex patients would be discussed with the Consultants for advice on further management or for consideration of review. Although the roles and dynamics had changed slightly within the confines of the ICP, all of the same key members remained involved. From a staffing point of view, the team were in a fairly steady state by the time of the ICP being implemented. The only potential issue was the impending maternity leave of the lead BFNS. A third BFNS (recruited to cover maternity leave initially) was appointed and trained prior to the lead BFNS going on maternity leave so that a complement of two BFNS would be in post at all times. This allowed a fairly seamless transition for the service as a whole, ensuring that the momentum of the ICP was maintained with a fresh perspective of the new lead BFNS adding value too.

Patients

From the focus group discussion there was a recurring theme that the ICP was a good idea. This was predicated on the fact that the key component of moving the location of clinic setting to the community was going to be of great benefit for patients. It would bring the care closer to patients' homes and also remove the need for parking at hospitals and the time and monetary costs associated with this. The idea of promoting those services or pathways such as this also found favour with the focus group participants as they had all experienced delays and difficulties in accessing services for their incontinence. Anything that could improve this process was looked upon favourably by the focus group. The focus group also commented on the positive outcomes that the patients who had been in the service previously had achieved and were hopeful that the change in pathway would either improve or maintain these positive outcomes.

Legitimation

(Will the participants see the point of the intervention easily?)

Staff

From the outset of the project, the staff involved with the service were already engaged, as they had already started working on the ICP. This was clear to see from an observational perspective and was reaffirmed by the first round of interviews. From these interviews it was obvious that all of the staff involved in the service truly believed in the fact that the introduction of this ICP would benefit patients. Every single staff member talked about improving the patient journey and streamlining the pathway with great intent and pride. This was further demonstrated by the fact that the current service was described as 'a little hit and miss'. This was actually quite an interesting point as during these interviews there were seemingly mixed views on how well the current service at the time, prior to the ICP, was working.

> *"I don't think it works very effectively at the moment because you know they'll get referred in and they'll go and see the consultant which – you know sometimes it's needed and then most of the time the patient really just needs to see me or even a community physio." (S8, lead BFNS, first round)*

> *"The service works reasonably well as a………reasonably large service compared to other hospitals, in that it's able to take the secondary referrals from other centres and tertiary referrals from other centres and also the referrals from local GPs who recognise there's a problem." (S1, Consultant, first round)*

Despite these mixed views on the original service all staff viewed the ICP as being essential to the development of the service.

The only exception to this was a statement regarding the fact that it took a long time for the lead BFNS to 'get on board' with the ICP. This statement was made in both the first and second round of interviews with the potential reasoning being due to the ICP being seen as a threat to this person's job. This comment was the only indication that not everyone had bought into the project from the beginning. However by the time the study had commenced everybody was committed and could see the benefits of the ICP.

GPs

From a GP perspective there was a definite sense of the ICP being a valuable tool for managing a difficult condition. All of the GPs saw the potential benefits of the ICP quite easily but again this has to be tempered by the fact that they openly admitted to seeing very few FI patients and therefore the overall use of the service, from their point of view, was questionable. It would allow them to be able to manage patients within an effective service. This would benefit patients and therefore GPs would be happy to have the service within their toolkit for the management of these patients. The GPs were certainly in favour of moving services such as this back into the community and they felt that this is what most patients would want as well as what most of their peers would want. They felt that the proposed changes were positive and would make for a more structured, smoother patient journey.

"I think a service based out in the community is definitely what patients would want and certainly what most GPs would like." (S5, GP, first round)

"I think it's very good to have a clear direction for GPs and I think that the very existence of these pathways, as long as they're properly advertised to us, does help. So I think from my own perspective, knowing that certainly there's a referral form there which plugs into the pathway is very useful because at that point, if I was deciding to refer someone, I'd print off the form from the network drive which is where we've got it and anything that I hadn't asked them that's useful to include in the referral, I can do there and then, which is what we do with other pathways as well. So although that can be a bind sometimes in certain cases, particularly rare things like this, they can be quite useful." (S3, GP, second round)

Activation

(Will the participants be prepared to invest work, time and energy into the intervention?)

Staff

Investing time, energy and work into the implementation of the ICP was very clear to see throughout the process. All of the lead members of staff (consultant, BFNS and SCCT) were at the forefront of the continual development of the pathway, document and governance processes. By their own admission, the lead for the SCCT did not have as greater role as the other members, this was due to a problem with staffing capacity meaning that her time was taken maintaining the service she already had rather than being able to devote time to the further development of the ICP.

> *"I think it's just, for us, because when the implementation and everything was coming in, we were so short staffed, I couldn't actually get as involved as I would have as normally as the manager of the continence service, because I was doing the clinical, I was covering the clinics and all the rest of it. So, it's probably just came at the wrong time for us, because normally I would have like said 'well I'll do that with the GPs', but it's just the way it all fell with sickness and everything." (S12, lead SCCT, second round)*

Despite this, the lead of the SCCT was continually informed of developments and consulted on key decisions. Following the process through to the point at which the ICP was implemented, it was evident all members of the team were prepared to work hard and invest their spare time (outside of clinical commitments). This is certainly the case with the clinical team, but from a management point of view the same could not be said. From an observational perspective there was very little attendance at ICP meetings that resulted in a lack of input and seemingly a lack of investment of time and energy. Within the interviews it was commented upon that there had been a ‘lack of a middle management champion from within the organisation since the previous DDM left’. With regards to attendance of the other team members at the ICP meetings, all meetings were well attended by the clinical staff with relevant ideas and solutions to problems or barriers being put forward by all team members. Again this reflects that the team members were not just present, but they were engaged in the process and they felt a sense of communal responsibility to drive the implementation forward in a timely manner. The fact that the team were doing this in their personal time outside of clinical commitments has to be mentioned at this stage. There was no time set aside in job plans or in regular day-to-day commitments to develop and implement the ICP. This required a vast amount of work, time and dedication from everyone involved to set up and developing a pathway such as this one.

GP

With regards to investment of time and work, the ICP did not affect the GPs at all. If anything it would make their jobs slightly easier when faced with patients with a complex condition such as FI. The fact that a service would be available meant that GPs had another option when attempting to manage these patients. The only element in which GPs would have to invest more time and energy would be in the identification of patients with FI. This is an element that all of them openly admitted to being poor at present, and all four of the GPs commented that in theory it would be good to change this behaviour, but in realistic terms given the number of conditions with a higher throughput of patients that they see, it is not high on their agenda.

> *"Because I don't see a lot of it, I can honestly say it is not something I focus on…. I'm too busy with other conditions" (S11, GP, second round)*

Overall their workload would not change but if they did encounter a patient with FI they would have a mechanism in place to manage this patient as effectively as possible.

Collective Action

(The investment of effort by participants, which can either promote or inhibit the enacting of an intervention)

Interactional Workability

(How will the intervention affect the work of the participants?)

Staff

When considering the effect the intervention would have on the work of the staff within the service, it was noted in the first round of interviews that there would be a shift as to who would be doing the greater proportion of work and where this work would take place. The idea of a shift of work was based on the fact that there would be a change in the triage process placing the emphasis on the BFNS rather than the consultants. The thoughts of the majority of staff were that this would mean more work for the BFNS and a different type of work for the consultants. From my observations and also the second round of interviews this was indeed the case, with the BFNS workload increasing and the consultant's workload being more appropriate.

> *"It is doing yeah because there's a lot more work now. Whereas before we had more time to do our paperwork, letters and everything else, we haven't got that time now." (S8, lead BFNS, second round)*

During the second round of interviews the consultants noted that they were seeing more appropriate patients in clinic, which was of benefit to them, but also that more work had started to come through the MDT meeting. This work was related to the ICP, insofar as patients were being discussed at the MDT following an initial assessment and management by the BFNS or SCCT. Interestingly, one of the consultants commented that the increased time needed in MDT to coordinate the care of these patients was not considered in their job planning and therefore was not strictly recognised as work.

> *"Yeah, in terms of shifts of work, I think it's taken the pressure off my clinics in the sense that, you know, obviously patients are now being triaged other places to start off with, as we've previously discussed, rather than all being seen in my clinic to start off with. The effect of that is that we're obviously putting more patients through the MDT. So that work is happening, it's just happening in a different way – it's a different way of working……What's interesting is, from an organisational point of view, they're happy to count regarding the clinics, but don't recognise the extra work." (S9, Consultant, second round)*

This has not had any effect on the service or the commitment of the consultants to this process but is far from ideal.

The location of care was a key component in the new ICP and this meant that the BFNS would be working within a community setting at different health centres. This was certainly the case by the time of the second round of interviews where the BFNS were running a clinic, alternate weeks at two different health centres. The BFNS were happy with this arrangement and talked positively about working in this different setting, aside from a minor hiccup when attempting to run a clinic from one health centre (health centre three). This unfortunately failed due to a lack of IT infrastructure within the rooms of the health centre in which they were working, resulting in work being repeated. The number of clinics being run was more than was originally planned for the ICP. The original plan was to run clinics twice a month but due to an increasing demand for the service from the time of implementation the need for further clinics was evident. With regards to capacity the BFNS were coping throughout the study. There was never a point in which the service was unable to cope with the number of referrals but it does mean that the two BFNS in post at present were running a number of clinics per week, not only in relation to the ICP but the service in general. The BFNS and consultants felt that although the service was coping at present, if the plans for further expansion were to occur then the need for a third BFNS would be essential. In fact, plans were already in place to ensure that when the BFNS who was currently on maternity leave returned that all three would be able to remain within the service.

> *"Yes it'll have to. If patient numbers as they are carry on going up, they carry on, the numbers improve that are being referred which we hope they do, we're going to need*

definitely one more at least to cope with the range of patients that we will be seeing without a doubt because we can only see four patients per clinic at the moment so that's eight patients a week. Thirty-two a month. If the numbers go up we're going to need to do more clinics to increase that so you're going to need more nurses to do that and it's not just seeing the patients in the clinics it's doing all the other stuff after if they need referrals doing, letters doing." (S8, lead BFNS, second round)

There appeared to be sufficient capacity but with the potential increase in demand this could become a problem. This problem was further highlighted by a period of sickness for the main SCP who performed the physiology investigations. This period of sickness meant that the second SCP was required to perform the investigations, but due to a period of inactivity in performing these investigations it was a slow process ensuring patients were investigated in a timely manner.

"We've had a little bit of illness in there, which proved why we needed two SCPs fully trained on doing the physiology. They were a bit slow to activate if somebody goes off sick then somebody else steps into the breach." (S1, Consultant, second round)

This was certainly something that was identified in the second round of interviews that the team wanted to rectify in the future.

GPs

From the perspective of the GPs, the ICP would have a significant effect on their patients who suffer from FI. Although admittedly they reported a very low identification rate of patients with FI, all of the GPs felt that these patients are often difficult to manage. Armed with the knowledge of a specific service for patients with FI, the GPs spoke positively about the ICP and felt that it would potentially make their work easier. It would allow them a mode of referral and subsequent treatment for this challenging group of patients that would ensure patient satisfaction as well as potentially reduce costs of containment products. Unfortunately, by the time of the second round of interviews, none of the interviewed GPs had used the ICP but two of them reported positive feedback from their fellow GPs. The fact that the referral pathway and documentation was available electronically was seen as a positive element that would assist the GPs with their work and also from a commissioning point of view with relation to GP access.

Relational Integration

(Will the intervention promote or impede the participant's work, and will it have any effect on consultations?)

Staff

The whole concept of the ICP was to improve patient care. However, there were expectations it was also going to change the way the staff within the service work. When discussing the ICP initially in the first round of interviews, the staff were very positive that it would be beneficial to the patient and therefore that was their main concern. Issues were raised regarding capacity if numerous referrals were to be made but this was an element that was going to be controlled if necessary. No mention was made as to how much work would be needed to implement and sustain the ICP. This was either due to the fact that they didn't realise, or they were not concerned as to how much work it would take; from the interviews it was unclear. From an observational point of view, however, it was clear to see that the staff within the service were wholly committed and did not mind how much work was needed; they just wanted the ICP to be a success. The implementation of the ICP did affect the work involved within the service as a whole, especially from a BFNS perspective. The increased workload for the BFNS meant that some areas of the service, not clinical care, were affected and time was spent trying to implement and promote the ICP. There was no real change for the consultants and physiologist/SCP with regards to the promotion or impedance of their general work. As mentioned previously, the consultant's work had changed slightly, with more time spent at MDT but the general amount was thought to be the same.

Consideration needs to be given to a number of elements when assessing what impact the ICP had on patient consultations. Firstly, the reiteration that none of the assessment or management tools used have changed. Therefore, the patient receives the same assessment and management strategies in the new pathway as the old pathway. The elements that have changed are, who the patient sees first (the majority of the time), based on the BFNS triage process and where the patient is seen (community setting). The staff within the service were convinced that this would be of benefit to the patient, in both the first and second round of interviews. In the second round of interviews, there had been very little feedback from the patients to the staff about the ICP. There had been limited feedback but mainly based around how their management had been successful, but not directly about the ICP process. The staff did note that patients seemed to be happier that their appointments were closer to home without the problems associated with timing and cost of parking in the hospital. This was also described in the patient interviews as a positive point for the ICP.

> *"Some of them have said it's better and mainly from a parking point of view because they don't have to pay. It's always about money. But you know they don't have to pay for parking, it's easier to park." (S8, lead BFNS, second round)*

From the BFNS perspective, they felt that since the introduction of the ICP and the relevant documentation, consultations had been simple and easy to complete as per the ICP document. Initially, there was an issue related to the document whereby the BFNS felt that it "didn't flow right" but this was soon resolved and was never a major problem, more of a teething problem. No problems were reported with relation to the patients forgetting to bring the document or the patients not understanding the document. Again, the only issue related to the electronic document was based around not having the IT infrastructure in place at one of the intended health centres (health centre three). As this was not going to be rectified anytime soon, the decision was made by the team to use health centres one and two only. The issue surrounding IT infrastructure was also a problem encountered by the SCCT at the same health centre.

> *"Yeah we had the problem with health centre three, as in there was no computer there so we had to change that quite quickly and find a different venue with computer access or more importantly internet access but other than that it's been fine." (S8, lead BFNS, second round)*

Consultant two did remark that it was now "a pleasure to do a pelvic floor clinic", when comparing their experience to pelvic floor clinics previously. This was based on the fact that the pelvic floor clinics now had more appropriate patients attending who were needing consultant review for specific purposes such as requiring an operation or having complex issues. Overall, the ICP had very little effect on the content and structure of the consultations for staff or patients.

GP

In both the first and second round interviews, the view of everyone interviewed was that the ICP would be of benefit to the GPs. As to what extent the benefit was to the GPs was debatable due to all of the GPs reporting that they reviewed very small numbers of patients with FI. No comments or observations were made which showed the ICP would impede a GP's work. This comment must be placed into context, with the fact that only a small sample of GPs were interviewed (four GPs) and by their own admission, these GPs had very limited experience with patients suffering from FI.

Very few comments were made by the GPs regarding any changes in their consultation. The key point made though was the fact that due to the issue of FI being highlighted to them, they would consider asking more patients directly about this or trying to establish a means of doing this within their practice. Some examples of this included placing the question regarding incontinence in the checklist for the practice nurse well person clinic or making FI a key performance indicator in the GP quality and outcomes framework (QOF) (227) . Comments were made by three GPs alluding to the fact that it will only be taken seriously if income is attached to it.

> *"If you were to put an incentive into recognising faecal incontinence it would stimulate the GP interest. Silly but true." (S11, GP, second round)*

Skill Set Workability

(How compatible is the intervention with existing work practices? Will staff require extensive training before they can use the intervention?)

There are two main differences between the ICP and the old pathway for patients suffering from FI: location of care and triage process (including first contact). The location of care changes from a largely hospital-based setting to a largely community-based setting (consultant clinics aside). With regards to the triage process, this has changed from a consultant triage to a BFNS triage. The reasoning for this, based on the first round of interviews, was that the most appropriate person for patients to have first contact with is either the BFNS or SCCT, in comparison to the first contact being with the consultant prior to the implementation of the ICP. Before the ICP was in place, patients with FI would be reviewed by the consultant with the majority of these patients going on to be reviewed and managed by either the BFNS or the SCCT. Therefore the triage process change would look to cut out the unnecessary step of visiting a consultant (unless required due to severity or unusual symptoms). These are fundamental changes that required a change in working practices from the existing pathway. Although they did require a change, every member of the team whom these changes involved or affected were fully engaged in these changes and the purpose of them. From an assessment and management point of view, there were no changes for the BFNS or the consultants. The SCCT did have some changes from an assessment and management perspective, as at the time of the first round of interviews they did not use the same bowel symptom severity scoring and quality of life outcome measure tools as the hospital team. Therefore the decision was made by the team as a whole to use the hospital scoring systems so that all aspects were uniform. This was advantageous for the team from an audit and research perspective. It allowed the regular auditing of patient outcomes to be performed easily as all patient outcomes were standardised, allowing easy pre and post-treatment comparison. The only issue identified with this change was the need for the SCCT to be trained in the use of the new assessment tools so that they could be completed accurately.

The only potential issue that was identified from a work practice point of view was the issue surrounding capacity. In the first round of interviews almost all of the staff members commented on their concerns surrounding the lack of capacity. These concerns were based on the notion that the ICP once implemented would attract a large increase in referrals and therefore workload for the staff members.

> *"However, we will have problems if we, I suspect we may open the floodgates if we advertised our service and proactively pulled patients into the service and the key is how to do that in a controlled way because the majority of patients don't actually need to see the surgeons, a lot of it can be nurse managed or nurse triaged." (S1, Consultant, first round)*

From the second round of interviews it was clear that although an increase in referrals had occurred, due to a number of issues, the number of referrals had not been as problematic as anticipated. This meant that the concerns regarding capacity were unfounded at the time of writing. The BFNS were running more ICP clinics than anticipated originally which was stretching their workload slightly, but with the anticipated addition of a third permanent BFNS this would be of little concern.

"I think we've got adequate capacity for just now. I think if we've got another hundred per cent next month, we might be in a bit of trouble. ... And in that sort of way, so we're seeing a steady rise of patients. And if we see the same rise in HOB, when we go into that side of things, then I'll be asking my other CNS to come back from maternity leave a bit sooner. But I think we've got adequate capacity." (S1, Consultant, second round)

For the majority of staff, very little training was required for the purposes of the ICP. For the hospital team, training was provided on the IT system, System One, as they had no prior knowledge of the system and it was an integral part of the ICP, especially for the BFNS. This training was provided by the trust IT department and was arranged promptly. This training was essential as otherwise the electronic element of the ICP would have been redundant and one of the key components would have been rendered useless. The SCCT already used System One and therefore did not require formal training. The SCCT did require training from the hospital team with regards to the bowel assessment tools used. A decision was made to standardise the assessment tools used for patients in the ICP. This was so that when the patient outcomes were assessed there would be no difficulties comparing one patient's outcomes to another, therefore aiding the research/audit element of the ICP. This training was scheduled to take place prior to the implementation of the ICP but at the second round of interviews the SCCT had still not had this training, albeit they had seen very few patients.

"There was talk about some training on the stimulation (see below) and things like that, which we haven't received, and the training on the scoring as well, we haven't received that, because we were unsure, you know, is it the Wexner scoring and that?" (S8, lead SCCT, second round)

The other training issue identified during the interviews was that of the SCCT providing neurostimulation. This idea was mooted in both rounds of interviews with the impression that both the SCCT and consultant were keen for this to go ahead. No training had been commenced or planned by the second round of interviews for this purpose. All staff members within the service did not require formal training on the handheld document but did need some time to review the document and familiarise themselves with it. The new BFNS who had been recruited as maternity leave cover, required training on general aspects of the job, but not specifically related to the ICP implementation, although this person was present at the majority of the ICP meetings, when in post, and contributed in whatever way possible. The main focus for this person was to ensure that they had the required skills needed to make sure the service continued to run smoothly as a whole. All training needs were met and there did not seem to be any issues when the lead BFNS went on maternity leave.

Contextual Integration

(What impact will the intervention have on the division of labour, resources, power and responsibility between the different professional groups? Will the intervention fit with the overall goals and activity of the organisation?)

When considering any shifts in power or responsibility brought about by the implementation of the ICP, consideration has to be given to the key players: consultants, BFNS and the SCCT. At the first round of interviews, the power and responsibility lay with the consultants, who made all of the triage decisions, had first contact with the patients and delegated the work out appropriately, mainly to the BFNS. At this point patients were referred to the BFNS, who would assess the patients and start their initial management, referring back to consultants when or if deemed necessary. This role had a fair amount of responsibility placed upon it. The SCCT were essentially outside of this pathway altogether and may have been referred patients deemed inappropriate for the secondary care team.

The implementation of the ICP changed these dynamics greatly. Firstly, the SCCT became integrated into the team in a way that saw them become a part of the triage process not merely an afterthought. Secondly, there was a large power and responsibility shift towards the BFNS. The introduction of the triage process and the idea that the BFNS should have first contact with patients brought about this shift. The BFNS were now controlling the flow of patients following the introduction of the ICP. The overall responsibility of the patients remained with the consultants but all initial decisions regarding assessment and management would be in the hands of the BFNS. Interestingly, the shift of power and responsibility was welcomed by both the BFNS and the consultants, again on the premise that it would benefit the patients by improving the pathway of care.

"Well we're definitely more autonomous with it now because we get the referral first. We see it. Obviously that has a lot of implications for us as in you know, if we get it wrong then we're going to be wholly accountable if you know, God forbid a patient's had cancer and we missed *it. So, from an autonomy point of view that's a lot more responsibility on us." (S8, lead BFNS, second round)*

"Don't get particularly hung up on that one." (S1, Consultant, second round)

The SCCT had been integrated into the pathway, but with regards to power and responsibility in the triage process they did not gain or lose anything.

With the increased power and responsibility though does come a price, time and labour. In the second round of interviews the BFNS did comment that the ICP had taken up a lot of their time throughout the implementation phase and also once it had been implemented. The increased work impacted mainly on less time being available to complete administrative work. The implementation phase also took a lot of time and effort from the consultants' perspective. They were trying to get this up and running in their own time, no time had been set aside in their job plan and so they certainly placed a lot of effort into the implementation phase with this effort continuing once the ICP had been implemented but in a slightly different format- through the MDT. As the majority of patients were being reviewed by the BFNS, the role of the consultant in the process changed slightly. They were still reviewing patients in clinic, albeit more appropriate patients, but the real shift in their work came with the fact that more patients were being reviewed in the local MDT meeting. This essentially meant they were still giving advice on patients but just in a slightly different format, one that both professional groups agreed was of benefit to them, despite it not being allocated to their job plan.

From the first round of interviews it was evident that the ICP fits well with the goals of the organisation. The trust was running a programme based around moving aspects of care from the hospital setting into the community setting. The ICP is not a formal part of this programme as it tended to address conditions that affect greater numbers of patients e.g. diabetes. However, the leads of the service were looking for health centres in the immediate geographical area so that the service was in keeping with the trust programme. An interesting point was raised about the fact that there is a “contracting health economy” which means that beds within the hospital were reducing and that there was an increased awareness of performance for clinicians and the services they run. To set up the pelvic floor dysfunction service and allow the implementation of the ICP required a ‘leap of faith’ by the trust, which was easier because the planning was done before the financial climate worsened. However, it was perceived to be much harder in times of austerity, which had arrived subsequently.

> *“And I suspect they’ll find it increasingly difficult to set these services up from scratch in the current environment. It took a leap of faith by our Trust to do it in good economic times and therefore I would see people thinking along the lines of contracting those services and not developing new services. We’ve probably got our unit to the stage where we can commission a new service with confidence that it’ll work.” (S1,* Consultant, *first round)*

During the first round of interviews it was felt that the hospital would be able to commission a service to any willing provider which should mean that there would be no issue with the GPs from the West Birmingham part of the trust referring to the SCCT. This was a comment that was later proven to be incorrect, as from the observational data it was clear that there were definite issues with GPs being able to access the ICP from West Birmingham. No patients were accepted on to the ICP unless they had a Sandwell GP.

The second round of interviews contained very similar messages. There was a clear belief that there was a big push politically for the trust to be moving services into the community because it was thought to be cheaper. From the DDM point of view, there was a distinct need for the service to be pushed out over the whole area that the trust serves, as this would be a key factor in trying to obtain commissioner engagement. Other team members also shared this view. Again the fact that a new service was being developed was seen as "positive and refreshing" in the financial situation that the NHS found itself.

> *"The preference will be for the community setting, because it's cheaper." (S6, DDM, second round)*

One particularly notable element found was the lack of input from the management within the organisation. This was evident from the observational data whereby attendance at ICP meetings and also for pelvic floor dysfunction service meetings in general was very poor. This may well have affected the speed with which the ICP was implemented. The barriers for the implementation will be detailed at a later point but this is potentially one of the key barriers. There are two reasons for this lack of management input. Firstly, during the implementation phase there was a change in DDM and with any change in personnel there can be a change in priorities. This was alluded to in the second round of interviews whereby the DDM was very honest about the need to increase their involvement. It had been difficult for them to do this previously due to being under pressure from other organisational matters such as bed crises, which was also mentioned by other members of the team.

> *"Everyone in the trust got down in winter because of bed crisis management. It's interesting how one part of the service can affect so many other different parts of the service. We're taking important people away from what they should be doing." (S1, Consultant, second round)*

Overall, the ICP certainly fitted with the goals and activity of the organisation, but the question was whether the lack of management input delayed the implementation process. The question must therefore be raised from a management point of view, was the ICP of importance to them? This was where mixed messages seemed to occur. From the second round of interviews, the DDM was very complimentary of the service and was very clear on how this service should be marketed to ensure that it became a financially sustainable service that would become a complete necessity for the trust, commissioners and patients. The actions or lack of, from the management within the organisation did not reinforce these words.

Reflexive Monitoring

(The process of appraising the intervention, whereby participants collect information that can help to define its collective or individual worth and guide future modifications)

Systematization

(How will participants/users perceive the intervention once it has been in use for a while?)

Staff

From the first round of interviews it was clear to see that every staff member had complete belief in the purpose of the ICP. This was not people 'towing the party line' as it were, but people truly believing that the ICP would improve care for patients suffering with FI. Throughout the observation phase regardless of any barriers faced by the team, this belief was still present by the time the second round of interviews were completed when the ICP had been in place for approximately four to six months. This period of time was enough to allow the staff within the service to form some early opinions of the ICP. Each and every staff member was very positive about the ICP and how the process of implementation had gone. When asked to comment on the ICP in its current state all staff members were satisfied with the current pathway, documentation and patient outcomes.

> *"I'm pleased with it from a governance point of view because it's designed that nurses have a governance framework within which to work……That is reassuring and quality at the same time. I'm pleased with it in the sense that it seems to be achieving what the objectives were initially." (S9, Consultant, second round)*

The focus did shift quickly in most interviews to the aspirations for the future including further development of the ICP, mainly based around expansion into different geographical areas. This will be discussed in more detail later. Another key point from the second round of interviews was again a slight shift in emphasis from solely better patient care to promotion of the service so that there would be improved patient accessibility. The basis of this was still attempting to improve patient care but as will be described shortly this is impossible if patients are not being referred or attending the service.

GP

From a GP perspective, the GPs interviewed had not used the ICP by the time the researcher performed the second round of interviews. This meant that they were unable to give any opinions on the intervention following its implementation. They did reiterate their previous thoughts that it would benefit patients through the fact that it offers a streamlined pathway for them to access a high-quality service.

Communal Appraisal

(Is the intervention perceived to be as advantageous for patients or staff? Will it be clear what the effects the intervention has had?)

Staff

All of the staff members interviewed felt that the ICP was advantageous for patients. From the first round of interviews, the aim was always to provide a streamlined pathway for patients allowing them to receive treatment for the condition promptly. During the second round of interviews the staff within the service felt that this had been achieved and that patients were starting to reap the benefits of this new pathway. From their own point of view there were very few comments within the interviews about whether the ICP was advantageous for the staff. This may well have been due to the fact that the main objective for implementing the ICP was based on the patient and improving patient care. The one potential advantage that was identified was from a consultant point of view, whereby they would potentially be seeing more appropriate patients. This would free up time for the consultants, to be used for other service commitments. From a BFNS perspective, their workload had increased which was seen as an advantageous point as it meant an increasing likelihood of keeping all three BFNSs, once the lead BFNS had returned from maternity leave. There were no complaints about the increased workload from the BFNS. With regards to the SCCT, the perceived advantage for the team was that they were now more closely integrated with the hospital team. The potential benefits included increasing FI referrals and new skill acquisition e.g. neurostimulation. Overall, the staff within the service felt that the ICP was advantageous for patients and there were advantages for themselves also.

GP

All four of the GPs who were interviewed felt that the proposed pathway would be beneficial to patients and to themselves. Unfortunately none of the GPs had used the ICP by the time of their second interview. This prevented them from being able to give a personal experience of the ICP but again they mentioned that the streamlined pathway would be advantageous to patients. The advantage that the ICP brings to the GPs is based around the fact that previously they had no service in which they could refer these patients to. By their own admission, all of the GPs were not entirely confident in managing patients with FI and therefore were relieved to know that there was a service into which these patients could be referred if deemed appropriate.

With regards to communal appraisal and the effects that the intervention has had, consideration must be given to the quantitative data that was collected during the study. This data describes whether some of the perceived effects or advantages for patients and staff detailed above were actually borne out in reality.

Individual appraisal

(Can patients or staff contribute feedback about the intervention when it is in use?)

Staff

The staff within the service can give feedback with regards to the ICP at the regularly scheduled ICP meetings. These meetings happen once a month on average and are dedicated to the ICP. Elements that have been discussed during my observation included issues relating to specific parts of the ICP (document and issue related to lack of IT infrastructure at one community setting), attempts at moving the implementation of the ICP forward (greater amount of promotion) and further/aspirational developments with the ICP (expansion to other geographical locations). These meetings were open to all staff within the service and were open and honest affairs whereby any issues could be spoken of and resolved within the meeting or plans put in place to resolve these issues outside of the meeting. These meetings were still ongoing even after data collection was completed; therefore this is the arena in which staff would be able to contribute feedback about the ICP in the long term. Giving feedback at these meetings could be deemed a collective process, but each individual would be able to feedback on their particular aspect and experience of the ICP. Alongside these meetings, team members would be able to approach the lead team members and each other on a one-to-one basis as needed. This was evident throughout the implementation process and there is no reason why this should not continue.

Patients

From a patient perspective the ability to feedback about the ICP would mainly be based around direct feedback to the staff within the service. In addition, the service has a long-standing history of trying to gain feedback from patients by sending out patient questionnaires. Previously they have had a good response rate and this practice will continue in the future, to aid further development and improvement of the service.

Reconfiguration

(Can the intervention be adapted/improved on the basis of experience?)

Following the implementation of the ICP there were three main issues identified that were fed back to the team and rectified. This feedback was provided by the lead Consultant and BFNS. Firstly, the lack of flow within both the handheld document and IT document was identified only once they were in clinical use, but this was quickly rectified by a re-ordering of the pages within the document. This may seem like a fairly minor adaptation, but it was one that was key to the BFNS to ensure that the consultations flowed smoothly. The second adaptation was related to the issue regarding the lack of IT infrastructure at health centre three. This was leading to repeated work for the BFNS and therefore a decision was made by the team to not use this health centre. Both of these adaptations were relatively minor but showed that the team were constantly evaluating what was working well and what wasn't and trying to improve.

The third main problem identified by the team following the implementation of the ICP was the lack of referrals. The team tried to increase the number of referrals by improving the promotion of the ICP to both the GPs and to patients. This was the point at which the hospital communications team were approached to try to help with the promotion of the service. The ICP team had already been into the GP practices highlighting the service, the benefits of the service and how the GPs could refer into the service but despite a spike in referrals this was not sustained. Therefore alongside repeating visits to the GP practices, in co-ordination with the communications team, posters were designed, meetings were held with the district nurses, and adverts were published in the local newspaper with advertisements being present in the hospital and on the plasma screen at the local council buildings. This was carried out in April 2013. These efforts brought about another spike in referrals in May 2013, but the number of referrals did decrease again in June and July, suggesting that this increase may not be sustained unless promotion is an on-going priority for the team.

"Well, initially we had lots of problems getting patients through the door as in referrals other than from the pelvic floor consultants so we had to regroup and look at how we can get more people knowing that the service is there so that they're actually referring in so we can get more people, bums on seats so to speak. So what we did was we've been out and visited lots of GPs in Sandwell, dropped off packs." (S8, lead BFNS, second round)

"Engaging the GPs earlier. I think we were slow in the mark, there. We should have thought about that and planned that, rather than in the way – the clinics were set up and then people thought about engaging the GPs." (S1, Consultant, second round)

"Now we've been allowed to promote in other ways because before we were just restricted to walking round to different GP practices and telling them about it and the district nurses. But we got the trust's communication person and marketing person involved and they've helped to push things forward, so we've got the poster, we've got a leaflet, we're going to put an advert in the paper, we've got banners that we're going to put up and all of that is now going ahead. The website's going to be up and running next week, so I think we seem to have gone from nothing to suddenly everything all in a few weeks." (S10, BFNS, second round)

From both rounds of interviews alongside the observational work it has been clear that the ICP team were never going to rest on their laurels. The plan from the outset was to establish the ICP in the Sandwell region and then expand out to neighbouring borders. Firstly, towards Birmingham and then out towards the Dudley, Walsall and Wolverhampton areas. By the second round of interviews the desire to expand the ICP was evident. This showed the ambition and the willingness of the team to try to improve and expand the service as much as possible. Contact had already been made with the Birmingham community continence team lead and discussions were at an advanced stage. Informal discussions have been held with consultants from the Wolverhampton and Dudley areas, but these were not at such an advanced stage.

> *"Next two years, I think we should have direct access of patients onto the incontinence ICP and I think we'll have it run across our patch and into neighbouring patches……And we will have extended our service, essentially, into our three neighbouring trusts." (S1, Consultant, second round)*

> *"I think we'll move into Birmingham is the next big step and I've arranged for the lead continence nurse from Birmingham to come to the next pelvic floor meeting. I've been liaising quite closely with her and forming links and just putting the feelers out further afield really, just to try and get them on board and we need to start looking at going out to Birmingham GPs and starting the whole ball rolling again really and doing the same old, same old but in a different area. Doing what worked best obviously though in Sandwell, in Birmingham, and not the stuff that didn't work not so well." (S8, lead BFNS, second round)*

> *"Yeah, I've talked to consultants from all three trusts. They're largely supportive but I think we need to go out formally and meet with them and gain their confidence and trust that we're not trying to steal their work. Without the support, they'd do – and actually give them all the resources." (S1, Consultant, second round)*

Throughout this chapter there have been a number of key findings identified with regards to the barriers and facilitators of implementing an ICP for FI, including:

- Change management
- Leadership
- Shared purpose and staff commitment
- Teamwork
- Capacity

In the discussion chapter (chapter 6), these barriers and facilitators will be highlighted with reference to the earlier literature review. The next chapter, chapter 5, will discuss the quantitative results based around referrals and patient reported outcome measures.

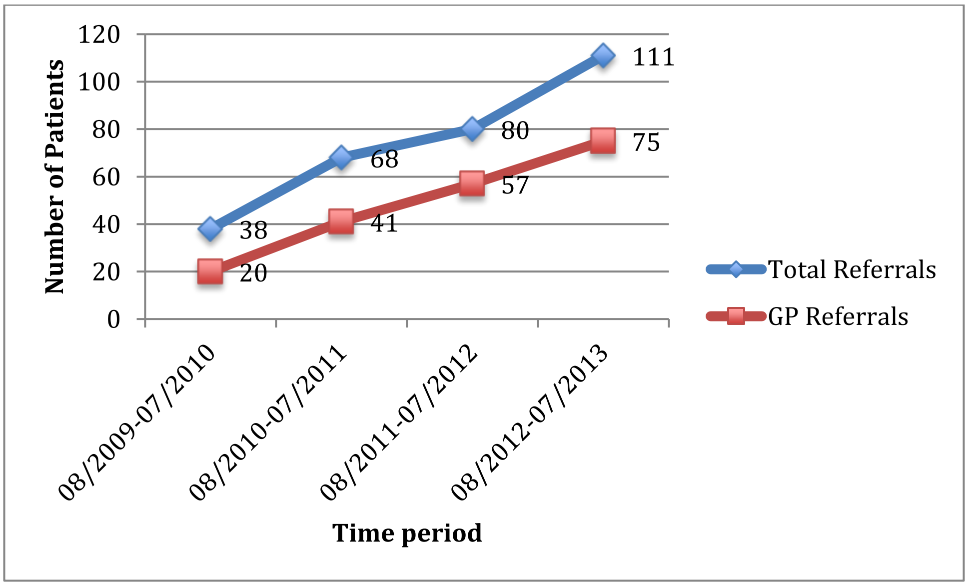
CHAPTER 5: QUANTITATIVE RESULTS

This chapter identifies the effect that the introduction of the ICP had on the number, source and appropriateness of referrals and patient outcomes, thereby attempting to answer one of the research questions. Additionally, following on from the stakeholder interview data, the quantitative results may be able to support the claims made in these interviews. The chapter is structured around exploring the referral data initially and then subsequently analysing the patient outcomes.

Referrals

The referral data is a comparison of before and after the implementation of the ICP. Total numbers have been used to reflect the number of patients entering into the service with faecal incontinence.

Figure 5: Trend of Pelvic Floor Consultant New Patient Referrals: August 2011-July 2013.



When comparing the total number of new referrals to the pelvic floor consultants they have increased year-on-year (figure 5). The number of GP referrals into the service also increased during the same period. The data came from the health informatics department at the hospital trust, which is based on the process of medical coding (228). Medical coding is a process where a particular diagnosis or reason for a patient's hospital attendance is identified and attributed a code, often so that a hospital trust can claim payment for that patients care. Medical coding can be a complex process within hospital trusts and can be inaccurate but is often the only recorded data available.

Figure 6: Trend of Referrals to the BFNS for FI Patients-August 2010-July 2012

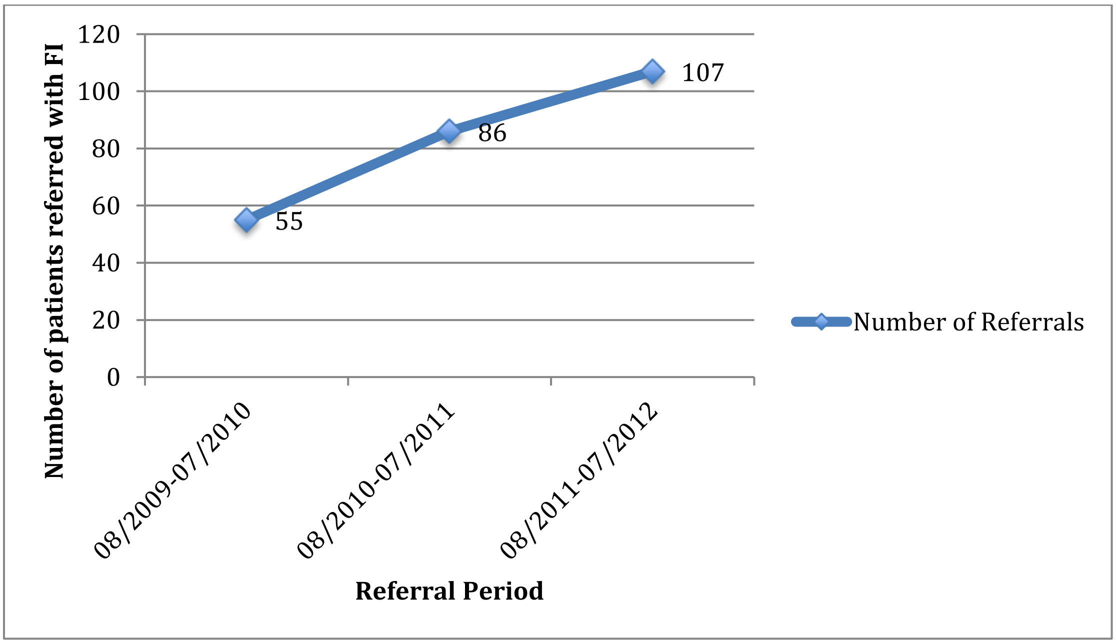


Figure 7: Source of Referral to BFNS via Traditional Pathway: August 2011- July 2012

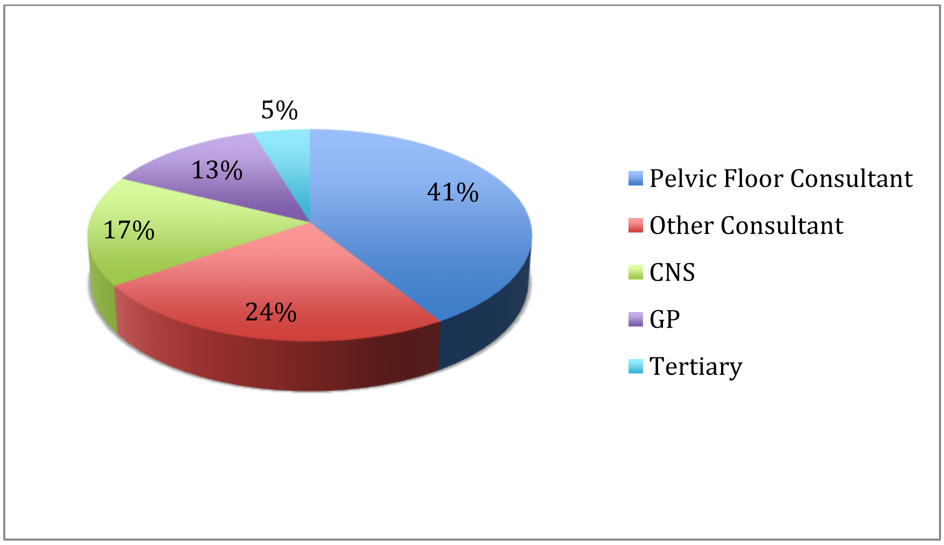


Figure 8: Source of referral to ICP: September 2012- July 2013.

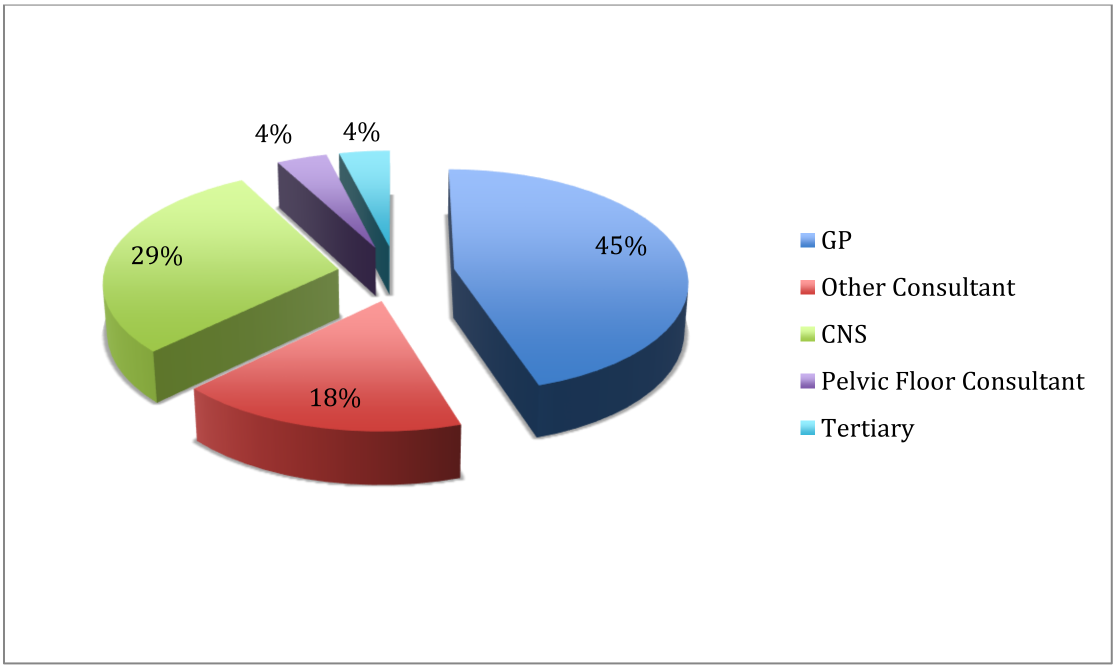
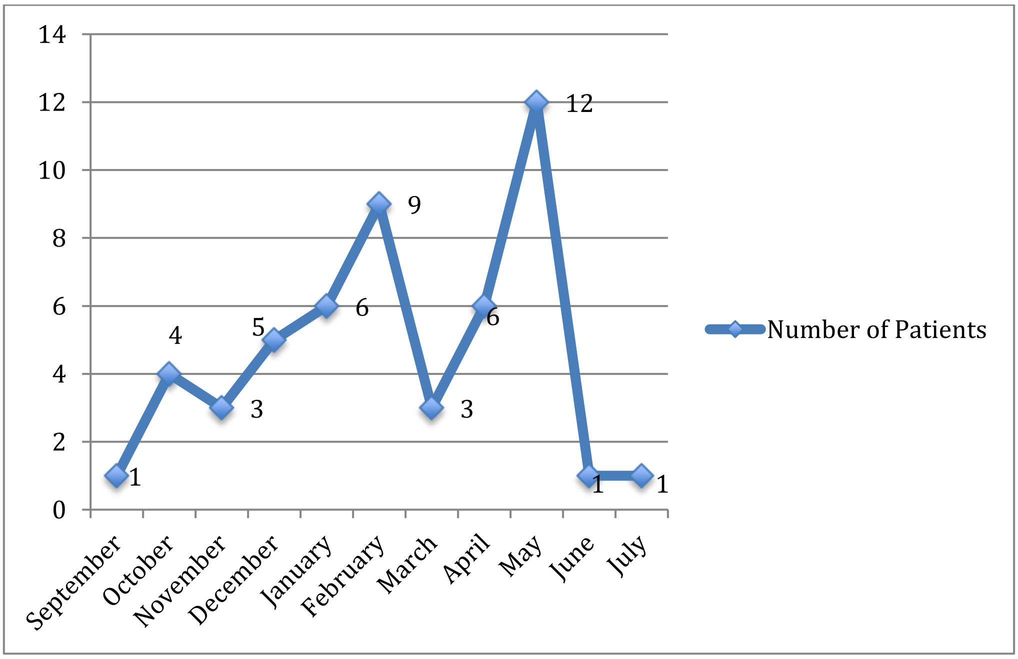


Figure 6 shows the trend in referrals to the BFNS of patients with FI. There is a year-on-year increase of 36% from the period of 2009-2010 to 2010-2011, with a 20% increase in the period of 2010-2011 to 2011-2012. The number of referrals into the ICP from September 2012 to July 2013 was 51. This is most likely to represent a drop in referrals of patients with FI in the preceding year. However there may be confounding factors associated with this.

If the source of referral prior to and following the implementation of the ICP is reviewed, it is evident that there are some changes in the pattern of who is referring into the service (figures 7 and 8). GP referrals increased along with colorectal nurse specialist (CNS) referrals. This is due to both groups having increased knowledge of the service and the ICP through promotion strategy from the ICP team. As expected the number of pelvic floor consultant referrals have decreased dramatically as they are now not the first contact with the patient. From a tertiary referral point of view the numbers have remained static. This was not what the team had in mind originally as they felt that this would increase. In-hospital consultant referrals have decreased slightly.

Figure 9: Monthly Trends of Referrals Post-ICP Implementation



When evaluating the number of referrals per month since the implementation of the ICP (figure 9) it is evident that there have been peaks and troughs associated with the number of referrals. The main reason for this is the lack of promotion of the ICP to the GPs and the engagement of this health professional group. This was alluded to in the interviews, by the consultants and BFNS as one of the main barriers as to why referrals had been relatively low.

Figure 10: Pathway Patients were triaged into.

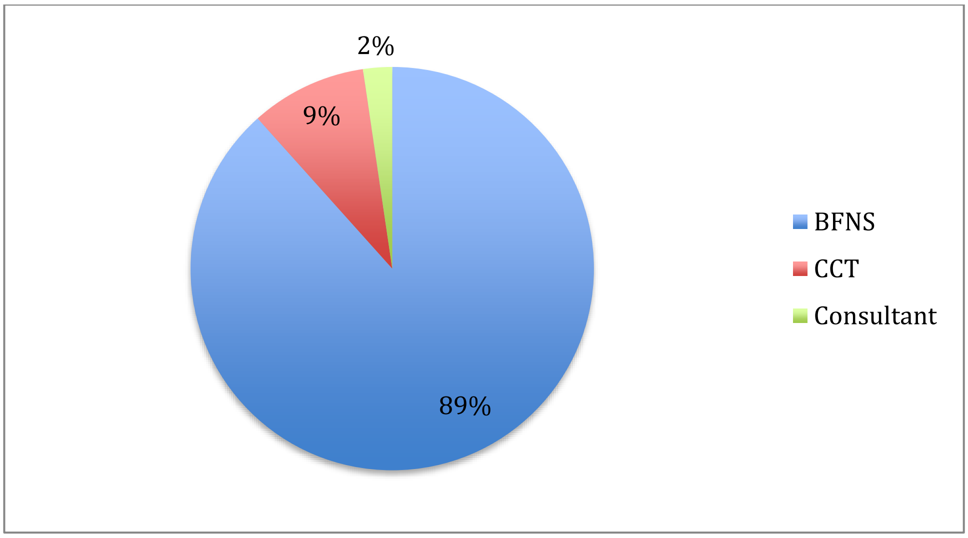
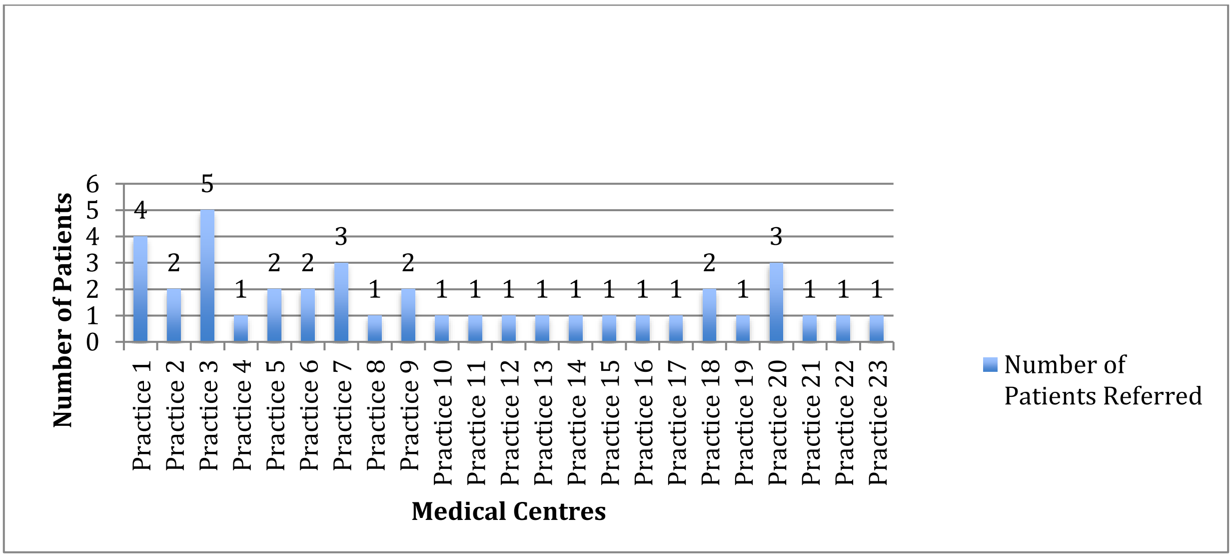


Figure 11: Source of GP referrals into the ICP

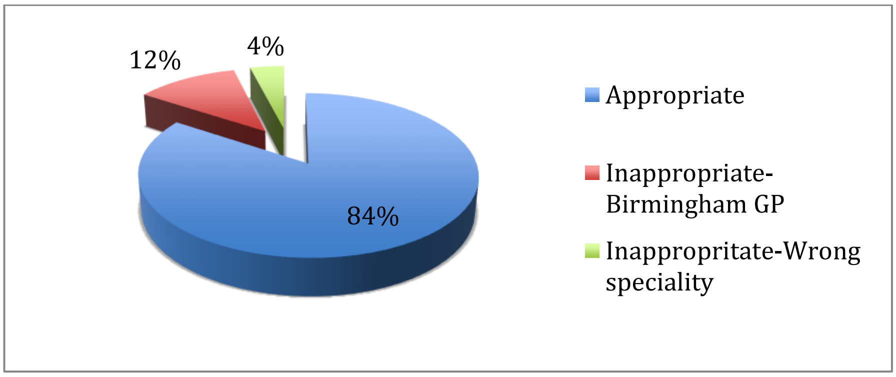


The majority of patients were triaged into the BFNS element of the pathway, an expected outcome (figure 10). A small proportion of patients were triaged to the SCCT and even smaller proportion to the consultants.

Figure 11 shows the source of the GP referrals. This graph highlights that there is a spread of GPs who are aware of the service within the Sandwell region and that nine out of twenty-three practices had referred more than one patient.

Not all referrals were appropriate for the ICP. Figure 12 shows the proportion of these inappropriate referrals and the reason why. At the time of writing, although expansion into West Birmingham was planned, patients with Birmingham GPs could not be referred directly into the ICP. The fact that Birmingham GPs were referring into the service does show promise for the team's future plans.

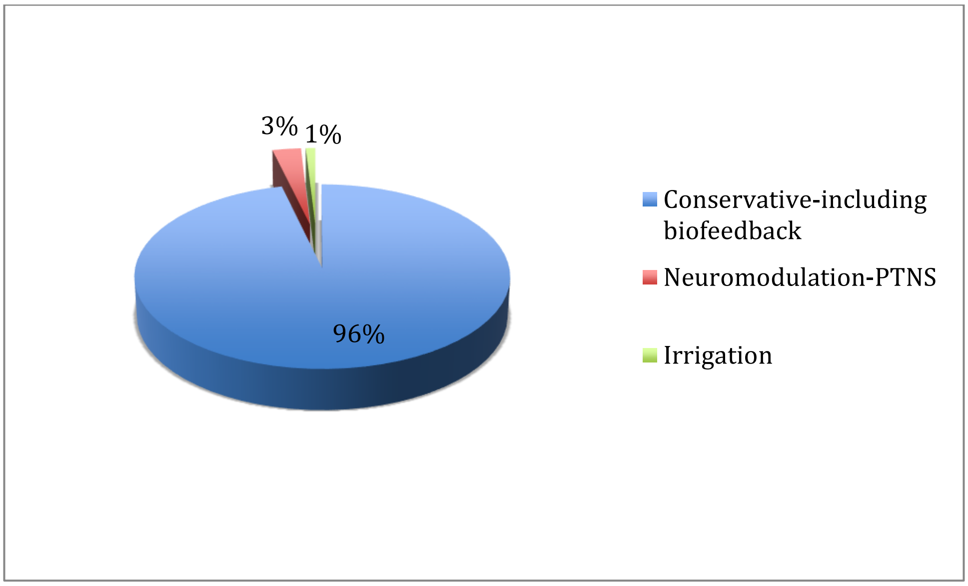
Figure 12: Appropriateness of Referrals



Patient Reported Outcome Measures

It is difficult to compare elements of treatment due to the low number of patients in the ICP group who had completed management. Figure 13 shows the management strategies used for the patients referred into the service from August 2011 to July 2012. This shows that the majority of management was conservative techniques such as pelvic floor muscle exercises and biofeedback. The need for neuromodulation and rectal irrigation was low. The difficulty at this point in trying to compare is that only seven patients had completed treatment and been discharged from the ICP and the majority of patients were still in the initial stages of treatment and had not been discharged. The seven patients who had been discharged only required conservative management techniques.

Figure 13: FI Management Strategies: August 2011-July 2012



Patient Outcomes: Symptom severity scoring and quality of life outcome measures

Tables 15 to 17 show the outcomes for patients in the year prior to the implementation of the ICP and those who have completed treatment within the ICP. As mentioned before only seven patients had completed the ICP therefore we would not be able to compare directly the outcomes. What can be described from this data is that patients who were managed by the service prior to the ICP and following the introduction of the ICP had improved outcomes.

Table 15: Symptom Severity Scoring: Comparison of Patients with FI August 2011-July 2012 and ICP Patients.

Outcome Measure	Pre-ICP: August 2011-July 2012 (143 patients)	Post-ICP Patients (7 patients)
Bowel Frequency/day, n		

Mean +/-SEM		
Pre-treatment	3.8 +/- 0.5	6.7 +/-2.7
Post-treatment	1.8+/-0.2	1.6 +/-0.5
P value	<0.001	<0.071
Deferment time, minutes **Mean +/- SEM**		
Pre-treatment	5.2 +/-1.0	13.2 +/-5.9
Post-treatment	12.1 +/-1.7	19.3 +/-5.1
P value	<0.002	<0.18
Incontinent Episodes per week **Mean +/- SEM**		
Pre-treatment	3.6 +/-0.7	0.6 +/-0.2
Post-treatment	0.4 +/-0.2	0.0 +/-0.0
P value	<0.001	<0.03
Leakages per week **Mean +/- SEM**		
Pre-treatment	4.4 +/-0.4	1.0 +/-0.0
Post-	0.5+/- 0.1	0.3 +/-0.2

treatment		
P value	<0.001	<0.008
Wexner Incontinence Score **Mean +/- SEM**		
Pre-treatment	8.00 +/-0.5	19.0 +/-9.3
Post-treatment	5.2 +/-0.4	8.0 +/-3.4
P value	<0.001	<0.024
FIQOL **Mean +/- SEM**		
Pre-treatment	63.0 +/-12.2	79.0 +/-50.6
Post-treatment	107.0 +/-10.6	109.0 +/-85.6
P value	<0.001	<0.021

Table 15 shows a comparison of pre and post-treatment (conservative management only) results for patients managed before and after the implementation of the ICP. Patient symptoms (bowel frequency, deferment time, incontinent episodes and leakages) improved in both groups, with statistically significant improvements in all patient symptoms in the pre-ICP group. Statistically significant improvements were seen in two of the symptoms in the post-ICP group (incontinent episodes and leakages), with the other two symptoms showing improvements. If we compare the mean pre-treatment figures of each symptom we can see that although from a bowel frequency point of view the post-ICP group seem more severe, the other three symptoms do not follow this pattern as the pre-ICP group's symptoms were seemingly more severe. When considering the symptom severity scoring and quality of life outcomes (Wexner (222), FIQOL (223)) both groups had significant improvements. The Wexner score (222) was higher in the post-ICP group, meaning that the patients' symptoms were deemed to be more severe in this symptom severity score (a higher score means more severe symptoms). However, the FIQOL (223) score was lower in the pre-ICP group implying that the patients' symptoms were more severe in this group, as the lower the score the worse the patient's quality of life.

When considering the principle of severity of these patients, it is not straightforward. Some of the pre-treatment scores suggest one group is more severe than the other, but then other scores contradict this. There was no screening or selection bias of the patients referred into the ICP as referrals were accepted and triaged appropriately. One reason why some of the scores in the post-ICP group are markedly different to the pre-ICP group may be due to the lack of patient numbers in this group, which may skew the data slightly. This could be improved by running further analysis when more patients have been through the ICP and have post-treatment results. The lack of post-ICP patient numbers may also account for the fact that despite a large improvement in patients' symptoms (bowel frequency/ deferment time) they were not statistically significant.

Table 16: SF-36 Quality of Life Outcomes: 143 Pre- ICP Patients with FI August 2011-July 2012.

SF-36 Domain	*Mean Pre-Treatment Score (+/-SEM)*	*Mean Post-Treatment Score (+/-SEM)*	*P value*
Physical Functioning	52.88 (+/-4.81)	61.63 (+/-4.94)	P<0.001
Role- Physical	51.42 (+/-5.02)	60.75(+/-4.67)	P<0.005
Bodily Pain	56.6 (+/-5.16)	64.9 (+/-4.83)	P<0.006
General Health	45.25 (+/-3.49)	53.38 (+/-3.54)	P<0.001
Vitality	34.18 (+/-3.70)	48.1 (+/-3.63)	P<0.001
Social Functioning	56.73 (+/-5.41)	64.75 (+/-4.97)	P<0.073
Role- Emotional	51.88 (+/-5.19)	62.88 (+/-4.21)	P<0.002
Mental Health	52.63 (+/-4.19)	59.88 (+/-3.57)	P<0.007
Health Transition	39.50 (+/-3.65)	67.38 (+/-4.21)	P<0.001
GI Symptoms	50.08 (+/-2.17)	58.73 (+/-1.65)	P<0.001
Physical Wellbeing	13.85 (+/-1.09)	16.15 (+/-0.99)	P<0.001
Social	12.65 (+/-0.84)	14.40 (+/-0.77)	P<0.001
Mental Wellbeing	9.88 (+/-0.77)	12.25 (+/-0.67)	P<0.001

Table 17: SF-36 Quality of Life Outcomes: 7 Post-ICP Implementation Patients

SF-36 Domain	*Mean Pre-Treatment Score (+/-SEM)*	*Mean Post-Treatment Score (+/-SEM)*	*P value*
Physical Functioning	40.0 (+/-8.2)	51.4 (+/-10.7)	P<0.034
Role- Physical	31.9 (+/-9.7)	52.3(+/-11.0)	P<0.071
Bodily Pain	31.6 (+/-8.4)	67.3 (+/-12.8)	P<0.034
General Health	26.4 (+/-4.3)	45.0 (+/-8.2)	P<0.093
Vitality	26.3 (+/-3.6)	46.1 (+/-10.4)	P<0.075
Social Functioning	34.6 (+/-7.9)	64.1 (+/-14.1)	P<0.092
Role- Emotional	27.7 (+/-6.0)	73.7 (+/-10.8)	P<0.017
Mental Health	50.7 (+/-10.8)	75.0 (+/-8.6)	P<0.084
Health Transition	28.60 (+/-6.5)	61.4 (+/-9.4)	P<0.047
GI Symptoms	36.5 (+/-6.9)	62.3 (+/-10.9)	P<0.043
Physical Wellbeing	11.54 (+/-3.09)	15.02 (+/-2.99)	P<0.097
Social	14.21 (+/-1.94)	16.20 (+/-2.51)	P<0.082
Mental Wellbeing	8.98 (+/-2.77)	11.29 (+/-2.67)	P<0.061

Tables 16 and 17 show the quality of life outcome measures from the SF-36 tool (224) for the pre and post-ICP implementation groups. The lower the score, the worse the patient's quality of life is within that domain. In both groups all domains improved, with all but one improving significantly in the pre-ICP group. Despite showing marked improvements in the mean scores only five out of the thirteen domains improved significantly in the post-ICP group. Once again, this is most likely due to the lack of patients in this group.

The quantitative element of the study does confirm some of the perceived advantages reported in the interview data within the communal appraisal construct.

Throughout chapters four and five there have been a number of key findings identified with regards to the barriers and facilitators of implementing an ICP for FI, including:

- Change management
- Leadership
- Shared purpose and staff commitment
- Teamwork
- Capacity
- Clinical outcomes

In the following chapter, chapter six, these barriers and facilitators will be highlighted with reference to the earlier literature review, whilst also identifying other key findings and weaknesses within the study.

CHAPTER 6: DISCUSSION

A community-based ICP for the management of patients with FI was implemented within a local NHS trust. The main aim of this ICP was to improve the patient pathway to avoid the long-standing problems that patients with FI face when attempting to obtain medical help for their symptoms. The key components of the ICP included a defined patient referral and triage pathway alongside a change in the location of care, being primarily in the community setting. The ICP was implemented successfully, albeit with a delay, and by the conclusion of the study was beginning to see an increase in referrals. However the implementation was not an entirely smooth process. This discussion chapter will focus on whether the aims and objectives of the study were met, followed by a brief statement of the main findings and their importance. These main findings will then be discussed in detail in relation to the existing literature that has been discussed in the literature review, alongside the impact of the ICP on the widely reported deficiencies in continence care (6,11,33). The use of NPT within the study has been described previously but within this chapter the usefulness of the theory during the analysis of the results will be discussed. Towards the latter end of the chapter the strengths and limitations of the study will be discussed, as will a critical reflection on what has been normalized and why? To complete the thesis, conclusions and suggestions for future research and implications for practice will be described.

Aims and Objectives

The aim of the study was to answer the research questions posed at the beginning of the process using a mixed methods research methodology:

1. *What are the facilitators or barriers to the implementation of an integrated care pathway for FI at a local and organisational level*
2. *How do these affect the key stakeholders (including patients) involved in the process?*
3. *How does the introduction of the ICP affect clinical outcomes and referral rates?*

In relation to the three research questions posed, six main elements emerged from the study allowing answers to be provided for each question. The main elements are change management, leadership, shared purpose and staff commitment, teamwork, capacity and patient outcomes (including referral rates); they will each be discussed in greater detail within this chapter. In relation to research question number one, all six elements described help to answer this question as all of these elements provide either a facilitator or barrier (or both) to the implementation of the ICP. Facilitators included effective clinical leadership, a true, shared sense of purpose, commitment and teamwork between all members of the continence team and effective change management. Barriers to the implementation included a lack of organisational leadership, a lack of capacity related to stakeholder time to set up and implement the ICP and an initial lack of referrals. Research question two is also answered by all of the six elements described above as each facilitator or barrier impacted upon the key stakeholders involved in the implementation process. The third research question is answered by the element of patient outcomes and describes the fact that no changes were identified in the clinical outcomes of patients and that referral rates had increased following promotional work around the service. All three of the above research questions have been answered and therefore the aims of this study have been achieved.

Importance of Findings

The importance of these findings lies in the fact that the ICP for FI, that was the focus of the study, was the first of its kind within the United Kingdom. Therefore the results of this study are unique to this setting and healthcare problem, potentially allowing other healthcare providers considering the introduction of an ICP for FI to take heed of the lessons learnt and apply them to their own implementation process. Given the relative standardisation (or perhaps limitation) of FI management in the United Kingdom, there is also a generalisable element to these findings that could be useful for further ICP implementation.

Change Management

When considering the process of change that occurred during the study, the observational and interview data describes how the changes affected the staff involved within the service. This data can be applied to Kotter's 8-step change model (81) that identifies the steps that are required for leading change. This model is useful to understand change, however it is a linear change model. Whilst, this is not generally appropriate when managing change in the NHS, when attempting to describe change that has happened it is a useful tool. The eight steps and their relevance within this study are now described.

'Create urgency'**:** By the time the study had commenced there was already a sense of urgency around the reason for changing to the ICP. The sense of urgency was shared by all of the members of the service at the first round of interviews and there was clear "buy in" from the organisational management perspective. The fact that this urgency had been created was crucial as this laid the foundations for the rest of the change process. 'Form a powerful coalition’: Initially there was visible support from the DDM but following a change in personnel in that role this support declined. The reasons behind this have been discussed previously. One area whereby visible support did not decline was from the lead clinicians within the service itself. This continued support from the consultants and lead BFNS ensured that the other members within the team were convinced that the change was necessary. The continued engagement of these key individuals also seemed to maintain the initial momentum throughout the change process. ‘Create a vision for change’: The overall vision that was developed initially with regards to improving the patient journey and the potential benefits of the ICP was maintained throughout. This consistent message allowed everyone involved in the process to be able to understand why the change was necessary. This shared sense of purpose was helpful in ensuring that instructions given by the leads in the service were followed effectively. ‘Communicate the vision’: The ability to communicate the vision of the ICP was taken at every opportunity, especially at the monthly ICP meetings. This was where any problems with the implementation could be ironed out but also the lead members of the service constantly reinforced the overall vision and purpose of the ICP. Having this forum whereby any concerns or anxieties could be discussed and then addressed, was of benefit to all members of the service. There was also informal communication via e-mail or chance meetings whereby any issues could be discussed and addressed. This was of great benefit to the service as communication between the team was open, honest and was not having to be fixed into a rigid slot within a meeting time. The fact that the communication between the team was of good quality, helped to reduce any further delays in implementation. ‘Remove obstacles’: When considering the obstacles that the team faced when attempting to implement the ICP the barriers (as described above) need to be considered. It was at this point whereby the shared sense of purpose of the ICP was of major benefit. Despite the obstacles or barriers that were encountered the team as a whole, discussed and addressed these obstacles allowing them to be removed from their path. These obstacles did delay the implementation, but overall momentum was maintained throughout the change process. At no point did any of the team members appear to be affected by the appearance of obstacles, with the team actually seeming to thrive on finding ways around these obstacles. ‘Create short-term wins’: This was one of the more difficult steps to achieve, as the only real goal of the team was to implement the ICP. This was seen more as a long-term goal rather than a short-term goal. The lack of a short-term goal did not seem to hinder the motivation of the staff in implementing the ICP. Whether it would have had an impact on the implementation process is difficult to ascertain.

‘Build on the change’: Kotter (81) stated that to achieve long-term change every success should be built upon with an evaluation of facilitators and barriers to the change leading to continuous improvement. The team were aware of the facilitators and barriers with regards to the implementation of the ICP. Interestingly, the team continued to build upon the implementation of the ICP by announcing their intention to expand the ICP into local surrounding areas involving different CCGs and hospital trusts. This shows the team’s intent to continue to build upon the change and develop it further in the future. ‘Anchor the changes’: Attempting to ensure that the change, in this case the ICP, becomes embedded in the organisation would require continuous efforts from the key players within the organisation. From a clinical perspective this was certainly the case throughout the study. However, the lack of management engagement within the organisation could potentially put the anchoring of changes at risk.

Overall, the implementation appeared to have been managed appropriately, which was certainly a facilitator to the implementation process. There are always improvements that could be made but given the barriers that the team faced the implementation should be deemed a success. When considering the change management theory of Kotter (81), seven out of the eight steps were completed during this implementation process.

Leadership

Clinical leadership was evident throughout the study. From both rounds of interviews and the observational data, the key person who was driving and leading the process was the lead consultant for the service. In the majority of interviews this person was named as the originator and key driver for the implementation of the ICP. The lead consultant was always present at the ICP meetings ensuring that progress was being made at each stage of the implementation process. This allowed the lead consultant to make key decisions following discussion with the other team members; therefore keeping them involved and active throughout the process. Any questions or issues that needed to be raised were always welcomed by this individual as the mindset was that if an issue was known about soon enough then steps could be taken to rectify it and reduce any further delays. This system seemed to work very well with the added benefit of individuals being given tasks to action prior to the next meeting. It is through this process that key elements of the ICP, such as the evidence base behind the pathway and measurement of clinical outcomes, were decided upon by a consensus opinion. Other key members who displayed leadership characteristics included the lead BFNS and the other consultant involved within the service, but certainly to a lesser degree than the lead consultant. Change is often disruptive and complicated with events rarely occurring exactly as people predict. The role of a leader within an organisation is to create, design and maintain a climate for change within the organisation (93). Although participation of all players is necessary, the role of a clear leader in the change process is crucial- this was present in the study in the form of the lead consultant. This was a definite facilitator for the implementation of the ICP.

The "champions of change" need to be the top management players within the organisation who keep the change process moving whilst maintaining the operational integrity of the organisation. With regard to the proposition that "champions of change" should be the top management players (93), this was a key finding within the study. The lack of organisational management involvement was evident throughout the study from an observational perspective. It was also clear from the second round of interviews that this was the case, but potential reasons why were offered by a number of participants, mainly around the fact that the service was not seen as a management priority. The DDM in place at the second round of interviews had not been involved with the process as much as they or the pelvic floor team would have liked. The lack of attendance at meetings and general lack of input into the service in general meant that delays occurred. Multiple meetings would pass whereby the same topic would be on the agenda, but questions or issues would remain unanswered, despite the team's best efforts to engage with the management. Even the presence of the second pelvic floor consultant, who also held the role of clinical director within the Trust, was not enough to garner any obvious support from the DDM. This issue hampered progress through governance and from a promotional point of view, as approval was always needed from the DDM before progressing to the next step. This lack of prioritisation was mainly due to the fact that there were more pressing acute concerns i.e. bed capacity issues within the trust, which the DDM needed to attend to. The DDM was very open and honest about this fact and did not attempt to deflect away from this. Both the DDM and the consultants identified that other more pressing general hospital issues tend to take over the workload and attention of the DDM. Organisational leadership was lacking and was a barrier to the implementation of the ICP.

The lead consultant displayed a number of different leadership styles during the implementation process. Goleman (108) identified six different leadership styles and believes that good leaders will adopt one of these six styles to meet the needs of different situations. Goleman (108) links these leadership styles to their effect upon organisational climate and describes ways in which the various styles can be effective or ineffective in different situations. Key to Goleman's argument is that good leaders must be emotionally intelligent or sufficiently sensitive and interpersonally aware to know which styles to adopt in different situations. The six styles have been split into two groups where four of the styles are thought to encourage team harmony and inclusion whilst the other two styles can potentially create dissonances and discord. The four styles encouraging team harmony are visionary, coaching, affiliative, and democratic (108). The other two leadership styles are more directional and focus on the setting down of expectations: pacesetting, and commanding (108).

Throughout the implementation the most dominant leadership styles displayed by the lead consultant were visionary, coaching and democratic. This allowed the lead consultant to motivate the team initially, provide them with a clear direction whilst ensuring throughout the process that the team were committed and engaged. At times a pacesetting style was used to try to drive results and attain targets. All of the leadership styles, apart from commanding, were used throughout the process. Overall, clinical leadership was a consistent presence throughout and facilitated the implementation process. Organisational leadership however, was a completely different story.

Project management was a concept that was touched upon in the second round of interviews, when one of the staff participants stated that a way of improving the implementation process would be to recruit an “effective project manager”. The role of project manager was not performed formally by anyone throughout the duration of this study. This role seemed to be automatically assumed by the lead consultant, who, outwardly at least, was prepared to take this role on. However, the staff participant did have a point, especially with the fact that all staff members, including the lead consultant, were doing this in their “spare” time. Consultants do not have much “spare time” so the fact of taking this extra workload on should be applauded and clearly the potential to improve the service for patients remained a key driver for the lead consultant. Despite all of this however, the fact still remains that there was no dedicated project manager (who could dedicate specific time to the project) and this could have led to delays in the implementation. It is possible that a project manager would have been more effective than the lead consultant having to manage the implementation in their spare time.

The inclusion of an ICP facilitator is also deemed a critical factor for successful ICP implementation. An ICP facilitator should be able to (69,74,75) support clinical staff through the process of developing and implementing ICPs, understand change management theories, facilitate group work and work closely with clinical staff and help to move things forward and to make things easier using teambuilding skills and their knowledge of the project. No specific team member was given the formal role of the ICP facilitator. The lead consultant attempted to fulfill elements of this role during the implementation process, but this was difficult due to time restrictions with their other clinical commitments. This meant that despite the lead consultant’s best efforts they were unable to dedicate as much time as they would have wished to the implementation process. When the lead consultant was involved there was a real willingness to listen and be receptive to responses or concerns of clinical staff, which is a factor, reported to greatly facilitate the implementation of ICPs (74). The fact that the lead consultant had taken on the role of project manager and ICP facilitator with limited time resources indicates a potential barrier to the implementation. Within the interviews the lead consultant did acknowledge that due to clinical commitments they were unable to devote as much time as they would like to the implementation process.

Within the NHS, the healthcare leadership model (109) has been developed to help those who work in healthcare to become better leaders. This model aimed to help healthcare professionals understand how their leadership behaviours affect the culture and climate in which they and their team's work. This model is made up of nine ‘leadership dimensions’ (109). For each dimension, leadership behaviours are detailed on a four-part scale that ranges from essential to exemplary (109). According to the healthcare leadership model (109), all nine dimensions are important in an individual's leadership role. However, the type of job, the needs of the people within the team and the context of the leader’s role within the organisation will affect which dimension is most important to use and develop. None of the clinical team were involved with the NHS leadership academy at the time of the study, nor was this model referred to, despite organisational and clinical leadership being factors that are critical to the success of implementing an ICP (65,71–73), alongside effective project management and having an effective care pathway facilitator.

Shared purpose and staff commitment

There is no doubt that the team had a shared sense of purpose with regards to the ICP. This was evident from the first round of interviews right through to the completion of the study. Shared purpose is the 'alignment of the belief systems or values of a group of individuals with a clear challenge, vision for the goal' (112). The NHS change model (229) was created to support the NHS in adopting a shared approach to leading change and transformation. There are eight components in the model of which shared purpose is the central concept. To truly understand the phrase, shared purpose, a definition of purpose is required. Purpose is the why, not the what or the how of our working lives (114). It encompasses or touches upon a number of other concepts such as vision; values; goals; organisational culture and engagement but sits above all these. Purpose becomes shared when three things happen. Firstly, listening to and understanding others' perspectives, the second stage is the discovery of these perspectives overlapping with our own. The third step is when an agreement is reached on how to translate these shared perspectives into action towards a common goal. Strong shared purpose is a common thread in successful change programmes (230). All three steps that are required for the facilitation of shared purpose were identified in this study.

The team members were involved from the beginning of the development of the ICP. It was at this point that all members were allowed to express their opinions on issues within the service alongside ways in which they could be improved. These meetings were free from any hierarchical influence and allowed the team to look for commonalities in their ambitions and goals for the service. Following this they had the opportunity to design the structure of the service as a group. During this process the shared purpose was created. It was maintained throughout the implementation due to the fact that all the team members had agreed on why the ICP needed to be implemented at the beginning of the process. The question of ‘how does this support our shared purpose?’ was asked a number of times during the implementation process when guidance over a difficult decision was needed. This would generally be at one of the ICP meetings whereby all team members could share their thoughts on the situation and arrive at a group consensus. The implementation process only plateaued at one stage, where governance issues were preventing the ICP from progressing. It would have been easy for the process to fail at this point but due to the shared purpose being revisited at each meeting during this frustrating time, this allowed the team to continue and complete the implementation. There was no sign of wavering commitment from any member of the team throughout the process, due to their shared belief that care for patients with FI needed to be improved and that the ICP was the best way of doing this. All members of the team were aiming to produce a “better patient journey” which in its ideal form would reduce any delays in patients seeking help and gaining access to the appropriate services, rather than being referred to inappropriate medical specialties. This shared purpose was a key facilitator to the implementation of the ICP as without it the implementation process could possibly have been delayed further, if implemented at all.

Whilst shared purpose was a key facilitator, staff commitment was also a facilitator. As has been mentioned previously, the lead consultant for the service took on the role of project manager and ICP facilitator. This required a great deal of commitment from the lead consultant as they had planned clinical obligations to uphold and therefore adding these roles to their already busy schedule required a great deal of commitment. Not only did this apply to the lead consultant but also the other team members whose spare time was also very limited yet at no point during the observational period did any single individual complain or use lack of time as an excuse, again reinforcing the whole team’s commitment to the ICP. Staff commitment and their shared sense of purpose were key facilitators but the next element to be considered is teamwork.

Teamwork

Teamwork was evident throughout the implementation process. From the beginning it was clear that the consultants and the BFNS had been working together for a number of years. Their interaction from an observational perspective was often clear, concise and consistent. Working as part of the team is a critical success factor when implementing any form of organisational change. During times of change the strength of the team will be tested and being able to maintain the strong bond of the team during periods of uncertainty could be the difference between success and failure. Within the literature there is a broad consensus on what constitutes a team. Katzenbach and Smith (231) stated that “... a team is a small number of people with complementary skills who are committed to a common purpose, performance goals, and approach for which they hold themselves mutually accountable”. In addition, regular communication, coordination, distinctive roles, interdependent tasks and shared norms are important features (232,233).

All of the team members involved in the implementation, including the SCCT (who had previously been outside of the pathway), displayed a clear purpose with a clear defined aim. Despite the SCCT being within the same hospital trust as the pelvic floor dysfunction service at the beginning of the study they did not work in tandem. By the end of the study the SCCT were more integrated with the pelvic floor dysfunction service allowing the ICP to function as it was originally planned whereby referrals could pass seamlessly between the SCCT, BFNS and consultants if needed. Building this teamwork was key to the potential success of the ICP as without it issues may arise when attempting to manage/triage patients. By the second round of interviews the SCCT clinical lead felt that the team were now more involved within the service from a decision-making point of view although at the time of the completion of the study the number of referrals they were seeing was low.

Following guidance from the lead consultant all team members had clear roles and following the conclusion of each meeting were given specific tasks to perform prior to the next meeting based around the implementation process. Leadership has already been discussed, but from a clinical leadership perspective this was present throughout. One key aspect of the leadership shown in this process was the delegation of tasks to appropriate members within the team, which gave these members a sense of ownership within the implementation process. The team itself had a heterogeneous mix of healthcare professionals and management members. This should have been a facilitator but due to issues identified previously with organisational leadership, it was not as successful as the team envisaged. The lack of organisational leadership was one of the key factors as to why there was a delay in the implementation of the ICP. However taking the rest of the team into account there were adequate numbers and skill mix for the ICP to be implemented successfully. When considering the resources available to the team, there was no real problem in this regard. Financially, there seemed to be very few issues. This was mainly due to the fact that the service was already up and running but the pathway of care for patients with FI was changing and this would potentially bring more money into the service. From a training perspective, there were very few training issues related to the ICP for the staff. Two BFNS had been recruited during the study period. One as a permanent member of the team, with the second being recruited on a temporary basis to cover maternity lead of the original lead BFNS. The training of these two new members of staff was performed by the lead BFNS prior to commencing her maternity leave. The training seemed to proceed very smoothly with no issues being raised by the two new BFNS. More importantly perhaps, these BFNS were adequately trained to continue the service when the lead BFNS went on maternity leave. As has been mentioned previously, the assessments and care given by the secondary care team did not change. One thing that did change was the triage process- giving more responsibility and autonomy to the BFNS. This responsibility was welcomed and despite there not being any specific guidelines for the BFNS to follow when triaging there was always support, certainly in the initial stages, from the consultants within the service. In contrast, from a SCCT perspective training needs were identified with respect to assessment tools and further management techniques, such as neuromodulation. Despite repeated discussions regarding this matter, no training sessions had been arranged by the time of the second round of interviews. The differing assessment tools being used were key to the ongoing audit of clinical outcomes, therefore it was vital to ensure that all staff members were familiar with the tools and were aware of how to use them, otherwise the process of auditing the ICP would fail. With regards to the training of neuromodulation techniques- this was not as urgent because the secondary care team were able to manage the workload easily from this point of view.

Teams are often viewed as a three-stage system where they utilise resources (input), maintain internal processes (throughput) and produce specific products (output). The most commonly described structural characteristics of an effective team are: clear purpose, appropriate culture, specified task, distinct roles, suitable leadership, relevant members and adequate resources, all of which were identified within this study. The characteristic of ‘clear purpose’ is described by organisations having a clear vision that encompasses their underlying values (131), and agreeing upon goals often being achieved through a common commitment to patients' needs (132,133). The clear purpose in this study was aiming to improve the patient journey. With regards to 'appropriate culture', teams should be recognised and integrated within their organisations (134), whilst organisational culture must transform shared values into behavioural norms (135,234). The recognition of the pelvic floor dysfunction service within the organisation was already in place, the key point here was the integration of the SCCT into the ICP. If a team is given a 'specified task' then that task needs to make a tangible contribution to the organisation and be consistent with the team's purpose, abilities and attitudes. The tasks also need to be sufficiently motivating for team members to share responsibility and accountability for achievement (235). All tasks given to members within the team were consistent with the required outcome and the motivation was gained by attempting to achieve this outcome. Healthcare teams need to clearly define the specific aspect of complex and inter-related patient care which they address (138). Within a team, 'distinct roles' need to be clarified and understood by all. However, role construction can be influenced by personal expectations, and by organisational and interpersonal factors (139) . Therefore, roles need to be flexible enough to accommodate individual differences, personal development needs and membership changes (135). Roles were already in place prior to commencement of the study and did not change throughout, although personnel did change. The more complex and dynamic the team's task, the more a leader is needed. 'Suitable leadership' should reflect the team's stage of development. Leaders need to maintain a strategic focus to support the organisation's vision, facilitate goal setting, educate, and evaluate achievements (140,236). When leaders delegate responsibility appropriately, team members become more confident and autonomous in their work (130). Clinical leadership was evident throughout the implementation. Teams require the right number of members with the appropriate mix and diversity of task and interpersonal skills- ‘relevant members’. A balance between homogeneity and heterogeneity of members’ skills, interests and backgrounds is preferred (141). West (131) emphasised that organisations need to provide teams with adequate financial resources, administrative and technical support and professional education, described as the ‘adequate resources’ characteristic. In healthcare environments, there may be conflict between clinical responsibilities and training needs, and over issues of patient risk and privacy (141). No financial details were disclosed during the study but there was an appropriate mix of clinical staff for the service provided, with no obvious constraints to the service.

Overall, the teamwork displayed during the implementation process was without doubt a facilitator. The five dysfunctions described by Lencioni (237) were not evident during the study. There was a clear element of trust between the team members potentially from previous working relationships prior to the commencement of the study. There were no signs of conflict in spite of the introduction of a new part of the pathway involving the SCCT, which could have created animosity if people thought their area of work could be threatened. Both trust and the lack of conflict may also have developed from the fact that the team were encouraged by the lead consultant to speak open and honestly at every meeting to ensure that all problems had been discussed and the plan of action put in place. At no point was any team member made to feel that they had spoken out of turn or that they could not express their thoughts in the group meetings. From an accountability and failure to focus on results perspective the lead consultant ensured that the team were focusing on the outcome needed (implementing the ICP). This focus was mainly around the sense of shared purpose that the team had developed from the very beginning of the implementation process. This never wavered and therefore the lead consultant only needed to reinforce the shared purpose to ensure that the team remained focused. Staff commitment has been discussed above and a lack of commitment was not evident at any stage during the process even when barriers were faced. When barriers did occur, the team would work even harder to ensure that they were overcome and that the ICP implementation process would continue to progress.

A barrier to the implementation process was the lack of IT infrastructure at one of the local health centres, which did delay the implementation slightly due to the fact that this centre could not be used to see patients. This lack of infrastructure was described as the health centre having no computers and no internet access. This meant that only one local health centre was available to run a clinic from that had sufficient resources. The team identifying a new local health centre that had the required IT infrastructure quickly rectified this issue. This new health centre was identified by the SCCT in combination with the BFNS. This barrier was overcome by the use of teamwork between the clinical nursing staff. This is another example of how well the team members worked together to try to overcome any barriers during the implementation process.

Capacity

From the first round of interviews fears were raised of an increase in referrals that would lead to a lack of capacity from a nursing point of view. From the second round of interviews, observational data and quantitative data these fears were unfounded. The number of referrals remained relatively low and therefore capacity was not an issue. Despite the lead BFNS being on maternity leave the remaining two BFNS seemed to cope with the implementation of the

ICP whilst still maintaining the service as a whole, with no obvious effect on patient care, according to the second round of interviews. Waiting lists are often spoken about within the NHS and there has been a great deal of analysis which has indicated that most waiting lists are actually relatively stable, suggesting that the variation in waiting lists is due to changes in capacity and demand (146). Capacity is defined as the resources available to do work, for example number of pieces of equipment available multiplied by the hours of staff time available to run it (146). Demand is defined as all the request/referrals coming in from all sources and how many resources they need to be dealt with (146). Variation in capacity and demand is one of the main reasons why waiting lists develop and waiting times increase. When aiming to identify patient flow through a healthcare system, it is necessary to address the entire patient process, allowing identification of where the delays for patients are and how these can be resolved (146).

A much larger issue was faced when the ICP was implemented, namely the lack of referrals, i.e. demand. From the first round of interviews the main concern from the team was based around not rushing the implementation as it could open the “floodgates” for referrals. However this was not the case as the influx of referrals was not as large as expected. The team were very aware of this and very responsive to this factor. With the relative paucity of referrals, the decision was taken to garner GP engagement as well as increase promotional activity for the service. This could be described as a delayed action by the team as GP engagement was always likely to be a key factor in the success of the ICP. From the GP interviews it appears that FI is not a priority in their everyday work. They do not actively enquire about FI nor were the GPs aware of any service or pathway that was available for patients with FI. The fact that the team only started to engage the GPs following the implementation process meant that referrals remained low in the short term. The team did seek to rectify this by firstly contacting large GP practices within the local area and visiting them to present the ICP aims and structure. These meetings did produce a slight increase in referrals around December 2012, however this increase only lasted until February 2013 when referrals per month dropped from nine to three. Again, the team was responsive to this and realised that referrals had dropped off again and enlisted the help of the communications department within the hospital trust to provide some promotional strategies to help improve awareness of the service. These promotional strategies included the development of posters that were displayed within GP practices, the hospital trust and also in local community areas such as supermarkets. Alongside the development of posters, advertisements were published in the local newspapers, with further advertisements present in the hospital grounds and also on a plasma screen at a local council building where patients and commissioners were present. This promotional work did lead to an improvement in this referral numbers from April 2013 onwards but whether this will be sustained is difficult to say. It is probable that persistent efforts on the GP engagement and promotional front will be needed to ensure that referrals continue to increase and be sustained. Overall, the strategies that the team put in place to increase referrals did seem to work in the short term, although questions still remain over sustainability. The main conclusion arising from this is the fact that GP engagement and promotion are key factors in the successful implementation of a local ICP for FI.

When considering the issue of capacity one problem that became evident was the lack of time available to the staff members within the service who were involved in the implementation process. This is not directly related to capacity for patient care but nonetheless was a barrier in the implementation process. This was apparent from both the observational perspective and the second round of interviews. This is a key factor because if these staff members had more time the implementation process would more than likely have been quicker. However, the team attempted to implement the ICP as quickly as they could, given their time restrictions. Most of the staff alluded to this in the second round of interviews with the changes in job planning and organisational pressures being described as the main reason why their time was restricted. A very sensible solution to the problem was raised by one of the participants in the form of a project manager whose job it would be to ensure that the implementation process was completed at an appropriate time. It is difficult to say whether this would have changed the implementation process in this case, but logic would dictate that it would have had a positive effect.

Patients who had entered into the ICP stated that they had been reviewed promptly in the clinic, indicating that the waiting time for patients was deemed acceptable at that point in the study. Staff members within the service also indicated that waiting times were much improved from that both the ICP and general service perspective. However the fact that referrals into the ICP had been low must be taken into account at this point. How the demand for the service affects the capacity and therefore waiting lists remains unanswered.

Clinical Outcomes

From the first round of interviews outcomes for patients with FI (symptom improvement, symptom severity scoring and quality-of-life related outcomes) were very good prior to the implementation of the ICP. This data had been presented on a national and international basis. The fact that none of the management strategies were changing would infer that the patient outcomes would not change significantly following the implementation of the ICP. Only seven patients had been through the pathway and discharged by the time of completion of the quantitative element of the study, but early indications suggested that patient outcomes are comparable with those prior to the ICP being implemented. Basing a comparison on seven patients who had been through the ICP is statistically flawed. Alongside this quantitative data, the patient interviews also suggested that their outcomes were acceptable. A number of patients commented on how the service had improved their symptoms, which subsequently improved their quality of life. Staff members within the service also reported anecdotally that patients had complimented the service, mainly based around an improvement in quality-of-life and symptoms. This improvement in symptoms and quality-of-life should be regarded as a facilitator to the implementation and sustainability of the ICP. It gives the service a strong selling point to the patients, GPs and CCG's.

Does the new pathway resolve the deficiencies in continence care?

There has been a distinct change in the pathway for patients brought about by the ICP. This change was aimed at “streamlining the patient journey” so that patients were not referred inappropriately to multiple different services. The change in patient pathway has definitely occurred and the initial signs are that patients are being referred into the service promptly. However, the number of referrals into the service remains lower than the team expected. There are a number of reasons for this that will be explored shortly.

The fact that all three key stakeholder groups: pelvic floor team, GPs and patients, agreed that the ICP would benefit patients greatly was a key finding in this study. This was the main aim of the pelvic floor team from the very beginning of the study and this aim was maintained throughout the study. By the second round of interviews, the pelvic floor team expressed the belief that they were on the way to achieving this aim. Revisiting the reasons why an ICP or a change in patient pathway was originally thought to be required for patients suffering with FI and discussing whether they have been addressed is a key factor in the success of this ICP.

Despite the recommendations from various Government papers and NICE guidelines (6,11,33), the provision of services for patients suffering from FI has remained poor. Elements that have been identified in these documents and other studies include:

- Poorly developed services or lack of awareness of existing services amongst clinicians (19)
- Changes to working practices including increased workload for community health care professionals (18)
- Poor acknowledgement by sufferers of the problem, and lack of awareness that help is available (14–16)
- Lack of recognition of the problem by clinicians and/or awareness of new, more effective techniques (17)

By analysing these elements individually the ICP that has been implemented potentially helps to solve some of these issues. Firstly, this redesigned service is far from being poorly developed. There are currently no published examples of similar services elsewhere in the country. There have been great strides made since the initiation of the pelvic floor service in

2008 (not the ICP), where previously patients would have to travel to different hospitals for investigations and certain management techniques. The service that is available at present is a comprehensive service that still has room for improvement, by the service leads own admission, but is leading the way for FI management in this country. Although the pathway has changed, all assessment and management strategies remain unaltered. This service was already achieving good clinical outcomes for patients with FI and the early evidence is that these have been maintained at the very least.

The second change the ICP brought about was to move the location of care for the majority of patients into the community. However, this has not resulted in an increased workload for community healthcare professionals. The BFNS have taken control of the clinics within the community setting therefore not placing pressure on the already stretched community healthcare professionals.

The general lack of awareness from both healthcare professionals and patients has long been an issue for numerous reasons and was yet again evident within this study. Patient awareness has always been an issue and has been highlighted previously in the literature. FI is seen as an embarrassing condition, which means sufferers are reluctant to come forward. This was also identified in the study from the patient interviews. The fact that there are services available for patients does not seem to be well advertised. Therefore if patients aren't aware of the services they cannot access them. GPs although aware of the condition were reluctant to place too much emphasis on identifying patients as their workload with more common conditions was deemed to be more important. This highlights the fact that as much as people can try to promote the condition, healthcare professionals will always tend to rationalise their time and resources to the most common conditions. However, the GPs who were interviewed thought that the ICP was a very good idea for two reasons: moving patient care into the community and providing them with a good quality service for a difficult condition to manage. Interestingly, the GPs mentioned that they did not actively seek to identify patients with the condition and that although the ICP had raised awareness it probably wouldn't change their working practice.

The issue of raising awareness and promoting the service was something that only became apparent to the pelvic floor team’s strategy when referrals into the ICP were low in number. There had been discussions around how to promote the service prior to this but the key driver for pushing the promotion of the service was the initial lack of referrals. This certainly worked in the fact that referrals did increase following the promotion of the service. The key principle for the promotion was to raise awareness for the GPs and also to patients. GP awareness was raised via regular visits to GP practices discussing the benefits of the ICP and the referral pathway by the pelvic floor team. It was also at this point that the trust communications team was brought in to help with the promotion of the service. Their knowledge of how to promote services certainly helped to broaden the range of promotion strategies available to the team. These strategies included the design of a poster aimed at encouraging patients to disclose their symptoms to relevant healthcare professionals, so they could be referred into the service. These posters were placed in GP practices, local supermarkets and public toilets. Alongside the posters there was an advert taken out in one of the local newspapers, a pull-down stand in the reception of the hospital and an electronic advert at the local CCG building. All of these strategies were aimed at increasing the awareness of patients and GPs to FI, therefore trying to breakdown one of the long-standing barriers for FI services.

As alluded to in the introduction section of the thesis, since the study has been completed, two further government documents have been published:

- Faecal incontinence in adults. Quality standard 54. National institute for Health and clinical Excellence. 2014 (35).
- Excellence in Continence Care. NHS England. 2015 (36).

The publication of these documents highlights the significant fact that continence care and specifically FI care has not seen the improvements that the initial government documents (6,11,33) had hoped for. The fact that the more recent documents are still trying to address the same deficiencies in care means that the findings from this study are as relevant now as they were when the study was first conceived. To further demonstrate this point, if we take the five quality standards that the FI in adults (35) document details and relate them to the findings from this study in relation to the ICP then all five standards would be met.

Table 18: The five quality standards related to the study findings.

Standard	Description	Study Findings
1	Adults in high-risk groups for FI are asked in a sensitive way, at the time the risk factor is identified and then at times according to local care	*Through promotion of the new ICP, this subsequently raised awareness amongst the GPs with regards to the scale of the problem and*

	pathways, whether they have bowel control problems.	*from the interviews highlighted the fact that GPs needed to enquire more often about the symptom.*
2	Adults reporting bowel control problems are offered a full baseline assessment, which is carried out by healthcare professionals who do not assume that symptoms are caused by any existing conditions or disabilities.	*A baseline assessment was the first phase of the ICP once a patient had been referred to the service.*
3	Adults with FI and their carers are offered practical support, advice and a choice of appropriate products for coping with symptoms during the period of assessment and for as long as they experience episodes of FI.	*Upon their first visit to the service, both patients and carers were offered support with both telephone consultations and further appointments if necessary, being made available. Continence products were always available and the team, especially the BFNS, provided the majority of this*

		support.
4	Adults with FI have an initial management plan that covers any specific conditions causing the incontinence, and diet, bowel habit, toilet access and medication.	*Management plans were given to all patients following their initial assessment and included all aspects of conservative management.*
5	Adults who continue to experience episodes of FI after initial management are offered referral for specialised management.	*A clear pathway is present for referral into the pelvic floor dysfunction Consultant, with access to biofeedback, neuromodulation and ultimately surgical procedures.*

Normalization Process Theory- how useful was it?

NPT was used in this study to inform, guide and structure emerging interpretations, conclusions and recommendations from the qualitative data. Whilst being used in the interpretation element of this study, there were still three ways in which NPT could be used (within the interpretation element) (37): as an aide memoir, as a sensitising device, or as a structuring device. NPT provided a structuring device within this study, which gave the researcher the potential to develop more focused answers to the research question. However, it was never the intention to allow NPT to be prescriptive. Ensuring that any emerging concepts were included whether they fitted in to the concept of NPT or not, was essential. The researcher's awareness of this issue was high, and attempts were made to remain responsive and not disregard any emerging findings throughout the analytical process that did not necessarily fit in to the NPT core constructs.

Using NPT in the evaluation of the implementation process of an ICP for FI has not been published previously. Upon consideration of the results of the study, the NPT was supported by the qualitative data, as all four constructs (coherence, cognitive participation, collective action and reflexive monitoring) covered all aspects of the ICP implementation, based on the data collected and analysed. This was the case despite NPT not being used to formulate the research question and subsequent interview/observational data collection. Each of the core constructs were very useful in allowing the data to be analysed succinctly, with the combination of quantitative and qualitative methodology. Very little of the qualitative data collected fell outside of the NPT propositions or constructs. The only aspect that fell outside of the NPT constructs was the element of future progress for the ICP. This is in relation to the fact that the team were hoping to take this out to a wider geographical area. This did not sit within any of the constructs specifically. Therefore the element of future work (outside of appraisal) could be an area in which NPT can be developed. However, NPT does not claim to be a theory of everything and this element of flexibility is beneficial for researchers.

Each of the four core constructs provided at least one of the main elements described previously in this chapter. 'Coherence' identified the shared sense of purpose from the staff within the service as one of the main drivers for the implementation of the ICP. This shared sense of purpose was based on improving and streamlining the patient journey. 'Cognitive participation’ was the construct where this shared sense of purpose highlighted the team’s commitment to the ICP, but also highlighted the teamwork element involved in the implementation process. The third construct, ‘collective action’, identified leadership and capacity as key elements in the implementation of this particular ICP. Change management was evident throughout the process and could have been placed in any of the constructs but ‘reflexive monitoring’ was the construct within which change management could be identified primarily as being a vital part of a successful implementation process. From the summary of the findings of the study in relation to NPT, it is evident that the NPT model was suitable for being used as a structuring device for interpretations, conclusions and recommendations.

Challenge of using NPT

Applying NPT to the implementation of the ICP for FI allowed the identification of how the ICP had started to become embedded as a result of the pelvic floor dysfunction team members working individually and collectively to achieve this aim. One challenge with the use of NPT was the occasional difficulty in assigning data to just one category within the theory when it could have fitted into a number of categories. The approach taken in this study was to ensure that the data was captured in the most appropriate (as deemed by the researcher) construct. The key was to ensure that all data was used, rather than be left out due to not fitting precisely into a construct.

Strengths of the Study

The researcher tried to ensure that the study was as robust possible. The main strength of the study lies within the methodology. The amount of time devoted to the development of the study allowed the researcher to develop the methodology extensively, giving the study every possible chance of yielding valid, reliable and informative results. This not only applies to the application of mixed methodology but also the development of both the quantitative and qualitative methodology elements as the study progressed. One example of this is the iterative development of the semi-structured interview schedules, which allowed the researcher the best possible chance of obtaining as much information as possible during these interviews. Also the use of three types of qualitative data methodology that complemented each other allowed for a wide range of data collection from a qualitative perspective, further enhancing the reliability of the results. Using mixed methodology meant that the researcher could look at a wide variety of elements involved in implementing an ICP and whether the implementation was successful. The idea of combining quantitative and qualitative elements was based on trying to obtain the widest perspective on the ICP as possible, related to both patient outcomes and the implementation process. One of the main strengths is the fact that the methodology included observations, quantitative measurements and interviews at different time points, over an eighteen-month period. This allowed a large amount of wide-ranging data to be obtained. Also when reviewing the development of the themes for the core constructs within NPT (table 16), the fact that the researcher used mixed methods within their qualitative research (observational, interview and focus groups) was a major strength of the study. Without using those methods then certain themes would not have been identified e.g. themes within individual appraisal relied on observational data alone, in comparison to the themes within communal appraisal being identified by the second round of stakeholder interviews. Generally, there was a combination of qualitative methods that the themes were derived from but there is no doubting the study benefitted greatly from this mixed qualitative methodology.

The methodology was followed precisely and the researcher dealt with any issues that became apparent. For instance, at one stage the researcher was struggling to recruit GPs despite having made letter and verbal contact via telephone. Having analysed the situation the researcher decided to contact the practice managers and try to arrange a meeting with GPs to discuss the study and see whether they would agree to participate. This did work and GPs were recruited. The strength here lies in the fact that the methodology was robust and if problems were encountered these were dealt with in an efficient and timely manner.

From a methodological perspective, the fact that the researcher was able to interview all members involved within the pelvic floor dysfunction service and the SCCT, was a strength as it allowed the researcher to get the views of all the staff members involved within the service both prior to and following the implementation of the ICP. This could not be improved, as there were no more staff members to interview. The researcher’s existing knowledge of quantitative data collection and analysis was an advantage in the study as this allowed easy identification of what information would need to be collected from the start of the study. The fact that there was prior experience of quantitative data analysis also meant that all quantitative data could be collected and analysed in a robust and reliable manner. Despite being a novice qualitative researcher, the researcher attempted to ensure that they developed qualitative skills that would allow valuable qualitative findings to be obtained. If anything this turned out to be a strength of the study, as the inexperience with qualitative research meant that throughout the whole of the study, rigour was at the forefront of the researcher’s efforts. The researcher ensured that not only the methodology but also that the analysis was both rigorous and thorough. This was achieved by critical reflection by the researcher at every point in the study. One example of this was the researcher ensuring that all interview schedules were constantly developed following each interview. This was essential as it ensured as much data as possible was identified from the interviews. Without this iterative approach, vital data may not have been collected. From the analysis perspective, an example is that of multiple versions of the analytical framework being produced due to new codes/themes emerging. The researcher was acutely aware that the analytical framework was never complete until the last transcript was indexed using it, ensuring no data was excluded.

Another strength of the study is that the researcher started with no preconceived ideas of what the results would or could show. This is vital in qualitative research, as the researcher has to remain open and aware to any emerging themes (218). The fact that the researcher had very little experience in FI care and ICPs, both separately and in conjunction, meant that all of the findings were from the research alone and not from any preconceived knowledge or notion. The researcher being from a medical background turned out to be a strength of the study, despite the fact of preconceived ideas about the clinical aspects of the study potentially being an issue. It allowed the researcher to blend in well with the team whilst actively observing the process. There was no perceived threat from the team by the researcher being present at meetings or at other places during the research. This allowed the researcher to have an “insider” role that did not influence the process or the outcome of the study. In relation to recruitment, the fact that the researcher was viewed as a doctor will definitely have had an influence on that patients and their willingness to be interviewed. This is displayed by the fact that until the researcher started attending clinics and speaking to patients directly, recruitment was non-existent. This was advantageous to the study overall, but the potential for patients feeling as though they must take part cannot be ruled out. However, all patients were provided with an information sheet and given a period of time to consider whether they wished to be interviewed, with a formal consent process being followed. From the perspective of the patient interviews and the focus group, the researcher being a doctor was certainly advantageous, as patients felt immediately comfortable to speak about their problems, knowing that it would be in a confidential manner. At no point did the patients ask the researcher for advice about their medical problem, which from an ethical perspective was advantageous, as this would have placed the researcher in a very difficult situation. The patient information sheet did explain that the researcher would not be able to provide medical advice.

The use of NPT in this study was beneficial as it gave a structure within which to interpret the qualitative findings. Having the four core concepts to guide the analytical process was useful, especially with the observational data where there were lots of notes which needed focusing. NPT enabled creative thinking about the research and the implementation processes taking place and it directed the analytical trajectory of the research. By using NPT solely at the analytical part of the project it allowed the researcher flexibility and the possibility of adapting the theory to the needs of the research.

Limitations of the study

There were limitations present within the study. The number of patients on the ICP that were interviewed was five. In the field of qualitative research, the emphasis is often placed on the quality of the data obtained and the scope or focus of the study, meaning that the sample size or number of interviewees required to support the conclusions will vary (188,238). However, the implicit aim of qualitative research is to reach the theoretical level of data saturation (239–241), which is not explicitly defined in the available literature (239,242,243). The majority of allocated data codes are reported to be created after analysis of twelve interviews, with analysis of six providing enough data to support overarching themes in qualitative studies similar to this one (238,242,243). This means that, according to this criterion, the stakeholder interviews reached an acceptable level of data saturation, but the narrative patient interviews did not. However, despite having only five narrative patient interviews, the data obtained from these interviews was consistent throughout and therefore it can be argued that the data saturation point had been reached. Interviewing more patients would have been preferable so that data saturation could have been confirmed. Discussing FI is difficult and embarrassing for patients, as has been evidenced in multiple publications that detail the difficulty in FI sufferers acknowledging and then discussing their symptoms with health professionals (6,14–16). This would go some way to explain the relatively small number of patients who agreed to be interviewed. Attempts were made to obtain patients who would give a maximum variation in symptoms and demographics. Whilst not entirely achieved, patients were interviewed of both sexes, three different ethnic groups with variations in symptom severity. The youngest patient interviewed was 48 years old, the researcher identifies that a greater age range (i.e. younger patient) for interviewed patients would improve the study. To increase the number of patients interviewed would have required a longer study period with constant researcher presence at all pelvic floor clinics, as the response rate was very low, possibly due to the reported issues of embarrassment related to having FI (12,13,22). When analysing the different types of stakeholder interviewed, the number of GPs interviewed was four. The research would have benefitted from a wider spread of GPs (differing geographical areas, practice sizes, seniority etc.) being involved to ensure that the sample used could be deemed as a representative sample. With only four GPs being interviewed it is difficult to say this. However, there were common themes that were consistent throughout both rounds of interviews with all of the GPs, with no real differences in their opinions with regards to FI, indicating that data saturation was achieved. Historically, GP response rates to research studies and surveys alike have been poor and this study was no exception (244,245). The GPs who did participate gave one potential reason for the lack of participation from their colleagues in this study: FI is not high on their agenda. Also a GP’s time is often limited and taking part in research will stretch that time further. Extending the study duration could have helped obtain more GP interviews.

When considering patient numbers with regards to the quantitative data, the difficulty in comparing patient outcomes (patient symptoms, symptom scoring and quality-of-life outcomes) was solely down to the fact that so few patients had been discharged from the ICP at the time of completion of the study period. The way to resolve this would be to compare the patient outcome data when more patients had been through the ICP and discharged or to interview patients still being treated to gain an insight into service users’ perspectives. This was not done in this study due to a lack of time and the priority mainly being based around the process of implementing the ICP.

Throughout the study the researcher was aware of the need to try to gain as many perspectives on the process of the ICP implementation as possible. In an ideal world, all of these perspectives would have been covered. However, due to time and resource restrictions this was not possible. An example of this is in relation to the organisational management input. The researcher was unable to comment on the organisational management input into the process, as they were not aware that any input was being made. This may, and most likely, be due to the fact that no input was being made, but the researcher cannot be certain that this was the case, as informal meetings or communication may have happened in forums that the researcher was not aware of or privy to.

One potential area within the research where there could have the potential to use NPT further was during the development of questions for the semi-structured interviews. Developing the topic guide around the four constructs of NPT that were going to be explored could have been beneficial.

Critical Reflection on what has normalized and why?

To be “normalized” a classification, artefact, technique or organisational practice becomes routinely embedded in everyday life (171). The study results do show that the ICP had become “normalized” for the stakeholders, as the ICP is now used routinely and is the only route of entry for patients with FI into the service. The ICP has been recognised by NHS England (246) as being a leader of change. The fact that NHS England have published on the ICP, in the format that the thesis describes, adds further credence to the suggestion that it has indeed been normalized to the stakeholders. One could argue that because the team have cut off any other routes of referral, that normalization has been achieved through “brute force”, by providing a lack of any other referral option, in order to embed the ICP in the service. The argument against this is that from the results of the study, it is clear to see that the team did successfully meet all four core constructs of the model to arrive at the point where the ICP was implemented and normalized. The decision to allow only one route of referral, described as “brute force” above, did speed up the normalization as it removed any potential doubt in the referral process and streamlined the implementation of the ICP. The decision to only have one access or referral point was taken by the team so that there was an element of clarity for referrers, in an attempt to reduce the possibility of patients being referred inappropriately to varying hospital specialities. This was one of the main issues identified initially by the team as a major barrier to quality, timely patient care. This one point of access also meant the team had an element of control about which patients were entering into the service, the appropriateness of these patients and gave the team an idea of capacity and demand from which they could implement and consolidate the service, therefore allowing it to be normalized in a more timely and controlled fashion.

However, one vital and perhaps the most important element of normalization that needed to occur was that of patients and their feelings and attitudes towards FI. This longstanding issue that has blighted FI care for many years is an issue that the implementation of an ICP is unlikely to solve, unless novel ideas are used to highlight the service and attempt to take the perceived stigma out of FI. This did not occur within this setting and is unlikely to unless there is a national change in attitude and belief towards FI. The real crux of this matter is the issue of stigma, the problem with stigma is that it often results in a reluctance to seek help and disclose symptoms because of a real, or often, perceived fear of being labelled or discriminated against (247–249). The stigma around bowel function even exists in relation to bowel cancer (250), where national awareness campaigns have been used to try to overcome this issue, with a limited degree of success (251).The potential impact of stigma is that this service or similar ones in the future, will never truly fulfil their aims and the true demand for a service such as this one, will never be realised or indeed be normalized.

Interestingly, one element that the team wanted to achieve, yet still have not, is the move to neighbouring hospital trusts. At the time of writing the thesis, the ambition for expansion had not been realised, despite being clearly described by the stakeholders during the semi-structured interviews. The reasoning for this is likely to be complex and based around a number of issues, including traversing complex inter-hospital governance procedures, potential power struggles between individual trusts and the CCG priorities in one area compared to the next. With the fact that this service would be deemed a low priority and borderline specialised service within the NHS (252) then it is reasonable to suggest that CCGs may not value the service as highly as the stakeholders involved within it.

Whilst the ICP described in the thesis is unique with regards to its area of focus (FI) and structure, does it have the potential to be used in other contexts? Fundamentally, yes it does. The thesis has provided evidence of a functioning service with good clinical outcomes and high rates of patient satisfaction. As alluded to above however there are a number of reasons why it may be difficult to establish the ICP in other contexts, such as inter-hospital governance procedures and perceived power struggles, but none of them is seemingly insurmountable. When considering the contexts into which the ICP could be placed, a review of external and internal influences on proposed healthcare organisations or providers would need to be undertaken. External influences, such as health policy and national frameworks, availability of therapies, equipment and technology and supply and demand, will have a significant impact on the uptake of an ICP such as this one. Internal influences, such as leadership, patient satisfaction and finances will also impact upon whether an ICP will be successful in a different health context (253).

Two broad choices have been described in relation to context: adapting the intervention to the context or adapting the context to the intervention (253). This raises a very interesting point when this sentence is related to the ICP and the stakeholder ambition to expand. The ICP is a simple pathway that was set up in the context of that individual trust. Moving this out to other trusts is a complex process which not only has to consider the external and internal influences within that trust, but also potentially having to adapt the ICP to allow the implementation to occur at all. However, quality standard 54 from NICE does encourage commissioners to commission services with expertise and capacity for specialised management of FI, further adding to the leverage of the team who set up the ICP (254). The overall likelihood of the trust adapting to the ICP is low however, due to the fact that it would potentially bring a greater workload (at least initially) and financial cost.

Therefore the likelihood of “full” normalization as perceived by the stakeholders with expansion into other neighbouring trusts is unlikely to be realised in the near future.

Conclusions

A number of barriers and facilitators have been identified in relation to the local implementation of an ICP for FI. Facilitators included effective clinical leadership, a true, shared sense of purpose, commitment and teamwork between all members of the continence team and effective change management. With barriers to the implementation including a lack of organisational leadership, a lack of capacity related to stakeholder time to setup and implement the ICP and an initial lack of referrals. Each of these facilitators or barriers impacted upon the key stakeholders involved in the implementation process often with positive consequences e.g. building leadership skills, improving teamwork and an enhanced patient journey. However, negative consequences such as high workloads were apparent, as there was a lack of capacity and organisational support for stakeholders to set up and implement the ICP, contributing to the delay in its implementation. Initial findings suggest that the introduction of this ICP for FI appears to be beneficial for patients and staff alike, with patient outcomes remaining on a par initially with the ‘traditional’ pathway and referral rates increasing following promotional work around the service. This ICP has the potential to solve some, if not all, of the issues related to the previously fragmented and disjointed continence services. However, one key barrier still remains regarding the effective promotion of the service to key stakeholders such as GPs, to ensure that appropriate patients are referred in a timely manner. The MDT involved in setting up this ICP are attempting to improve referral rates and trying to ensure that clinical outcomes are maintained and improved if possible. However, this is an initial exploratory evaluation and therefore further work is needed before results can be described as generalisable.

Implications for Practice

The introduction of an ICP for FI has the potential to improve the management of FI patients, by ensuring the appropriate patients get to see the most appropriate healthcare professional at the right time. Some of the longstanding issues with continence care could be resolved if the work commenced in the study is continued and embedded, leading to a generalisability of the ICP into neighbouring trusts and potentially, nationally. If these changes were to happen, and patients with FI were managed more appropriately with symptom improvement occurring more quickly, then the social and financial implications for these patients could be of benefit to the country as a whole. However, it must be highlighted that not every hospital trust has a bowel function service within it and there would be considerable cost in setting one up, which would be a major challenge especially in a NHS that is currently in the midst of a financial crisis. Overall though, the provision of a service that would enable patients to regain control of their lives and significantly improve their quality of lives would be welcomed by patients and healthcare professionals in community and hospital settings alike, if funding allows.

Suggestions for Future Research

A follow-up qualitative interview study would allow an assessment of whether the current patient/participant views outlined in this study, remain following the introduction of the ICP over a sustained period of time. In accordance with this, the patient outcome measures will need to be monitored (patient symptoms, symptom severity scoring and quality of life outcomes) so that the ICP outcomes can be compared with the ‘traditional’ pathway outcomes. This will allow the team to ensure that the improvement in patient symptoms, for patients referred to the ICP, is equal to or better than the ‘traditional’ pathway. Alongside further work into the patient element of the study, continuing to observe the impact that the ICP has on the staff within the service would also be relevant as the plan to expand the ICP out to neighbouring areas will no doubt bring more challenges, which the team will have to overcome. To observe this process in different geographical areas with a different population mix would help to make the findings more generalisable and a definitive multicentre trial would ensure that after this has been achieved the ICP could be implemented on a national basis.

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Appendix 1: Participant Interview Schedule Round One

Evaluation of an integrated care pathway approach to the management of faecal incontinence across primary and secondary care.

Participant Interview schedule: November 2011

Interviewee's name: ……………………………………………………………………

Job title: …………………………………………………………………………….

Date: ……………………………………………………………………………………

Interviewer: ……………………………………………………………………………

Preamble

- Introductions: self; purpose of research; summary of topics to be covered etc.
- Previous paperwork was sent to show the aim of this research: to review process of change following the introduction of an integrated care pathway for the provision of faecal incontinence services.
- Participants to understand objective of research, confirm willingness to contribute, and have an opportunity to ask any questions about the project before starting.
- It should also be explained that this is a generic set of questions, and they are not expected to have answers for all the questions.
- Please state the name of the person you are interviewing and the date before the interview commences.

1. Could you tell me about your current role and how it relates to the pelvic floor service?

Brief resumé of career, leading up to current job and brief description
Challenges of current role

2. Tell me about the current faecal incontinence service in your Trust?
Where is this happening? (Identify site e.g. community/hospital, other facilities: theatre)
How is this different from other Trusts?

3. Can you talk me through the current patient pathway for a patient referred with faecal incontinence?
How are patients kept informed about their illness, treatment and logistics of treatment?
Including aspects of referral process

4. Who are the different health professionals involved?
Explore multispeciality working; extra responsibility/ownership of patients; additional training?
How well do they work together?

5. Are you aware of any formal guidelines/documents related to faecal incontinence in practice and how useful are they?
Clinical guidelines; evidence base; national, international, Trust level protocols

6. How well do you think the current service is working?

7. Do you feel there is need for change? If so, why?
*Prompt: Is a specific model for service redesign being followed***?**

8. What are your perceptions of how information is used and provided/shared along the pathway? E.g. are IT systems effective, diagnostics etc.?
Try and find out how information is used, created, managed along the pathway, how it is stored, distributed and applied by different people.

9. What are the three most important pieces of information you receive every month/quarterly? How do you use these pieces of information/data? Where do they come from?
Try to find out how this information influences the behaviour of the interviewee.

10. Are you aware of any changes planned in the near future for the faecal incontinence service? Why do you think they are required? What will happen to patients over the next 6/12/18 months or 5 years?
What are the drivers (in detail) for these changes e.g. clinical, financial, policy? What might stop this happening? What is needed to make it happen? Identify facilitative and constructive elements. On whom will it impact (organisation, patient, health professional)?

11. What would count as success? If this change worked, what would the service look like when it was completed?

Closure

Explain next steps in project/likely timescales for completion etc… Can you suggest anybody else that it might be helpful for us to interview? Thank you.

12. Post interview: Three emerging messages and any comments on process

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-
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Appendix 2: Participant Information Sheet

Evaluation of an integrated care pathway approach to the management of faecal incontinence across primary and secondary care.

You are being invited to take part in a study, which evaluates service redesign. This Information Sheet is provided to explain why the study is being done and what it will involve to help you decide if you would like to participate. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information and please take time to decide whether or not you wish to participate.

Thank you for reading this.

What is the purpose of the study?

As health service technologies improve and societal expectations of health care change, so the nature of delivery itself is changing, and Trusts across the NHS have been looking at ways of redesigning or 'reinventing' themselves to be more efficient, and better prepared to face increasing competition. Specialist care is changing from a bed based, reactive service based in publicly owned buildings, to become less venue dependent, more responsive to individual and population needs, and more proactive in its approach.

The overall aim of this study is to evaluate one of the service redesign programmes being implemented at the Sandwell and West Birmingham NHS Trust, which are driven in part by extensive capital redevelopments. This study is one of nine 'themes' within the overall Birmingham 'Collaborations for Leadership in Applied Health Research and Care' (CLARHC) programme commissioned by the NHS National Institute for Health Research (NIHR).

This is an evaluation of the faecal incontinence service in your Trust and we are hoping to evaluate how this specific service is running at present.

The specific objectives of the study include:

- To identify the extent to which the service is currently meeting patient's needs;
- To identify the vision that key members of the clinical team have for the service currently;
- To contribute to the redesign programmes' impact by including a strong baseline component from which we can develop further evaluation following the implementation of a new care pathway;
- To incorporate multiple dimensions of change (including clinical, economic, organisational, management and cultural factors) in our analyses to appropriately reflect the complexities of the various elements.

Why have I been chosen?

We would like you to participate in this study because we wish to seek the views of key staff with knowledge and insight into how redesign initiatives are being implemented across your organisation or in your department.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign two consent forms (one for yourself and one for the researcher). If you decide to take part you are still free to withdraw at any time (up to six months following collection of your data i.e. your interview) and without giving a reason. Any data collected from you will be destroyed and will not be used in the study. To withdraw from the study, please contact Craig Rimmer on [redacted] or [redacted].

What will happen to me if I take part?

We wish to interview you about your experience of redesign initiatives and your perspective on how these are being implemented in your organisation or specialty. The study will undertake face-to-face interviews, and with your permission, we may ask for one or more follow up interviews. Each interview will last around one hour.

The interviews will be conducted by myself, Craig Rimmer, who has appropriate training and qualifications. The interviews will normally take place at your workplace on dates and at times agreed with you in advance.

How will I be recruited?

We have asked potentially key participants to recommend people who could make an interesting and insightful contribution to the study based on their experience and perspective. You were identified as one of these people.

Will my taking part in this study be kept confidential?

The interview data will be kept confidential and reported anonymously. Any direct quotation will be attributed to general job title only (e.g. “Clinician A”), however, it may not be possible to totally anonymise quotations as we cannot categorically rule out that readers of the report will be able to attribute quotations to the person(s) involved.

The interviews will be recorded and transcribed. The digital recordings will be securely stored until the end of the study in September 2013, when they will be deleted, and only the research team will have access to these records. In line with the University of Birmingham’s code of conduct for research, the interview transcripts will be destroyed ten years after publication of the study’s findings. The transcripts will not identify the interviewees by name.

What will happen to the results of the study?

One of the study objectives is to provide practitioners with timely, formative feedback in order to strengthen the impact of the redesign initiatives. Interim reports will be disseminated to participants as the research progresses.

We will pursue a wide range of dissemination activity, incorporating active knowledge transfer events with defined stakeholder communities during the study, and actively disseminate findings within policy, managerial and academic communities.

Who is organising and funding the study?

The study is being organised and sponsored by the University of Birmingham in collaboration with the participating Trust.

What indemnity arrangements are in place?

This study is covered by the University of Birmingham's insurance policy for negligent harm. The study is not covered for non-negligent harm, as this is not included in the University of Birmingham's standard insurance policy.

Who has reviewed the study?

This study has been reviewed by the Science, Technology, Engineering and Mathematics Ethical Review Committee at the University of Birmingham (https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-of-Research.aspx) and the Sandwell and West Birmingham NHS Trust R&D department, and all have confirmed the service evaluation status and therefore the study does not require formal national ethical review.

What if there is a problem?

In the event of a complaint relating to the research, you are requested to inform Jonathan Shapiro who will try to resolve the matter (see contact details below). Alternatively you may wish to contact your Trust R&D department.

How can I get further information?

Please ask Craig Rimmer (tel: [redacted] email: [redacted]) if you have any questions or would like more information about this invitation. For any complaints please contact [redacted]

Thank you for your help.

Appendix 3: Participant Information Sheet

See next page

Who is organising and funding the research?

The study is being organised and sponsored by the University of Birmingham. The study has been funded by the National Institute for Health Research (NIHR) which is a national government funding body.

CLAHRC's have been established to undertake high-quality applied heath research focused on the needs of patients and to support the translation of research evidence into practice in the NHS.

Contact for further information

We hope this information sheet has told you what you need to know before deciding whether or not to take part in the study. If you have any questions about the study or wish to make a complaint please telephone Craig Rimmer on [redacted] or e-mail [redacted].

Given the nature of the study it is highly unlikely that you will suffer any harm from taking part, however if you are harmed by taking part you may have grounds for legal action for compensation against the University of Birmingham.

Thank you for reading this information sheet.

Faecal Incontinence Service
Redesign Group

If you would like some further information about the research team please go to www.clahrc-bbc.nihr.ac.uk

NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRC) for Birmingham & Black Country

Improving our health by translating research evidence into local NHS Practice

www.clahrc-bbc.nihr.ac.uk

UNIVERSITY OF
BIRMINGHAM

NHS
National Institute for
Health Research

Theme 1:
Health Service Redesign

Participant Information Sheet

A study of experiences of faecal incontinence

We are a group of researchers working at the University of Birmingham and we are asking you to take part in a study. Before you decide if you would like to take part or not, we would like to tell you why the study is being done, and what you can expect if you do take part. Please read the following information carefully and discuss with friends, relatives and your GP if you wish. Please take as much time as you need to decide and ask us if you have any other questions.

Our group is independent of the influence of the NHS and the relevant hospital trusts within which this evaluation is taking place.

What is the purpose of the study?

The study is being carried out to improve understanding of people's experiences of faecal incontinence. The study will also to help us understand what could be changed to improve services now and in the future from a patient's point of view.

We will be collecting audio and written interviews from people which may be used in the following ways:

To give you a chance to have your say
To find out what is important to people with faecal incontinence
To inform how services are run in the future to improve patient care
To contribute to wider research being undertaken for improving services
To write research articles for other academics and healthcare professionals
To feedback to the NHS (via audios and website)

Why have I been chosen?

You have been contacted because we want to interview people who have had experience of faecal incontinence.

We will be interviewing a range of people who have had similar experiences.

Do I have to take part in the research?

No, it is entirely up to you to decide if would like to take part or not. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to stop at any time without giving a reason. No questions will be asked if you wish to stop.

If I agree to take part in the study what will happen?

You will be contacted by a member of the study team to arrange an interview at a time and place that suits you, usually in your own home. Before the interview the researchers will answer any questions you may have.

What will the interview be like?

We will ask you if you are willing to have the interview audio tape recorded and you will be given a consent form to read and sign. You only sign this form if you agree to take part in the interview and you will be given a copy of the consent form to keep.

The interview will be like a conversation in which you will be asked to talk about yourself and your experience of faecal incontinence in your own words. There are no right or wrong answers as you will be asked to talk about what happened to you, what your thoughts and feelings have been at different stages, how you have got information, what you have done, and what have been the good and bad parts of your experience.

Whilst some people sometimes find it helpful to talk about their experiences to researchers, this research is not the same as counselling. However, if you wish we can give you a list of useful contacts which can be used to get more information and help if you want.

How long will the interview take?

The time it takes for the interview will vary depending on how much you have to talk about. Most interviews last for at least one hour. Remember if you wish to stop the interview at any time you can do so without giving a reason.

What will happen after the interview?

The interview will be given to a typist to type out. The typist will have signed an agreement to keep everything you say in the interview confidential. The recorded interview and typed up script will be kept in a safe and secure place at the University of Birmingham, and it will not be possible to identify you.

We will offer to send you a copy of the typed up interview and/or the audio recording to confirm that you are still happy for us to use the information in our research. You will be asked to read the interview and listen to the audio and think about if there is anything you would like to remove. We will remove any sections that you do not want us to use.

How will the interview be used?

Before the interview begins the researchers will discuss with you the possible ways that the interview will be used, for example:

Audio clips of the interview and a summary to be used on the research website www.clahrc-bbc.nihr.ac.uk
Audio clips (which will be anonymous) to be used at events/meetings to feedback to the NHS
Interviews used to inform the final CLAHRC research report

Appendix 4: Consent Form

Title of study: Evaluation of an integrated care pathway approach to the management of faecal incontinence across primary and secondary care.

Please initial box

1. I confirm that I have read and understand the participant/patient information sheet dated for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw from any part of the involvement at any time (up to six months following your participation), without giving any reason, and without my legal rights being affected. The data you have given us will be destroyed should you decide to withdraw from the study. ☐

3. I agree to take part in the above study. ☐

4. I confirm that I give permission to use direct quotations (which will be anonymised) and which may be used in subsequent publications in the form of research papers and reports. (including the world wide web) ☐

________________________	________________	____________________
Name of interviewee (Please print)		Date Signature
_________________________	________________	____________________
Researcher (Please print)	Signature	Date

Appendix 5: Observational Meeting Proforma

Name of Meeting: Date

Who is in attendance?

Layout of room

Main topics discussed

Group Dynamics

Responses of attendees

Post Observation- Reflections

Follow-up Work

Appendix 6: Focus Group Protocol

Introduction

Welcome. I want to thank you for coming today. My name is Craig Rimmer and I will be the facilitator for today's group discussion. I am a researcher from the University of Birmingham

I have invited you to take part in this group discussion today because you are all members of the continence group and having met you I know that you are vocal and will give me your honest opinions.

What I learn from today's discussion will help me to improve faecal continence services in the region.

Ground rules

Before we begin, I would like to review a few ground rules for the discussion.

- I am going to ask you several questions; we do not have to go in any particular order but I do want everyone to take part in the discussion. I ask that only one person speak at a time.

- Feel free to treat this as a discussion and respond to what others are saying, whether you agree or disagree. I am interested in your opinions and whatever you have to say is fine with me. There are no right or wrong answers. I am just asking for your opinions based on your own personal experience. I am here to learn from you.

- Don't worry about having a different opinion than someone else. But please do respect each other's answers or opinions.

- If there is a particular question you don't want to answer, you don't have to.

- All answers will be treated as confidential. I shall not ask for anything that could identify you and we will only use first names during the discussion. I also ask that each of you respect the privacy of everyone in the room and not share or repeat what is said here in any way that could identify anyone in this room.

- I am tape recording the discussion today and also taking notes because I don't want to miss any of your comments. However, once I start the tape recorder I will not use anyone's full name and I ask that you do the same. Is everyone OK with this session being tape recorded? [GET VERBAL CONSENT TO TAPE RECORD DISCUSSION. IF A PARTICIPANT DECIDES THAT S/HE DOES NOT WANT TO BE TAPED ALLOW THEM TO LEAVE]

- I will not include your names or any other information that could identify you in any reports we write. I will destroy the notes and audiotapes after I complete our study and publish the results.

- Finally, this discussion is going to take about 45-60mins

- **Does anyone have any questions before we start?**

Group Discussion

1. **What are your impressions of continence services in the region?**
    a. Community and secondary care
    b. Facilities
    c. Accessibility

2. **How would you improve the services?**
    a. What would be ideal?
    b. Change in location?
    c. Who would you prefer to see- consultant versus specialist nurses

3. **Given the change in faecal incontinence services proposed by Sandwell hospital and community services- what do you think will be the impact on patients accessing the service?**

Those are all of the questions that I wanted to ask.

Does anyone have any final thoughts that they haven’t gotten to share yet?

Appendix 7: Participant Interview Schedule Round Two

Evaluation of an integrated care pathway approach to the management of faecal incontinence across primary and secondary care.

Participant Interview schedule Second Round: March 2013

Interviewee's name: ……………………………………………………………………

Job title: …………………………………………………………………………………….

Date: ……………………………………………………………………………………….

Interviewer: ……………………………………………………………………………….

Preamble

- Introductions: self; purpose of research; summary of topics to be covered etc.
- Previous paperwork was sent to show the aim of this research: to review process of change following the introduction of an integrated care pathway for the provision of faecal incontinence services.
- Participants to understand objective of research, confirm willingness to contribute, and have an opportunity to ask any questions about the project before starting.
- It should also be explained that this is a generic set of questions, and they are not expected to have answers for all the questions.
- Please state the name of the person you are interviewing and the date before the interview commences.

1. Could you tell me about your current role and how it relates to the pelvic floor service?

Brief resumé of career, leading up to current job and brief description

Challenges of current role

2. Tell me about the current faecal incontinence service in your Trust?

Where is this happening? (Identify site e.g. community/hospital, other facilities: theatre)

How is this different from other Trusts?

3. Can you talk me through the current patient pathway for a patient referred with faecal incontinence?

How are patients kept informed about their illness, treatment and logistics of treatment?

Including aspects of referral process

4. Who are the different health professionals involved?

Explore multi-speciality working; extra responsibility/ownership of patients; additional training?

How well do they work together?

5. How has the process of implementing the new pathway been?

Explore facilitators/barriers from each individuals point of view. Middle management/organisational issues to be explored. Capacity and compatibility with existing practices.

6. How has the new pathway affected patient care?

Explore patient responses to the pathway.

7. Has it changed the way you work? Do you see the point in having the pathway?

8. Are there any changes you would make to the new pathway?

Document, process issues

9. How do you view the new pathway overall? What is the overall purpose of the new pathway?

Workload increased, power shifts. Requirement for further training.

10. What are your perceptions of how information is used and provided/shared along the pathway? E.g. are IT systems effective, diagnostics etc.?

Try and find out how information is used, created, managed along the pathway, how it is stored, distributed and applied by different people.

11. What will happen to the service and patients over the next 2 years?

What are the drivers (in detail) for these changes e.g. clinical, financial, policy? What might stop this happening? What is needed to make it happen? Identify facilitative and constructive elements. On whom will it impact (organisation, patient, health professional)?

12. What would count as success for the service? If this change worked, what would the service look like when it was completed?

Closure

Explain next steps in project/likely timescales for completion etc… Can you suggest anybody else that it might be helpful for us to interview? Thank you.

13. Post interview: Three emerging messages and any comments on process

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-
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Appendix 8: Patient Narrative Interview Schedule

Evaluation of an integrated care pathway approach to the management of faecal incontinence across primary and secondary care.

Patient Interview schedule: November 2012

Interviewee's name: ………………………………………………………………….

Job title: ……………………………………………………………………………….

Date: ……………………………………………………………………………………

Interviewer: ……………………………………………………………………………

Preamble

- Introductions: self; purpose of research; summary of topics to be covered etc.
- Previous paperwork was sent to show the aim of this research: to review process of change following the introduction of an integrated care pathway for the provision of faecal incontinence services.
- Participants to understand objective of research, confirm willingness to contribute, and have an opportunity to ask any questions about the project before starting.
- It should also be explained that this is a generic set of questions, and they are not expected to have answers for all the questions.
- Please state the name of the person you are interviewing and the date before the interview commences.

1. **Tell me about your condition?**
   Onset, duration, effects on daily life

2. Can you talk me through the pathway of access to care, management and treatment for your faecal incontinence?

How were you kept informed about your illness, treatment and logistics of treatment?

3. Which different health professionals have been involved in your care?

Number, roles, referred directly/separately?
Smooth pathway?
How long did you have to wait to see them?

4. How do you feel about the ease of access to the faecal incontinence service?

Logistical/administrative ease, did your GP know who you should see at the hospital?

5. What is your impression of how well the service is working? *Has it helped you? If so, how? If not, why not?*

6. Are you aware of any changes planned in the near future for the faecal incontinence service?

7. In your opinion, how could the service be improved?

Appointments, logistics, diagnostics, treatments, location

8. What would count as success for you?

Clinical, lifestyle etc

Closure

Explain next steps in project/likely timescales for completion etc… Can you suggest anybody else that it might be helpful for us to interview? Thank you.

9. Post interview: Three emerging messages and any comments on process

-
-
-