Patient-reported long term complications after ileal conduit surgery and the implementation of a surveillance protocol

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Abstract

Introduction and aim of the study Ileal conduit(IC) is the most frequent urinary diversion following radical cystectomy. Reports highlighted high rates of long term complications but the best schedule of surveillance remains undecided. The main aim of this study to investigate IC patients' experience after surgery and to explore current practice of surveillance and investigate stakeholders' views about alternative models.

Materials and Methods This study was formed of two parts. *Part A:* 2000 IC patients were invited to complete a postal questionnaire. The questionnaire explored patients' experience of complications and their views of follow up. Statistical analysis was conducted using Stata®14 software to identify association between reporting complications, patients' satisfaction or views and patient characteristics. *Part B:* A multicentre qualitative study, using semi-structured interviews among health professionals involved in IC care was conducted. Interviews explored participants' views of current practice and best surveillance model. Following thematic analysis, the framework of the NPT was used to analyse the data.

Results Part A: 1092 completed questionnaires were analysed (response rate= 60%). 88% of respondents reported ≥1 complication, and 45% ≥1 frequent complication. UTIs, hernia and appliances problems are the most reported ones. Multivariable logistic regression showed female gender, age < 60 years, benign indication for surgery and difficult access to stoma nurse were associated with reporting complications. Of the 44% who felt GP follow up is inappropriate; lack of experience was the main cause. *Part B:* 17 interviews were conducted with different types of health professionals at three centres. Participants described good understanding of surveillance scope and value. They highlighted the need for change due to lack of guidelines and service workload. The stoma nurse role was seen as pivotal in making surveillance workable. There was a lack of agreement over surveillance length. Participants raised concern regarding GPs willingness to participate and about lack of resources.

Conclusion The high and cumulative incidence of IC related complications suggest the development of a standardised, evidence based long term surveillance protocol. A shared care community based nurse led scheme could be a suitable model.

Dedication

This doctorate thesis is dedicated to:

My parents to whom I will always be grateful.

My supervisors for their great support and help.

Prof. Rob. Pickard for his great support and encouragement

My wife and my best friend Nada.

My two sons Omar and Ramy, the blessings Allah gave me.

And to those who lost their lives at Tahrir square, Cairo in 2011 protesting for freedom.

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List of Abbreviation

AA	Ather Abdelbaky
AUA	American Urology Association
BAUS	British Association of Urological surgeons
BMI	Body Mass Index
CI	Chief Investigator
CS	Case series
CT	Computed tomography scan
EDTA	Ethylenediaminetetraacetic acid
EHS	European Hernia society
ESWL	Extracorporeal shock wave lithotripsy
GFR	Glomerular filtration rate
GP	General Practitioner
HEFT	Heart of England NHS Foundation Trust
HES	Hospital Episode Statistics
HRQL	Health-related quality of life
IC	Ileal conduit
JO	James O’Donovan
LS	Linda Sharp
LR	Literature review
MDRD	Modification of Diet in Renal Disease
MIBC	Muscle invasive bladder cancer
NICE	National Institute for Health and Care Excellence
NPT	Normalisation process theory
NS	Nurse Specialist
PCNL	Percutaneous nephrolithotomy
PH	Parastomal hernia
PI	Principal Investigator
PIS	Participant Information sheet

PROM	Patient reported outcome measure
QoL	Quality of life
R&D	Research and Development
RC	Radical cystectomy
RCT	Randomised controlled trial
REC	Research Ethics committee
RSP	Robert Pickard
SN	Stoma nurse
SR	Systematic review
TF	Tracy Finch
UA	Urostomy Association
UD	Urinary diversion
UK	United Kingdom
USA	United States of America
UTI	Urinary tract infection

Chapter 1: Introduction

1.1. Ileal conduit: History and trends in use

The ileal conduit (IC) is a non-continent urinary diversion (UD) that is performed surgically following radical cystectomy (RC) for bladder cancer. It has also been used with or without RC as a last resort surgical option for benign intractable bladder conditions such as neurogenic bladder, interstitial cystitis and small bladder capacity (Osborn *et al.*, 2014). This surgical technique was initially described in 1909 by Verhoogen and De Graeuve and has been used widely since then (Verhoogen and De Graeuwe, 1909). Further refinements of the technique have been described, these refinements focused mainly on different techniques of uretero-ileal anastomosis (Bricker, 1950; Wallace, 1970).

Despite the development of different continent urinary diversion surgical techniques in an attempt to improve body image (Studer *et al.*, 1989; Wenderoth *et al.*, 1990; Philip *et al.*, 2009), incontinent urinary diversion remained the predominant technique. It was seen as a simple, quick technique with lower risk of complications compared to continent diversion such as neobladder formation (Colombo and Naspro, 2010). Ileal conduit was the most commonly used UD (80.6%) following radical cystectomy in the UK over the period between 2004-2012 (Cresswell *et al.*, 2015). The frequency of use of IC has shown a further increase on reporting on the open radical cystectomies performed in the UK in 2014 & 2015 reaching up to 86.4 % (Jefferies *et al.*, 2018). In a comparison of the trends of UD after RC in the US and Germany from 2006 to 2014, ileal conduit was the most common UD in both countries. The trend in IC use was stable in the US at 87-88%, and increased in Germany from 52.2% to 55.4% (Groeben *et al.*, 2018). The data obtained from the Swedish registry for bladder cancer has shown conduit diversion as the UD technique for 81% of patients after RC in 2008 (Hautmann *et al.*, 2011). The data obtained from several centres at 3 different continents (North America, Europe and Africa) for 16,867 patients who had RC over different periods between 1968 and 2010 , report a frequency of choosing incontinent conduit diversion at 42.2% of cases compared to 38.0% having neobladders (Hautmann *et al.*, 2011). The rest of the cases in the series had continent cutaneous diversion.

Knowing the trends of UD with RC and the number of yearly RC performed, the number of IC performed each year can be estimated. Between 2004 and 2012, 12,539 RC were performed in England according to data obtained from the HES website; this has increased from 1406 cases in 2004/2005 to 1798 cases in 2011/2012 (Cresswell *et al.*, 2015). According to the British Association of Urological Surgeons (BAUS) national audit there were 5,857 radical cystectomies undertaken in England during the time period 2014-2016 (2,028 in 2014, 1,952 in 2015 and 1,877 in 2016) (BAUS, 2018b). In another European country, Germany, a total of 60,447 RC procedures were performed between 2006 -2014 with an annual increase in the number from 5627 in 2006, to 7390 in 2014 (Groeben *et al.*, 2018). Over the same period, 17,711 RC procedures were performed in the US with an annual caseload range of 1666–2009.

1.2. Ileal conduit: The surgical technique

The IC operation comprises three main steps:1) isolation of a loop of ileum, 2) uretero-ileal anastomosis and 3) formation of the stoma (Smith *et al.*, 2016). A loop of ileum with a length of 15-20 cm, 10-12 cm away from the ileocoecal junction is selected to form the conduit. This is done to provide enough length for the conduit to reach up to the stoma site and to avoid the terminal ileum where vitamin B_{12} and bile salts are absorbed (Bricker, 1950). Once a suitable segment is marked, the segment is isolated with its mesenteric blood supply by dividing both ends from the ileum. The continuity of the ileum is restored by suturing or stapling the divided ends back together and the mesenteric defect is closed to avoid internal hernia formation (Figure 1.1) (Colombo and Naspro, 2010).

The proximal end (non-stoma side) is then anastomosed to the distal end of the ureters. Two famous techniques have been described for this step: Bricker and Wallace (Bricker, 1950; Wallace, 1970). At the Bricker technique, an enterotomy is made on the IC proximal end and the spatulated end of the ureter is anastomosed to it using absorbable suture. The same is done for the other side and the anastomosis is supported by temporary stent that will be brought through the conduit out of the stoma. Instead of doing 2 enterotomies , one ureter could be anastomosed to the proximal open end of the IC, otherwise it is closed by sutures (Figure 1.2) (Lobo *et al.*, 2016a). In the Wallace technique, both ureters are spatulated and the inner walls are sutured together. The outer walls are then sutured to the circumference of the opened proximal end of the IC using absorbable sutures. Again, this is supported by two stents (Figure 1.3) (Lobo *et al.*, 2016a).

The stoma is then created by excising a circle of skin at the pre-marked stoma site. The subcutaneous tissue is dissected down to the rectus muscle sheath. A cruciate incision is made in the sheath and the muscle is dissected to create a route to the abdominal cavity. The proximal end of the stoma is delivered through the abdominal wall created defect to the stoma site and secured by sutures to the rectus sheath. The mucosa is the then everted using absorbable suture that run between the sheath or the skin and the mucosal edge.

In essence, this operation involves modification and surgical changes to three different body systems; the urinary tract, the small bowel and the anterior abdominal wall.

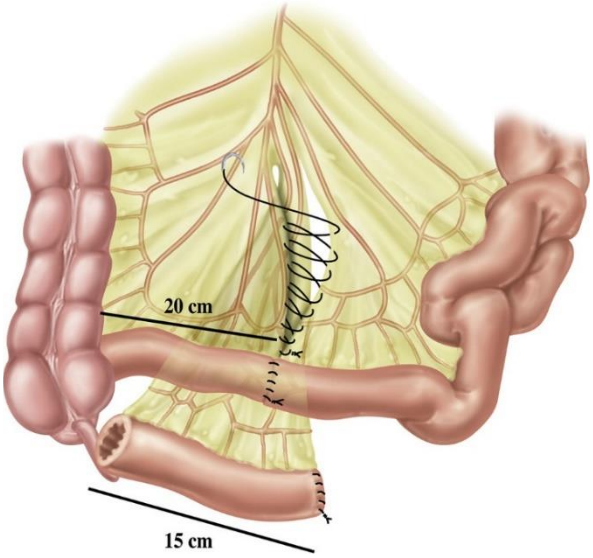

Figure 1.1. A segment of ileum isolated and the continuity of the ileum is regained using suturing, reproduced with permission from corresponding author (Colombo and Naspro, 2010).

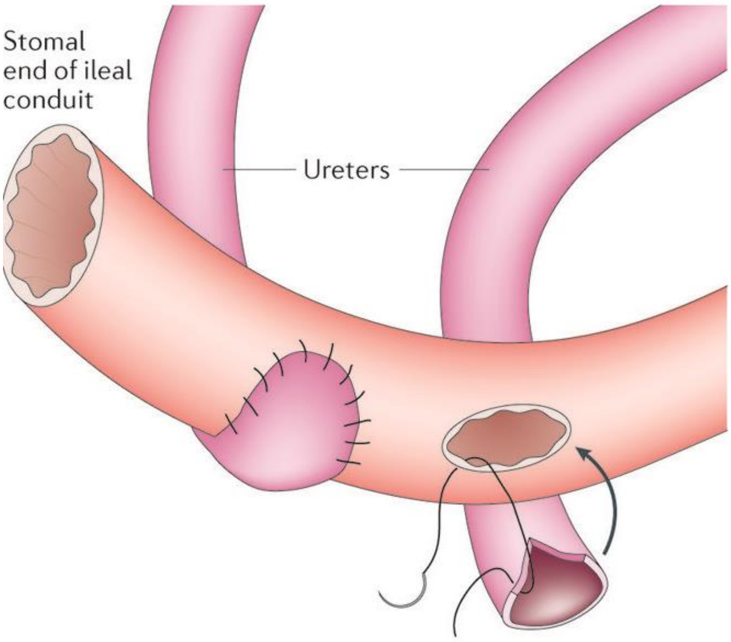

Figure 1.2. Bricker technique of uretero-ileal anastomosis, reproduced with permission from corresponding author (Lobo *et al.*, 2016a).

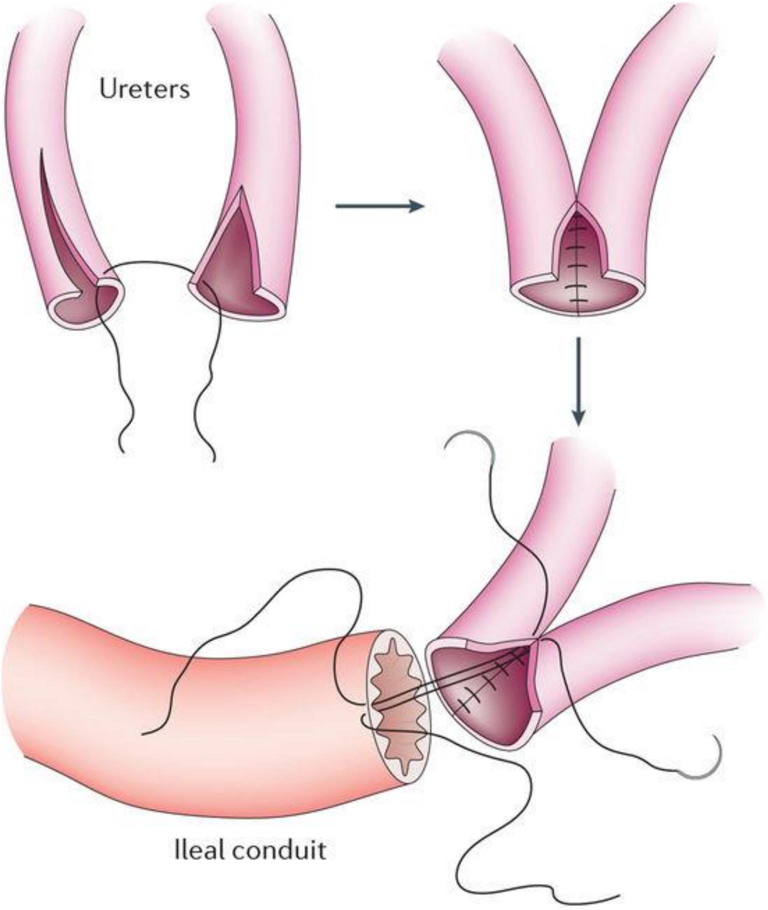

Figure1.3. Wallace technique of uretero-ileal anastomosis, reproduced with permission from corresponding author (Lobo *et al.*, 2016a).

1.3. Pathophysiological and pressure changes following ileal conduit

Following the formation of the IC, several changes can occur secondary to the new variations such as exposure of urine to bowel mucosa and absence of the ureteric anti-reflux mechanism. These alterations lead to metabolic and upper tract changes that can lead to the development of complications later on.

1.3.1. Metabolic changes

While the bladder urothelium is highly impermeable to urinary solutes, the bowel mucosa is highly permeable to water. On exposure of bowel segment to highly concentrated urine with an osmolality 500-850mOsmo per litre, the water is shifted into the IC lumen leading to loss of body fluid. This causes nocturia and leads to fluid depletion for IC patients (Cruz and Huot, 1997; Mills and Studer, 1999; Mundy, 1999; Newman and Price, 1999; Chang and Koch, 2000; Roth and Koch, 2018)

Due to the nature of the antiports present on the surface membrane of the ileal mucosa, chloride is absorbed from urine and bicarbonate is excreted into the lumen of the IC leading to metabolic acidosis. In an attempt for compensation, the kidneys excrete hydrogen ions (H^+) which is buffered by phosphate (PO_4^{3-}) leading to depletion and bone demineralisation. In order to avoid further loss of phosphate, the kidneys create another buffer which is ammonium (NH_4^+). Subsequently, this gets reabsorbed leading to further acidosis in the form of hypercholermioc metabolic acidosis (Turnberg *et al.*, 1970; Koch *et al.*, 1990; McDougal *et al.*, 1995; Stampfer and McDougal, 1997; Roth and Koch, 2018).

In addition, the vitamin B_{12} receptors are more concentrated at the terminal ileum mainly at the last 120 cm. The loss of a significant length of the terminal ileum could affect the process of absorption leading to slow depletion of body stores over few years and eventually resulting in macrocytic anaemia and peripheral neuropathy (Jahnson and Pedersen, 1993; Mills and Studer, 1999; Roth and Koch, 2018).

Normally, fatty acids are absorbed after binding to bile salts at the terminal ileum. The interruption of this process due to less absorbing surface of terminal ileum could lead to malabsorption of fat and steatorrhea. The passage of bile salts into the colon could damage the mucosa and cause secretory diarrhoea (Durrans *et al.*, 1989; Roth and Koch, 2018).

1.3.2. Effect on upper urinary tract

One of the driving forces for urological surgeons to develop the IC technique was the finding of significant reflux when colon was used as a conduit (Coffey, 1911). The effect of urine reflux on the morphology of the renal papillae has been demonstrated in animal modules (Hodson *et al.*, 1975; Ransley and Risdon, 1975). Another animal model compared the incidence of pyelonephritis between two samples, where an anti-reflux implantation technique was used for anastomosis in one group (Richie *et al.*, 1974).The results indicated incidence of pyelonephritis of 83 % in the reflux group compared to 7% in the anti-reflux one. The thin muscle layer of the ileum compared to colon, and the ileal peristaltic movement compared to the mass contraction of the colon, were both considered likely to make IC a low pressure conduit (Sagalowsky, 1995). Compared to colon, ileum is a lower pressurised conduit but unfortunately there is still an element of reflux. Several studies confirmed radiologically the reflux of urine from the ileal conduit back into the ureter and renal pelvis using loopogorams (Neal, 1985). In addition, scarring of the kidney was detected by means of renal scintigraphy using (99m)Tc-dimercaptosuccinic acid (Kristjansson *et al.*, 1995a). This occurs as a result of using the non-anti-reflux surgical technique of uretero-ileal anastomosis and also because of the increase of pressure inside the conduit. Not only stomal stenosis, but also the normal peristaltic waves that occur in the ileal conduit wall, can cause that rise in pressure. This was shown in a study that compared the pressure within the IC in 27 patients with normal upper tract to 17 patients who had upper tract dilatation, where a vigorous type of peristaltic waves with high frequency and amplitude occurred more frequently in the hydronephrotic group (Neal *et al.*, 1985; Neal, 1989).

This led to further attempts to refine the surgical technique to develop non-refluxing IC to overcome the back pressure resulting from the ileal peristaltic waves. Several such techniques were described in literature including Afferent nipple valve, afferent ileal loop, Le Duc technique, Split-cuff ureteric nipple, the serous-lined extramural tunnel (The Abol–Enein technique)(Warwick and Ashken, 1967; Studer *et al.*, 1988; Shaaban *et al.*, 1992; Abol-Enein and Ghoneim, 1994; Stein *et al.*, 1996; Sagalowsky, 1998; Schwaibold *et al.*, 1998). Despite being successful in minimising reflux, further reports showed a higher incidence of ureteric stricture with these techniques (Shaaban *et al.*, 1992; Stein *et al.*, 1996).

1.4. Long-term complications associated with ileal conduit

There is emerging evidence of the development of IC related complications over time, and that complications can continue to develop up to 20 yrs. after surgery (Shimko *et al.*, 2011). However, there are paucity of reports in the literature on rates of complication in long-term IC patients. Most of the available studies report on a mixture of short and long term complications, with a very small proportion of the patients who are 10 years or more after surgery (Hautmann *et al.*, 2011). Studies reporting complications rates continue to be added to literature, however due the lack of standardisation in reporting, comparisons between studies and drawing conclusions from the results is challenging. For example, reports of incidence of renal function deterioration following IC may differ due to the use of different methods of assessment of renal function. While some series rely on serum creatinine measures, others use MDRD formula or radiographic changes to estimate the kidney function deterioration (Kristjansson *et al.*, 1995b; Madersbacher *et al.*, 2003; Rouanne *et al.*, 2015). Similarly, the diagnosis of parastomal hernia is based on radiological evidence in some studies and only on clinical examination in others (Narang *et al.*, 2017). With the reported incidence of postoperative complications following IC reaching up to 66% of patients (Madersbacher *et al.*, 2003), there is a need to standardise the method of reporting in order to enable clinicians as well as patients to take informed decisions regarding the choice of the method of UD.

The following sections report the rates of different types of complications associated with IC as described in three of the largest available series with long median follow up. Two of the three large series that reported on long term IC complications were published by Madersbacher et al and by Shimko et al in 2003 and 2011 respectively (Madersbacher *et al.*, 2003; Shimko *et al.*, 2011). Madersbacher et al retrospectively analysed the records of 412 patients who had IC between 1971 and 1995 in Bern, and reported on 131 patients who survived for 5 years or more following their surgery. Of those, only 43 patients were survivors for 10 years or more. Shimko et al reported on their experience from the Mayo clinic in the US. The cohort was of 1507 patients who had RC and conduit urinary diversion between 1980 and 1998. 409 patients were a decade or more survivors and 215 survived 15 years or more post-surgery. In the third study, Gilbert et al reported on the rate of complications for 544 bladder cancer survivors who had IC using the registry of the 5% Medicare sample from 1998 to 2005,. The study reported the complications rate at different periods following their surgery, up to 4-5 years (Gilbert *et al.*, 2013). In addition to these three series, results from other studies that have focused only on a particular complication are described below under the relevant section describing this complication.

A list of the studies that have reported complication frequency is shown in table 1.1. Under each section, the complication will be explained with its possible causes and presentation, followed by the frequency reported in literature and then methods of treatment or prevention described.

First author	Year	Country	No. of patients	Complication reported	Type of study
Madersbacher	2003	Sweden	412	All	CS
Shimko	2011	US	1507	All	CS
Gilbert	2013	US	544	All	CS
Donahue	2014	US	433	PH	CS
Narang	2017	UK	3170	PH	SR
Kouba	2007	US	137	PH	CS
Liu	2014	US	516	PH	CS
Pisters	2014	US	496	PH	CS
Movassaghi	2016	US	670	PH	CS
Klein	1989	US	319	Stoma stenosis	CS
Magnusson	1996	Sweden	12	Stoma stenosis	CS
Wood	2004	UK	93	Stoma retraction	CS
Taneja	2009	US	45	Stoma retraction	CS
Brooke	1993	UK	37	Stoma prolapse	CS
Pernet	1985	Netherlands	132	UTI	CS
Kristjansson	1995	Sweden	18	Renal impairment	RCT
Samuel	2006	UK	340	Renal impairment	CS
Rouanne	2015	France	226	Renal impairment	CS
Tal	2007	Israel	221	Ureteric stricture	CS
Lobo	2016	UK	478	Ureteric stricture	LR
Schmidt	1973	USA	178	Urolithiasis	CS
Hall	1989	USA	898	Urolithiasis	CS
Turk	1999	USA	94	Urolithiasis	CS
Gupta	2014	USA	4,878	Bone demineralisation	CS

CS, case series; LR, literature review; RCT, randomised controlled trial; SR, systematic review

Table 1.1. Summary of studies reporting on different IC related complications.

1.4.1. Parastomal hernia:

As described above the formation of the stoma involves the creation of a channel at the abdominal wall to bring the distal end of the IC externally. The channel is created by removing an ellipse of skin, incising of the rectus sheath and dissection of the rectus muscle (Smith *et al.*, 2012). This breach of the abdominal wall creates weakness at the integrity of the wall predisposing patients to the risk of parastomal hernia (PH). Parastomal hernia was defined by Pearl as '*an incisional hernia that develops in the vicinity of a colostomy or ileostomy'* (Pearl, 1989). The European Hernia society (EHS) had defined incisional hernia as *'an abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible by clinical examination or imaging'* (Korenkov et al., 2001). On a further attempt to define PH, the EHS defined PH as *'an abnormal protrusion of the contents of the abdominal cavity through the abdominal wall defect created during placement of a colostomy, ileostomy or ileal conduit stoma'* (Smietanski *et al.*, 2014). On the same document the PH was classified into 4 categories according to size (small is ≤5 cm) and the presence of a concomitant incisional hernia. Patients with PH could present with symptoms such as pain or abdominal mass, but could also remain asymptomatic. A study of 433 patients with PH following IC showed that 40% of patients had symptomatic PH in the form of discomfort, pain or poor fit of appliance (Donahue *et al.*, 2014).

As a result of the variation of definition, the method of diagnosis, and the length of follow up, the incidence of reporting PH following IC is variable in literature (Narang *et al.*, 2017). A systematic review reported on 12 studies that matched the review inclusion criteria and of a pooled total of 3170 patients who underwent IC surgery; it reported an incidence of PH of 17% (4-35%) (Narang *et al.*, 2017). The diagnostic criteria were not reported in most of the studies. The Bern and the Mayo studies - with the longest median follow up in the review - reported an incidence of PH of 13.7 % and 14.5% respectively. In one of the 12 studies, Donahue *et al* described the incidence of PH diagnosis when clinical examination is compared to radiology to establish the diagnosis. The results showed PH diagnosed clinically in 24% of the series in comparison to 35% when imaging was used (Donahue *et al.*, 2014). The same review reported on the results of an analysis of data obtained from 5 cohorts that studied the possible risk factors for PH; this showed that female gender, high

BMI, low preoperative albumin and previous history of laparotomy were significantly associated with the development of PH (Kouba *et al.*, 2007b; Donahue *et al.*, 2014; Liu *et al.*, 2014; Pisters *et al.*, 2014; Movassaghi *et al.*, 2016).

The results of the systematic review by Narang and colleagues indicated that between 8% and 75% with a PH were offered a repair at different series. It is worth noting that the incidence of recurrence of PH following repair was 27%-50% (Narang *et al.*, 2017). In an attempt to minimise the rate of PH, some surgeons started to adopt prophylactic mesh at the area of the stoma during the surgery and RCTs showed a significant reduction of PH (Janes *et al.*, 2004; Hammond *et al.*, 2008; Lambrecht *et al.*, 2015).

1.4.2. Stomal stenosis, retraction and prolapse

One of the possible causes of stomal stenosis is the surgical technique when a small opening is created at the fascia prior to maturing the stoma (Syan-Bhanvadia and Daneshmand, 2017). Another cause is skin hyperkeratsosis which can occur due to stoma retraction leading to urine regular contact with skin causing skin irritation and keratsosis. Failure of emptying because of the stenosis could result into urinary stasis leading to infection, formation of stones and impaired renal function.

Stomal stenosis was reported to occur to 2%-8% of patients after IC (Klein *et al.*, 1989; Magnusson *et al.*, 1996; Colwell *et al.*, 2001; Madersbacher *et al.*, 2003) . Shimko et al reported an incidence of stomal stenosis in 2% of their series at a median of 9.2 years postoperatively (Shimko *et al.*, 2011).

Usually stenosis can be treated by gentle dilatation and patients might need to perform self-catheterisation to keep the stoma open (Lee *et al.*, 2018). Sometimes surgical excision of skin or even distal end of the conduit and mobilisation of the stoma could be required. In a series of 300 patients, stomal stenosis developed in 8 % of patients and only 5% of the whole series needed surgical repair (Klein *et al.*, 1989).

Stoma retraction or prolapse are two other stoma-related complications described in literature. Both have been reported collectively as stoma-related complications together with PH and stoma stenosis in some series (Madersbacher *et al.*, 2003;

Gilbert *et al.*, 2013).These two complications could possibly occur secondary to poor surgical technique or the change of the patient's body habitus.

Retraction occurrence has been reported as low as 0.5% (Klein *et al.*, 1989), but another series reported the incidence to be as high as 31% in females who have the surgery for intractable urinary symptoms (Wood *et al.*, 2004).

Stoma prolapse was reported in 0.5%-5.4% of patients (Klein *et al.*, 1989; Brooke, 1993; Kouba *et al.*, 2007b). Kouba et al showed a significantly higher rate of stoma complications (27%) in obese (BMI more than 30 kg/m^2) compared to patients with a normal BMI (less than 25 kg/m^2)(4%).

Taneja and Godoy described a new technique to minimise the risk of stoma retraction where maturing the stoma is performed prior to transposing it to the skin by defatting of the distal mesentery, placement of everting sutures immediately adjacent to the bowel mesentery in a diamond configuration, and full-thickness locking sutures to fix the eversion (Taneja and Godoy, 2009). In their series the retraction was observed in 2% of patients.

1.4.3. Infection

Urinary tract infection (UTI) is one of the most common reported complications following IC. The ascending contamination of the IC with bacteria combined with the urinary reflux into the kidney, and the use of a loop of bowel that is normally colonised with bacteria could all be predisposing factors for the development of infection at this group of patients. A series of 106 patients diagnosed with muscle invasive bladder cancer (MIBC) and treated with RC and different forms of urinary diversion demonstrated the presence of urinary bacterial colonisation at 97% of the IC group (Prcic and Begic, 2017). Neal et al reported the presence of reflux on loopogram in 72% of the normal renal units and 93% of the hydronephrotic ones in a series of 111 IC patients with a minimum 5 years of follow up (Neal, 1985). In urinary conduit patients the urine is usually contaminated by ascending gram positive mixed skin flora (i.e., streptococcal species and Staphylococcus epidermidis), however patients are mostly asymptomatic (Wullt *et al.*, 2004).

In a series of 132 patients who had IC and a mean follow up of 4.5 years pyelonephritis was found to have developed in 22 (16.6%) patients (Pernet and

Jonas, 1985).Gilbert et al reported on the rate of infection in a series of 1278 patients who underwent IC (Gilbert *et al.*, 2013). By the end of the second year post operatively, 27% had developed UTIs. During the period between 4-5 years 13.7% had UTIs. The Mayo clinic and Bern series reported an occurrence of infection in16% and 23% of patients respectively (Madersbacher *et al.*, 2003; Shimko *et al.*, 2011).The Mayo series results showed an occurrence of recurrent UTIs to 7% of patients at a median of 2.1 years (Shimko *et al.*, 2011).

Prompt treatment for active infection and investigating possible cause of recurrent infections seem to be the adequate management of UTIs in those patient rather than using long term prophylactic antibiotics , as any effort to eradicate bacteria will be in vain due to the continuous contamination from skin flora (Wullt *et al.*, 2004).

1.4.4. Renal Impairment

By far, renal impairment is the most serious long term sequela of IC urinary diversion. Renal failure following IC could occur secondary to a list of causes such as stoma or ureteric stenosis, reflux and recurrent urosepsis. The pressure effect of the IC on the upper tract has been discussed earlier in this chapter (Section 1.3.2.) , and the reflux of urine into the kidney and the effect of that reflux had been demonstrated in animal models (Hodson *et al.*, 1975; Ransley and Risdon, 1975). The radiological changes and the reflux evidence on loopograms confirmed these findings at patients' series (Neal, 1985).

Different methods were used to measure renal deterioration in patients including blood creatinine level, estimated glomerular filtration rate (eGFR), upper tract imaging, renogram and isotopic GFR (Kristjansson *et al.*, 1995a; Madersbacher *et al.*, 2003; Samuel *et al.*, 2006; Hautmann *et al.*, 2011; Shimko *et al.*, 2011; Jin *et al.*, 2012; Eisenberg *et al.*, 2014; Rouanne *et al.*, 2015). This led to a wide range of reported rates of renal impairment following IC postoperatively. The use of isotopic GFR measurement is considered to be the most accurate way of assessment of the renal function in those patients. Chromium -51 is ideal for this assessment as it is freely filtered by the glomeruli and its reabsorption by the intestinal mucosa is minimal (Hautmann *et al.*, 2011).

In 1995 Kristjansson used 51Cr-EDTA to measure the renal function pre-operatively and after a mean follow-up of 123 months (range 36-198) (Kristjansson *et al.*, 1995b). The results showed a drop of GFR by >25% in 28% of the IC group. Samuel *et al* used serial isotopic (99m) technetium-diethylenetriaminepentaacetic acid GFR and F+20 (99m) technetium-mercaptoacetyltriglycine renography to monitor the renal function in 178 patients who had more than four years of follow up (Samuel *et al.*, 2006). 29% of the cohort demonstrated worsening renal function, and hypertension, recurrent urinary sepsis and an initial post-diversion GFR < 50 ml / minute / 1.73 m were found to be risk factors. No surgical cause was found in 18% of the cases who had deteriorating renal function. A retrospective study of 226 patients who underwent RC and IC and had a median follow-up period of 91 months (range, 61-235 months), showed median eGFR decreased from 66 to 59 mL/min/1.73 m2 (Rouanne *et al.*, 2015). The results showed a rapid decline during the first 2 postoperative years (-9 mL/min/1.73 m2 and -4 mL/min/1.73 m2 in the first and second year, respectively). Urinary obstruction was only diagnosed in 51 patients (23%)**.** There seems to be no confirmed association between the type of UD and the rate of development of renal failure when IC is compared with bladder substitution (Jin *et al.*, 2012; Eisenberg *et al.*, 2014; Nishikawa *et al.*, 2014).

Surgical management to correctable cause is warranted in those patients to halt the loss of renal function and ureteric re-implantation was shown to preserve the renal function (Neal, 1985; Samuel *et al.*, 2006; Rouanne *et al.*, 2015)(Table 1.1).

1.4.5. Uretero-ileal stenosis

Uretero-ileal stricture is one of the IC complications that demonstrates the necessity of follow-up for those patients. This is because, while some patients who have stricture develop symptoms like flank pain or infection, most are asymptomatic. In a case series of 221 patients of which 12.7% developed uretero-ileal stricture, 75% of those patients were asymptomatic (Tal *et al.*, 2007). Untreated stricture could lead to impaired renal function and recurrent UTIs. The stricture usually develop on the left side (Anderson *et al.*, 2013; Richards *et al.*, 2015a), which could be explained by the increase of tension on the anastomosis due to the formation of the stoma usually on the right side and the need to mobilise the left ureter to pass in between the aorta and the inferior mesenteric artery . For asymptomatic patients, the presence of hydronephrosis on upper tract imaging and the level of obstruction demonstrated on CT urogram or loopogram can confirm the diagnosis. It is not clear what is the exact cause for development of uretero-ileal stricture, but urine leak, tension and ischaemia are all believed to play a role (Large *et al.*, 2013; Richards *et al.*, 2015b).

On average 10% of patients develop uretero-ileal stricture usually within the first year although it can develop later (Tal *et al.*, 2007; Shimko *et al.*, 2011; Lobo *et al.*, 2016b; Lee *et al.*, 2018). Stricture was not particularly associated with certain technique on comparing Wallace and Bricker anastomotic techniques (Kouba *et al.*, 2007a; Davis *et al.*, 2015) (Table 1.1).

Immediate management should involve insertion of a nephrostomy or a stent if possible to preserve the kidney followed by treatment of the stricture. Endoscopic management have evolved significantly where balloon dilatation or endoureterotomy have shown good success rate (Wolf *et al.*, 1997; Lin *et al.*, 1999; Laven *et al.*, 2003). Nevertheless, open repair is required in recurrent or difficult cases but with usually high sustainable success rates reaching up to 80% compared to 30-50% success rate for endourological approach (Laven *et al.*, 2003).

1.4.6. Urolithiasis

Patients with IC are prone to development of urinary calculi due to the existence of several risk factors for stone formation. As discussed earlier (section 1.3.1), the high permeability of ileum and the concentrated nature of urine lead to shift of fluid from the body to IC leading to a state of dehydration (Newman and Price, 1999; Roth and Koch, 2018). Lack of fatty acids absorption due to loss of long segments of ileum could cause binding to calcium leaving oxalate free causing hyperoxaluria forming calcium oxalate stones (Steiner and Morton, 1991). Chronic acidosis result into failure of the kidney to produce citrate; a stone crystallisation inhibitor; increasing the risk further (Rudman *et al.*, 1980; Pak, 1991). In addition, the colonisation of IC with urea-splitting organisms can predispose those patients to struvite stones (Chang and Koch, 2000).

Similar to other complications, the reported incidence of urinary calculi in IC is variable. It has been reported to be as low as 1.1% and as high as 38 % (Schmidt *et al.*, 1973; Hall *et al.*, 1989; Gilbert *et al.*, 2013).The incidence of stone formation following IC was reported either within comparative studies of different urinary diversion techniques or a retrospective cohort reporting on IC complications. One study comparing the incidence of upper tract calculus amongst two groups, one which received a non-continent conduit diversion and another which had a continent diversion reported an incidence of 11% in the conduit group (Turk *et al.*, 1999). Another study comparing stone formation in refluxing and non-refluxing IC found the incidence to be 38% and 11% respectively (Hall *et al.*, 1989). Madersbacher et al have reported in their series of 412 patients an incidence of urolithiasis of 9% during a median follow up of 98 months. In the Mayo clinic series, 15.3% developed stones at a median of 2.5 years post-surgery.

The treatment of stone disease in this group of patients was found to be challenging due to the anatomical changes and the higher incidence of co-morbidities (Okhunov *et al.*, 2011; Hertzig *et al.*, 2013). Patients could be treated with all 3 modalities of stone surgery; ESWL, PCNL and ureteroscopy; but with higher complication and recurrence rate. Preventative measure have been suggested by Okhuno et al such as empting the conduit with catheterisation, correction of hypovolemia or hypocitraturia, prophylactic antibiotics and the use of acetohydroxamic acid as a urease inhibitor (Okhunov *et al.*, 2011).

1.4.7. Metabolic acidosis

As described earlier (section 1.3.1), chloride absorption from urine, excretion of bicarbonate and the reabsorption of ammonium could all lead to hyperchloremic metabolic acidosis (Turnberg *et al.*, 1970; Koch *et al.*, 1990; McDougal *et al.*, 1995; Stampfer and McDougal, 1997; Roth and Koch, 2018). This complication is expected to occur with lower incidence in IC compared to colonic conduit and continent diversion due to short contact time between urine and bowel mucosa. The development of such a complication should raise concern regarding the conduit emptying and initiate investigation such as loopogram to rule out stoma stenosis (Amini and Djaladat, 2015).Patient with metabolic acidosis could present with symptoms of weakness, lethargy, and weight loss.

Gilbert et al reported an incidence of metabolic changes/ acidosis in 19.4% (242/1,248) patients at 0-2 years and 8.6% (47/544) at 4-5 years (Gilbert *et al.*, 2013). The Mayo series defined metabolic acidosis as bicarbonate level < 20 mg/dl or requiring treatment and was found in 108 patients (10.2%) at a median of 1 year (Shimko *et al.*, 2011).

Alkalinising agents such as potassium citrate and sodium bicarbonate are used to correct the acidosis in those patients(Amini and Djaladat, 2015).

1.4.8. Vitamin B_{12} deficiency

Because of the lengthy presence of vitamin B_{12} receptors at the terminal ileum and the large human stores, this complication usually takes up to 3 years to develop (Thompson and Wrathell, 1977; Mills and Studer, 1999).

At the Mayo series, low vitamin B_{12} levels were detected in 32 patients (3%) of the series at a median of 9.1 years (Shimko *et al.*, 2011).

Vitamin B_{12} could easily be monitored by an annual blood check of serum levels and equally easy to treat by replacement oral supplements (Roth and Koch, 2018).

1.4.9. Bone demineralisation

Due to the development of acidosis, the kidney compensate by excreting hydrogen ions buffered by phosphate which is essential for bone mineralisation (Newman and Price, 1999). Experiments in animal models have confirmed that negative effect over bones (Lemann *et al.*, 1967).

In a cohort of 50,520 of non-metastatic bladder cancer patients of whom 4,878 of had cystectomy and urinary diversion, cystectomy was associated with a 21% greater risk of fracture compared to the rest of the cohort who received endoscopic treatment (Gupta *et al.*, 2014). The incidence of fracture in the cystectomy group was 6.55 fractures per 100 person-years.

For this complication, it is better to treat the underlying acidosis rather than only using calcium and Vitamin D supplements for treatment (Roth and Koch, 2018).

1.4.10. Bowel complications

Following RC and IC, different bowel complications can occur. These could be in the form of diarrhoea secondary to the metabolic effects described earlier, constipation or obstruction due to adhesions, and enteric fistula secondary to bowel injury and poor healing.

Most of the reports have understandably focused on serious bowel related complication such as bowel obstruction and development of enteric fistula. Other less concerning complications such as constipation or diarrhoea are less reported in literature. Bowel related complications were reported in 20% and 24% patients at a median follow up of 18 and 36 months in the Mayo clinic and Bern series respectively (Madersbacher *et al.*, 2003; Shimko *et al.*, 2011). Obstruction was the most common bowel related complication in both series. The bowel obstruction is believed to occur secondary to intestinal stenosis, adhesion bands, internal hernia, or volvulus (Amini and Djaladat, 2015). Gilbert et al reported an incidence of enteric fistula of 1.8% during the first 2 years following surgery; this dropped to only 0.4% 4-5 years postoperatively (Gilbert *et al.*, 2013).

In the Mayo clinic series 7% of the bowel obstruction required surgical intervention, while the percentage rose to 50% at the Bern group of patients.

1.5. Patient reported outcomes and quality of life after ileal conduit

Over the past decade, the use of patient-reported outcomes (PROMs) have become more popular and these measures has been used by researchers to investigate how the outcomes of treatment and surgery can be improved (Sanda *et al.*, 2008; Coyne and Kelleher, 2010; Glaser *et al.*, 2013; Borofsky *et al.*, 2017). PROMs allow researchers to explore a different perspective from that of the clinician team, one that is only experienced by the patients and also, in some instances, their families. A PROM is defined as any report coming directly from the patient, without interpretation by physicians or anyone else (Health *et al.*, 2006; Patrick *et al.*, 2007). This could include how they function or feel in relation to a disease or treatment, health-related quality of life (HRQoL) and treatment satisfaction.

To date, PROMS have been relatively little used among IC patients, although IC surgery can potentially have a significant impact on patient quality of life (QoL), functioning, wellbeing and daily life. In one study, having a stoma, wearing bags, urine leak and the odour were found to negatively affect patients' functional, emotional, social and mental wellbeing (Bjerre *et al.*, 1994). This study compared survey responses of 26 patients who had a continent urinary diversion to 50 who had IC found a significant increase at leakage related distress (80%) at the IC group (Bjerre *et al.*, 1994). The same study showed a significant decrease at the physical contact between patient and partner reaching to 43% of the respondents. In a literature review of 21 studies which compared IC to orthotopic neobladder with a total of 2285 patients, sixteen studies reported no difference in QoL and four studies reported a better QoL with orthotopic neobladder (Ali *et al.*, 2015). One study reported a better QoL in ileal conduit patients.

The adverse effect of IC could go beyond health and wellbeing, to impact patients' careers and financial status. A study of 47 patients who were working before surgery found that 34% had made permanent changes in their working conditions after surgery (Nordström *et al.*, 1990). While some of them changed from full-time to part-time working, others stopped work all together. On further follow up to the same cohort, a further 32% of patients who initially resumed work after their operation subsequently made permanent changes in their working conditions (Nordström *et al.*, 1990).

The literature lacks studies in which IC patients report on physical complications. Most of the available series (such as those in Table 1.1) relied on hospital attendance and investigations, rather than patient reports, to identify complications. While this is of great value, it does not necessarily capture the patients' perspectives, personal community experience and expectations. Due to the nature of the effect of IC on the patient's life, not only physical but also psychological and social, data on patient reported complications could add valuable information for those who provide care to this patients.

1.6. Follow up

As a result of the risk of complications and the potential adverse effect on patients' quality of life following IC, a follow up/surveillance scheme seems essential to allow for early detection of medical complications and provide the patient with the emotional and psychological support they require. Traditionally, cancer patients have received follow-up care at the hospital at which they were treated. This approach was believed to be safer as it provides specialist care for patients thus enabling best support and early detection of recurrence. However, this model was scrutinised over the last years and alternative models have started to be examined (Howell *et al.*, 2012; Emery *et al.*, 2014).

1.6.1. Current guidelines

Review of the current Urological national and international guidelines indicates there is no guidelines dedicated specifically to the follow up of ileal conduit (American Urological Association, 2018; BAUS, 2018a; European Association of Urology, 2018; The National Institute for Health and Care Excellence (NICE), 2018). Generally, the follow up of IC constitutes - if present at all - a short part of the follow up section in guidelines on the management of bladder cancer.(The National Institute for Health and Care Excellence 2015; Alfred Witjes *et al.*, 2017; Chang *et al.*, 2017).

The American Urological Association (AUA) guidelines recommends imaging for the abdomen including upper tract every 6-12 months for up to 3 years, then suggests that this may continue annually(Chang *et al.*, 2017). The guidelines states that one of the aims for this imaging is to detect hydronephrosis in addition to cancer recurrence. An annual blood test is recommended for renal function. The guidelines highlighted the need to monitor for metabolic changes such as hyperchloremic metabolic acidosis and vitamin B_{12} levels without specifying the frequency of monitoring.

At the end of the European guidelines on muscle invasive bladder cancer and its follow up, it is stated that bladder cancer patients who had urinary diversion '*deserve functional follow-up'* (Alfred Witjes *et al.*, 2017). It is suggested that follow up could stop after 15 years. These guidelines also name the potential complications associated with ileal conduit, but there are no recommendations regarding tests required and the frequency of investigations to detect the named complications.

The National Institute for Health and Care Excellence (NICE) guidelines recommend at least an annual upper tract imaging and glomerular filtration rate estimate to monitor for hydronephrosis, stone formation and renal function(The National Institute for Health and Care Excellence 2015). NICE further recommended monitoring for metabolic acidosis, vitamin B_{12} deficiency and folic acid level at least once a year. In the research recommendation section, these guidelines raise the question of whether scheduled follow up or symptom-driven review is better for the overall survival, patients' quality of life and cost.

1.6.2. Bladder cancer survival and models of follow up

Supported by several randomised trial results, the use of neo-adjuvant chemotherapy over the last decade has led to significantly improved survival of bladder cancer patients (Sherif *et al.*, 2004; Advanced Bladder Cancer Meta-analysis, 2005; International Collaboration of *et al.*, 2011). The combined results of 2 NORDIC studies showed an absolute mortality risk reduction of 8% in 5 years (Sherif *et al.*, 2004). A phase III trial of 976 patients showed a significant reduction in death rate equivalent to an increase of 10 years cancer survival from 30% to 36% (International Collaboration of *et al.*, 2011). With the increasing number of cancer survivors -for both bladder and other cancers - it is increasingly recognised that the limited resources in secondary care may not provide the most appropriate follow-up care and support required for cancer patients (Richards *et al.*, 2011). For example, the limited time available for outpatient follow up appointments might not suffice to allow for the provision of the support many survivors need. In addition, it may be that traditional hospital-based follow-up may not be optimal from the perspective of the patient. A national quantitative study of cancer survivors in the UK found that patients feel abandoned after finishing their treatment (Cardy *et al.*, 2006).This has stimulated interest in exploring whether other methods of non-hospital follow up could be implemented. Clearly, any model of surveillance for post-RC bladder cancer patients should not only address cancer recurrence detection, but also IC follow up as it is the most commonly used urinary diversion surgical approach following cystectomy (Cresswell *et al.*, 2015; Groeben *et al.*, 2018; Jefferies *et al.*, 2018).

The conventional hospital based follow up was challenged by several studies in which the usual physician led follow up was compared to nurse-led or primary care follow up (Howell *et al.*, 2012; Emery *et al.*, 2014). A systematic review of ten practice guidelines and 9 RCT showed no significant difference in the recurrence detection rate when comparing conventional follow up with nurse led or primary care led follow up (Howell *et al.*, 2012). These studies covered a variety of cancers such as colorectal, breast and prostate. Another review demonstrated similar findings when comparing physician led and nurse led follow up (Lewis *et al.*, 2009a). This review found not only no significant difference in recurrence detection and survival but also reported on one study that found that nurse-led follow-up was associated with better HRQoL outcomes. The results of a non-randomised cohort of 169 patients with prostate cancer who were allocated to telephone nurse-led follow up or the standard medical follow up showed no significant difference at patient satisfaction after 6 months (Leahy *et al.*, 2013). There was a suggestion of a greater patient satisfaction for the nurse-led model in this study, but this was not statistically significant.

In terms of primary-care based follow-up, it is recognised that it could be less costly but would require the development of clear guidelines, well established channels of communication between primary, secondary and tertiary care and ready accessibility to specialist service when required (Emery *et al.*, 2014). One qualitative study which explored cancer patients' views found that while patients appreciate having their care locally, they emphasised the need for further training to GPs to fulfil this role (Hall *et al.*, 2011). Another review of qualitative studies exploring patients' and health professionals' views about cancer follow up showed that patients find hospital-based regular specialist follow up reassuring (Lewis *et al.*, 2009b). On the other hand, participants noted that secondary care appointments could lack the dedicated time required to discuss issues and obtain/provide psychological support, due to the pressures on the service.

One of the models that could address the burden in secondary health care and, at the same time, patients' concerns regarding lack of cancer care experience in the community is shared community based care model. This was examined and found to be successful for prostate cancer follow-up (Emery *et al.*, 2017). A prospective randomised trial of 88 men who completed their treatment for low / intermediate risk prostate cancer were randomised to usual care or shared care, there was no statistically significant differences between groups with regard to prostate cancer-specific quality of life ,satisfaction with care and compliance with PSA monitoring.

Along the same lines, there is growing evidence that patients' active involvement in their own care could minimise pressure on both primary and secondary care. A review of literature has found that there is a growing trend towards cancer patients' empowerment that allows them to self-manage their condition and even self-refer to specialist care (Davies and Batehup, 2011). The review concluded that an active role for specialist nurses, and more use of technology as a mean of communication, could facilitate this approach of patient self-management. The results relied on 20 studies covering breast, colorectal and lung cancer; and one study involved patients with a variety of urological conditions (Fletcher *et al.*, 2006).

1.7. Normalisation process theory and the study of implementation

1.7.1. Rationale for a new (alternative) surveillance schedule for IC patients

The high rate of IC related complications, the improvement in survival of bladder cancer patients and the annual thousands of patients who had ileal conduit as a method of urinary diversion are all reasons for the development of a standardised long term surveillance schedule or protocol for IC patients. The developers of such a protocol should take into consideration not only the clinical effectiveness of the protocol in terms of early detection of complications and the effectiveness at addressing QoL issues, but also the process of implementation of the new protocol. A new follow-up protocol could be considered a complex intervention as it will involve several stakeholders and will be implemented within the complexity of the health system.

1.7.2. Frameworks and theories for developing and evaluating interventions

The Medical Research Council developed a widely-used framework for the development and testing of complex interventions(Campbell *et al.*, 2007; Craig *et al.*, 2008). It was suggested that the development of intervention should rely on a theoretical foundation and that qualitative methods could represent a helpful tool in understanding the process involved in developing the intervention and its evaluation (Hardeman *et al.*, 2005; Oakley *et al.*, 2006; Lewin *et al.*, 2009)

The Normalisation process theory (NPT) is a middle range social theory that proposes '*a working model of implementation, embedding and integration in conditions marked by complexity and emergence'* (May and Finch, 2009). This theory provides a framework that aids the understanding and evaluation of how an intervention, such as a surveillance schedule for example, is embedded and sustained into practice. The NPT aids the understanding of the promoters and inhibitors in the process of implementation and evaluation of an intervention (i.e. new follow up protocol, a new technology, etc.) into a complex organisation, such as the NHS. It extends beyond the early stages of implementation to an advanced stage of normalisation where the new intervention is embedded into routine practice. The theory suggests that the understanding of the process of implementation should rely on the work that people do or their acts rather than what they say or believe.

At its early iteration, the NPT focused largely on explaining the operationalisation of interventions in health care (May, 2006; May *et al.*, 2007). This was based on secondary analysis of several qualitative studies. Later on, the theory broadened in scope to explain how individuals are enrolled into the intervention, and how intervention are appraised. The value of NPT as a theory of implementation is that it provides a holistic approach for the understanding of how a practice is embedded into day practice in comparison to other frameworks where individual actors' behaviours and popularity of the intervention into organisation are the main focus of study for innovations introduction (Greenhalgh *et al.*, 2004; King and He, 2006; Elwyn *et al.*, 2008). A systematic review of studies that have adopted the NPT framework showed that many authors found that NPT provides a generalised framework that is beneficial for the analysis of the implementation process at variable settings and allowed for the gradual development of knowledge over time (McEvoy *et al.*, 2014). Because NPT is an action theory, and therefore more concerned with explaining what people do rather than their attitudes or beliefs, it comprises four main constructs that represent different kinds of work that people do around implementing a new practice **-**Coherence, Cognitive Participation, Collective Action, and Reflexive Monitoring **-** which are described by its founders as follows (May *et al.*, 2018):

Coherence

This represents the **sense-making work** that people do when they are implementing a new practice or intervention. It describes the participants' understanding of the intervention, why it was introduced, how is different from other practice, and its benefits. This involves:

- **Differentiation** – the understanding how the new practice is different from others including existing ones**.**
- **Communal specification** – people working together to build a shared understanding of the objectives, and expected benefits of a set of practices.
- **Individual specification** – the individuals' work that will help them to understand their own role.
- **Internalisation** – the work of understanding the value of the intervention.

Cognitive Participation

*'It is the **relational work** that people do to build and maintain a community of practice around a new intervention.'* This reflects the participants' commitment to and engagements with the new practice, their willingness to invest time and effort to implement it. This includes:

- **Initiation** – the work done by key persons to drive the new practice forward.
- **Enrolment** – participants' work to organise themselves to enact the new practice effectively, for example getting members of the team to buy in the new protocol or intervention.
- **Legitimation** – the work of ensuring that other participants believe it is right for them to play an active role.
- **Activation** – after starting the new practice, this is the work of defining the actions that is required to sustain the new practice.

Collective Action

This is the **operational work** that people do to implement an intervention and embed it into their daily practice. It describes what actually happen on the ground, how actors deal with artefacts and how skills and resources are allocated to implement the intervention. It is formed of:

- **Interactional Workability** – this describes the interaction work that people do with each other, and with the new intervention itself to make it work.
- **Relational Integration** – the knowledge work that people do to build confidence in the effectiveness of the new practice.
- **Skill set Workability** – the tasks allocation work according to the available skills within the team members.
- **Contextual Integration** – the work of allocation and management of available resources to operationalise a new practice.

Reflexive Monitoring

It is the **appraisal work** that people do to assess and build a feedback on how the new practices affect them. It also describes how participants make changes following the appraisal work. This includes:

- **Systematization** – the work of collecting information**.**
- **Communal appraisal** – working together to evaluate the practices.
- **Individual appraisal** – individual’s work to appraise the impact of the new intervention on them.
- **Reconfiguration –** the work of modifying practice as a result of appraisal work.

One of the recognised challenges of using NPT was the perceived overlap between different constructs which can make the allocation of codes challenging in some instances. Another observation was the inability to map some themes under the theory constructs, however the authors of the theory do recognise this and as a middle-range theory it is not expected to explain everything (McEvoy *et al.*, 2014).

The NPT has been used extensively as a theoretical framework to conduct many studies that have investigated the implementation of new interventions inside and outside the health care system. For example, it has been used to investigate the implementation of different types of interventions such as an alcohol screening tool, a chronic kidney disease management protocol, and a maternity electronic record system (Gask *et al.*, 2010; Atkins *et al.*, 2011; Blakeman *et al.*, 2012; Bamford *et al.*, 2014; O'Donnell and Kaner, 2017; Scantlebury *et al.*, 2017; May *et al.*, 2018). In addition, Murray et al proposed that the use of NPT could facilitate the considerations regarding the implementation of an intervention at the very beginning of the development process (Murray *et al.*, 2010).

Many of the studies that adopted NPT as theoretical framework used qualitative methods to collect data (May *et al.*, 2018). Qualitative research methods have been increasingly embraced in the health research field, as these methods enable the researchers to obtain a deep understanding from the participants’ perspectives; this can enable answering different types of questions - such as ‘how’ and ‘why’ - that are not normally answered by quantitative methods (Davison *et al.*, 2008; Bristowe *et al.*, 2015).

In the process of the development and/or implementation of a standard surveillance protocol for IC patients, different health care professionals in both primary and secondary care may be involved. Qualitative methods could produce valuable data that informs the development of alternative follow-up protocol for these patients.

1.8. Aim and objectives of the study

The main aim of this study is to investigate IC patients' short and long term experience following their operation and to explore the implementation of current practices of follow up for IC patients and to understand why and how a "new" (alternative) model of surveillance for IC patients could be successfully developed and implemented. In order to fulfil its aims, the study was formed of two parts:

- **Study A:** Patient national survey
- **Study B:** Current practice & alternative models of surveillance for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory

1.8.1. Study A objectives:

- To use patients' own reports and experiences of complications at different periods following surgery to quantify their frequency and determine whether this is affected by demographic and clinical factors, including age, gender, time since operation, and indication of surgery.
- To record the nature of the follow up received by patients after surgery, including their access to stoma nurse.
- To assess patients' satisfaction with their current follow up.
- To explore patients' views of the optimum follow-up and to identify the factors (such as experience of complications or access to stoma nurse) that could be associated with those views.

1.8.2. Study B objectives:

- To describe current practice with regard to follow-up of IC patients and any associated problems/challenges/limitations.
- To explore health professionals' views regarding the need for an alternative model of surveillance, its best setting and the appropriate investigations.
- To identify barriers and facilitators to implementing alternative models.

1.9. Thesis outline

Following this Introduction chapter (literature review and aim of the study), chapter 2 will describe the methodology of both study A & B in details. On chapter 3, the results from study A (Patient national survey) will be presented. This will describe patients' demographics, their experience post-surgery, their satisfaction with follow up and their preference of surveillance settings. The results of the statistical analysis examining the association between patient characteristics and their reporting of complications, their satisfaction and their preferences for follow up will be presented in details.

Chapter 4 contains the results of thematic analysis of the interviews with health professionals and the outcome of mapping the resulting themes under the NPT constructs.

Chapter 5 presents the key findings and the strengths and limitations of each of the studies. A comparison of the findings with literature will be described followed by the implications of the study results and potential areas for future research.

Chapter 2. Materials and Methods

2.1. Study A: Patient national survey

The aim of this phase of the study was to investigate IC patients' short and long term experience following their operation and identify their preferences for follow up.

2.1.1. The role of the Urostomy Association

The survey took place in the UK through the Urostomy Association (UA) which is a UK registered national charity representing the interests of people with a urinary diversion. The survey was developed by AA and RSP (MD supervisor) following discussions with UA members at one of their annual meetings. The discussions that took place with the patients at the UA meeting were about the need for getting the voice of urostomy patients heard regarding their condition and their follow-up. These discussions revealed the variations in the follow-up received by patients and the possible lack of awareness at primary care of patients' care needs that arise because of urostomy associated complications. Subsequent literature review (chapter 1) showed the absence of patient reported outcomes after IC apart from measurement of HRQoL. This drove the development of the questionnaire, the purpose of which was to measure IC-related complications as experienced by patients and explore their experiences of, and preferences for, follow up. The UA carries out regular surveys of its members and the survey for the current study was adopted by the UA as their annual survey for the year 2012.

2.1.2. Designing the patient questionnaire

The questionnaire explored four main areas. These were: patients' experience of complications following IC; the follow up they have received; their satisfaction of care; and their views of the optimum surveillance. The review of literature (chapter 1) reporting the complications of IC operations informed the questionnaire development. The main complications identified in the literature were: urinary tract infections (UTI), parastomal hernia, urolithiasis, appliances issues, bowel, renal and skin complications. These were used to develop a list of complications that patients were asked about throughout the questionnaire. The differences in reports of the frequency of complications in literature resulted in the development of a separate question asking the patients to rank the complications they had experienced according to frequency. In addition, the increasing evidence of successful models of a community based pathways developed for cancer patients follow up encouraged us to explore this setting of follow up by asking the patients about their view of primary care follow up (Howell *et al.*, 2012).

It was considered that a self-administered questionnaire would be preferable to an interviewer-administered one for the following reasons. Firstly, it would allow patients to express themselves freely, reducing the possibility of bias. Secondly, it would minimise the burden on the student of data collection, allowing the possibility of increasing the sample size within the same amount of resources (Bowling, 2005)

The first draft of the questionnaire was pre-tested among 14 patients who were members of the UA and all were ≥ 5 yrs. after IC surgery. These members were selected and approached by the secretary of the association and agreed to help with the pre-testing of the questionnaire. The aim of the pre-testing was to check for the clarity of questions, face validity and to reveal any complications that were not addressed in literature but experienced by this population of patients. The demographics of the 14 patients are shown at table 2.1. The patients received the first draft personally from the UA secretary in an envelope containing a covering letter and information sheet in addition to the questionnaire. A free text box was provided at the end of the questionnaire inviting participants to give their opinion of the questionnaire and to suggest modifications or additions.

Patient characteristics	N
Gender	
Male	4
Female	10
Age at surgery	
<60	2
≥60	12
Indication for surgery	
Benign	8
Cancer	6
Time since surgery(yrs.)	
5-10	2
>10	12

Table 2.1. Demographics of the pre-test sample.

The pre-testing results were used to refine the content and to produce the final version of the patient survey. The following changes were made:

1. Adding a phrase after question 11 to ask the patient to skip questions 12 and 13 if their answer was ‘No’ to Q11.

2. Adding a question about the easiness of access to stoma nurse.

3. Adding a question asking those patients who indicated that transfer of (follow-up) care to their local doctor was inappropriate, why they felt this.

4. Revising the wording of the question where patients were asked to rank the complications according to the frequency. A key was added to the question to explain what each number represent in term of frequency. For example 0 represents never, 1 represents rarely etc.

The final questionnaire was formed of 5 main sections and was named ‘Ileal conduit experience questionnaire’ (ICE-Q) (Appendix 1). The first section included demographic questions, the indication and the date of surgery. Section 2 explored the patient experience of complications during three periods following surgery: up to 2 years, 2-5 years and after 5 years. The third section asked about experience of post-hospital discharge if applicable, patient satisfaction with care and access to stoma nurse (SN). The fourth section of the ICE-Q explored the care needs of patients with a urostomy, their view of community follow up by local doctor and their opinions of the optimum follow up schedule for the first 2 years and afterwards. The final section asked the patients to rate the IC-related problems they suffered from according to their frequency. The questionnaire was over 9 pages and had 21 questions in total.

The questionnaires were dispatched between May and July 2012 to 2000 members selected randomly by UA from their membership database. Each member received a covering letter, information sheet (Appendix 2) and a freepost return envelope with the questionnaire. It was emphasised that participation was entirely voluntary and that the questionnaire responses would be analysed and presented anonymously. Filling the questionnaire and returning it was considered to be consent for participation.

The completed questionnaires were returned to the UA national office and all were delivered to the RSP office at the Freeman hospital. The completed questionnaires were stored in secure NHS offices of, firstly, RSP and then, AA.

2.1.3. Data entry, checking and clearing

Of the 2000 patients invited to participate, 1190 (59.5%) returned the questionnaire. AA set up an Excel spread sheet where the responses were manually transferred from the questionnaire into Excel spread sheet by two individuals (AA, JO). AA entered the data from 442 questionnaires and JO from 650. Returned questionnaires from 98 patients were excluded due to incomplete answers; questionnaires with incomplete answers to any of the questions at the first section (demographics, date and time of surgery) or second section (report of complications) were considered incomplete. The data was all then re-checked for accuracy by AA. For each of the 1092 included questionnaires, the answer to a randomly selected question on the hard copy was compared to the equivalent response on the dataset spreadsheet. All data entry errors found in this way were corrected.

2.1.4. Data analysis

The data was coded to facilitate analysis. The data was in the form of 21 variables initially corresponding to the number of questions. Another 24 new variables were created for analysis. Two variables were created where patients were categorised into three age groups (according to their age at the operation) (<60, 60-74, ≥75) and three categories according to time in years since operation (<5, 5-10, >10). For each of the seven complications, two new categorical variables were created, one' Ever reported' (Yes/No) and another 'Ever reported as frequent' (Yes/No). In addition, two new categorical variables were created for 'Ever reported a complication' (Yes/No) and 'Ever reported a frequent complication' (Yes/No). Another 2 continuous variables were created to represent the number of 'Ever reported' and 'Ever reported as frequent' complications; these took values in the range 0-7. A categorical variable was created to identify patients who reported ≥ 3 complications (Yes/No). Another categorical variable was created to show those who preferred lifelong follow up (Yes/No). For simplicity, the access to stoma nurse variable was converted to a binary variable (Easy / Very easy or Difficult / Very difficult). Another categorical variable was created to identify whether respondents had answered a question that asked them to give a reason if they think GP follow up is inappropriate; Answering this question was considered implicitly to represent ‘Lack of preference of community follow up’.

The coded data was exported to Stata®14 software in which statistical analysis was conducted. All the variables and values were labelled in Stata. Chi square tests were used to identify associations between reporting complications, reporting being discharged from secondary care follow up, dissatisfaction with follow up, lifelong preference of follow up, lack of preference of community follow up and each of the patient characteristics (age group, years since surgery, indication for surgery, discharge from secondary care and access to stoma nurse). One-way anova was used to compare the mean number of reported complications (Ever reported and Ever reported as frequent) across different categories of patients characteristics variables. When there were unequal variances in the compared groups, the Kruskall-Wallis test was used instead of anova to compare the medians and distributions.

Multivariable logistic regression models were developed to identify associations between reporting complications and respondents’ characteristics (age group, years since surgery, indication of surgery, discharge from secondary care and access to stoma nurse). This was done separately for each type of complication (Ever reported and Ever reported as frequent), for reporting any complication (Ever reported a complication and Ever reported a frequent complication) and for reporting ≥ 3 complications. Similarly three models were developed to identify associations between each of dissatisfaction with follow up, lifelong preference of follow up, lack of preference of community follow up and the patient characteristics. These 3 models were re-run adding 2 more variables (Ever reported a complication and Ever reported a frequent complication) to identify further possible associations with reporting complications. A multivariable logistic regression models was developed to identify association between reporting discharge from secondary care and respondents’ characteristics (age group, years since surgery and indication of surgery). Another multivariable logistic regression model was run to identify the association between referral back to secondary care after discharge and patients’ characteristics (age group, years since surgery, indication of surgery and access to stoma nurse) initially, with this repeated adding 2 more variables (existence of a regular GP follow up and reporting ≥ 1 frequent complication).

Goodness of fit was checked for each model using the Hosmer & Lemeshow test (Hosmer Jr *et al.*, 2013)and fit was adequate in each instance.

Throughout a two-sided p value <0.05 was considered statistically significant.

2.2. Study B: Current practice & alternative models of surveillance for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process Theory

The aim of this part of the study was to explore the implementation of current practices of follow up for IC patients and to understand why and how a "new" (alternative) model of surveillance for IC patients could be successfully developed and implemented.

2.2.1. Study design and setting

This was a multicentre qualitative study, with a semi-structured interview design. The study took place at three Trusts in different regions in England: North, Yorkshire and the Midlands. The centres were selected on the basis of the following criteria: different geographic areas, large catchment population, and being a regional centre for the treatment of bladder cancer ± urology reconstructive surgery. From previous working experience at two of the three centers, AA was aware of the differences in the approach to follow up in the two sites and it was considered that this variation would be valuable to explore diversity of experiences and views. The follow up schedule for the third centre emerged during the interviews. The study followed a research protocol that was modified to reach its final shape by the fourth version (Appendix 3) before obtaining ethical approval (07/09/2017). The study was sponsored by Heart of England NHS Foundation Trust (Appendix 4&5).

2.2.2. Study population

A purposive sample of 20 potential participants were identified through a designated PI at each of the 3 participating centres. The aim was to recruit health professionals from different disciplines who were actively involved in IC patients' surveillance and care: i.e. surgeons, specialist nurses and stoma nurses. They were invited to participate by AA via their work email address; a participant information sheet (Appendix 6) was attached to the email. A reminder email was sent to the non-responders after 2 weeks. The date and time of the interview was agreed via email with the health professionals who agreed to participate.

2.2.3. Ethical approval

After consulting the R&D department at HEFT and review of HRA guidelines, it was determined that ethical approval was not required initially as the study started at a single site and Newcastle University ethical approval was considered sufficient at this stage (Appendix 7). After deciding to extent the study to cover multiple sites, an application for ethical approval through IRAS was started and the study was then approved by Health Research Authority on the 07/09/2017 (IRAS ID: 194469 as a multicenter study (Appendix8). The research team (MD student and supervisors) signed a confidentiality agreement as required by Newcastle University which stated that the student will ‘ *treat all information received through the University Project as confidential, entering into a confidentiality agreement on request from the University, and only disclose such results as are agreed with the Project Supervisor on the University Project’*. ;http://www.ncl.ac.uk/res/assets/documents/PGRPolicyv10111114FINALClean.pdf

2.2.4. Data collection

Face-to face semi structured interviews were conducted by AA with the participants at their place of work. The interviews were conducted during the period between 31/01/2017 until 6/02/2018. All interviews were conducted in English. The participant’s job title, and years and areas of experience were among the data collected.

The interviewer obtained written informed consent from all the participants (Appendix 9). The consent confirmed that participants understand that their participation is voluntary and that they were willing to let the project researcher include anonymous quotations from them in the write up of the study. Participants had adequate chance to ask questions, and these were answered to the participant’s satisfaction prior to giving written informed consent. Participants were also assured that their views and opinions will not be revealed to the senior colleague who nominated them as a potential participant, nor anyone outside of the research team. Furthermore, they were told that no interviewees would be identified in the thesis or any publications arising from the study.

The interviews were guided by a topic guide and audio-recorded (after obtaining verbal consent for this). The development of the topic guide was influenced by the literature reporting on IC long term complications, the NPT constructs and review of guidelines (chapter 1). The guide was refined following review and discussions between AA, LS (MD supervisor) and TF (one of the authors of the NPT). The guide was divided into three major areas: area 1 explored participants' views of the purpose of long-term follow-up following IC; area 2 discussed participants' current practice in following up IC patients; and area 3 explored the views of the participants of the best follow up strategy and the potential barriers and facilitators to implementation of this (Appendix 10). The first few interview transcripts were reviewed and discussed with LS, and comments about areas of probing and new ideas emerging were incorporated into the subsequent interviews. In addition, the topic guide was used flexibly and allowed to evolve as the interviews progress; if new issues were raised by interviewees these were added to the guide for subsequent interviews, so that sufficient depth was reached. The number of interviews was planned to be decided by reaching saturation of themes (Francis *et al.*, 2010; Baker *et al.*, 2012). Saturation of themes from the interviews was reached after 14 interviews; a further 3 interviews were conducted as the participants had already agreed to participate and this enabled checks for saturation. No new themes emerged from the additional three interviews.

2.2.5. Data management

Each participant was allocated a personal identity code to protect their identity. Interviews were transcribed verbatim and anonymized, prior to analysis. The transcription was carried by a medical secretary at the Urology department at Heart of England NHS Trust (Verdelle Stewart) and the transcript was compared to the audio record by AA to check for accuracy.

2.2.6. Data analysis

The data analysis took place in two stages, (1) Thematic analysis; followed by (2) Mapping the emergent themes onto the four constructs of the NPT (i.e an application of the Framework approach)(Ritchie *et al.*, 2013). AA conducted the initial analysis of the first few interviews using a thematic analysis approach (Spencer and Ritchie, 2002). First, familiarity was obtained by reading and then re-reading the transcripts. Secondly, a thematic framework was developed by generating initial codes using line by line inductive analysis. Similar codes were collated under potential themes. The themes were reviewed to check they worked in relation to the dataset. Similar themes (sub-themes) were grouped under seven main themes. Thirdly, the thematic framework was applied to the rest of the transcripts. At the second stage, the sub-themes then were mapped onto Normalization Process Theory four main constructs of the theory; ie the constructs formed the analysis framework. These were further categorised into facilitating factors and barriers to implementation.

The initial coding framework and its analysis using the NPT four constructs was discussed with LS and reviewed by TF. After completing the coding for the whole dataset, the final framework of analysis was established guided by discussions with LS and TF.

Recruitment and analysis were simultaneous, so that issues that emerged from preliminary analysis of early interviews informed later interviews. The three clinical groups were analysed together and the results are presented for all three combined; in the event that a view was expressed by individuals in only one group (e.g. stoma nurses), or not expressed by individuals in a specific group, this has been made clear in the text.

Chapter 3. Study A: Results of patient national survey

3.1. Introduction:

This part of the study aimed to investigate IC patients’ short and long term experience following their operation. Using this survey, patients were asked to report on complications they believed were IC related and the follow up care they had received and to express their views on the optimum follow up (chapter 2). The following are the responses received from the 1092 eligible questionnaires. The results are organised into four sections:

- Respondents’ demographics & characteristics
- Patient reported complications
- Discharge and satisfaction with follow up
- Patients’ preference for follow up

3.2. Respondents’ demographics & follow up characteristics

The mean (SD) age of respondents when they had their surgery was 71.2 (SD=10.39) years, with 88.9% of patients aged 60 year or older. Males comprised 58.2% of the respondents. The mean (SD) time since operation was 10.1 (9.36) years. The indication for surgery was cancer for the majority (78%) of respondents. 38% of the respondents reported they had been discharged from secondary care follow up. Only 16.5% reported that they had difficulty in accessing a stoma nurse (Table 3.1.).

Female respondents represented 41.8% of the whole sample, however they were the majority in certain subgroups. They were 73.6 %(n= 89) of the respondents below the age of 60, and 83.9 %(n=203) of the group who had ileal conduit surgery for a benign indication. Male respondents who had surgery for benign indication were the smallest subgroup of the respondents (3.6%, n= 39), and males who had surgery for a cancerous indication were the largest (54.7%, n=597).

Mean age (range), years	71.2 (24-97)	SD 10.39
Age N (%)		
<60	121 (11.1)	
60-74	528 (48.3)	
≥ 75	443 (40.6)	
Gender N (%)		
Male	636 (58.2)	
Female	456 (41.8)	
Mean time since surgery (range), years	10.1 (1-68)	SD 9.36
Time (in years) since surgery, N (%)		
<5	307 (28.1)	
5-10	401 (36.7)	
>10	384 (35.2)	
Indication for surgery, N (%)		
Benign	245 (22.4)	
Cancer	847 (77.6)	
Discharged* N (%)		
Yes	415 (38)	
No	677 (62)	
Access to stoma nurse, N (%)		
Easy / Very easy	822 (83.5)	
Difficult / Very difficult	163 (16.5)	

*Discharged from follow up at secondary care

Table 3.1. Respondents' demographics and characteristics.

Category	Male	Female
Age N (%)		
<60	32 (26.5)	89 (73.5)
60-74	306 (57.9)	222 (42.1)
≥ 75	298 (67.3)	145 (32.7)
Time (in years) since surgery, N (%)		
<5	198 (64.5)	109 (35.5)
5-10	235 (58.6)	166 (41.4)
>10	203 (52.9)	181 (47.1)
Indication for surgery, N (%)		
Benign	39 (16.2)	203 (83.8)
Cancer	597 (70.3)	253 (29.7)

Table 3.2. Gender distribution by age, time since surgery and indication for surgery.

3.3. Patient-reported complications

3.3.1. Reported complications at different post-operative periods

Patients were asked to report on complications they had experienced during different periods following their surgery. During the first 2 years after the procedure, UTI was the most commonly reported complication (reported by 38.1% of respondents), followed by appliances issues (30.7%) and parastomal hernia (27.3%). Between 2 and 5 years post-surgery, UTIs remained the most common complication (38.1%) followed by parastomal hernia (32.4%) and skin related complications (22.0%). After 5 years from IC operation, patients still reported UTIs, hernia and skin most often (38.8%, 36.0% and 20.6%, respectively). UTI (48.2%), parastomal hernia (39.3%) and appliance complications (36.3%) were the most 'Ever reported' complications. 12.1% (132) of the respondents reported no complications at any time. (Table 3.3 & Figure 3.1)

Time since surgery*	UTI N (%)	Appliances N (%)	Hernia N (%)	Skin N (%)	Bowel N (%)	Kidney N (%)	Stones N (%)	Narrow Stoma N (%)
<2 years	416 (38.1)	335 (30.7)	298 (27.3)	283 (25.9)	207 (18.9)	124 (11.4)	28 (2.5)	34 (3.1)
2-5 years	355 (38.1)	180 (19.3)	302 (32.4)	205 (22.0)	165 (17.7)	115 (12.3)	27 (2.9)	27 (2.9)
>5 years	276 (38.8)	109 (15.3)	256 (36.0)	146 (20.5)	118 (16.6)	103 (14.5)	33 (4.6)	28 (3.9)
Any time (n=1092)	527 (48.2)	400 (36.6)	430 (39.3)	368 (33.7)	258 (23.6)	188 (17.2)	57 (5.2)	59 (5.4)

* The analysis of complications in <2 years from the procedure included all 1092 respondents; that for 2-5 years included 931 respondents; and that for >5 years included 711 respondents.

Table 3.3.Patient reported complications overall and by time since procedure.

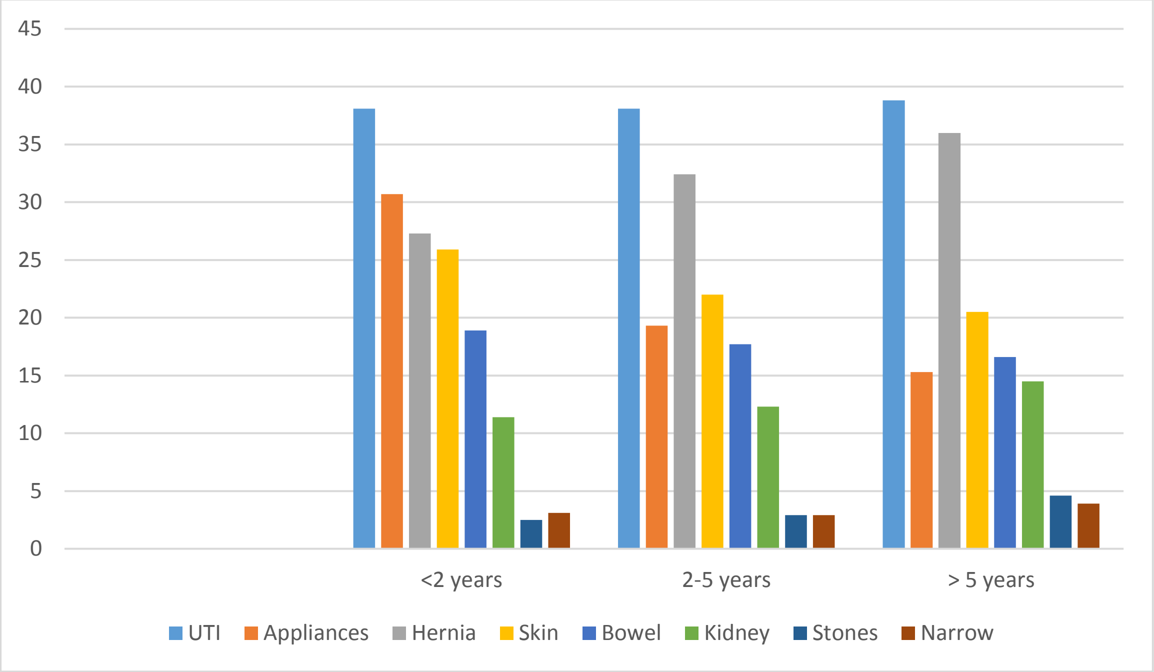

Figure 3.1. Percentage of patients reporting complications by time since procedure and type of complication.

3.3.2. Ever reported a complication

In total 87.9% of respondents reported one or more complication(s) at any time since the procedure. More than half (52.7%) of the respondents reported one (26.0%) or two (26.7 %) complications. 18.4% reported three, 11.0% reported 4, 4.1% reported 5 and 1.4 reported 6 complications. Only 3 patients (0.3%) reported all 7 listed complications (Table 3.4).

Number of reported complications	No. of respondents	Percentage of all respondents	Percentage of respondents who reported ≥1complication(s)*
0	132	12.1	-
1	284	26.0	29.6
2	292	26.7	30.4
3	201	18.4	20.9
4	120	11	12.5
5	45	4.1	4.6
6	15	1.4	1.6
7	3	0.3	0.3

* Total number of respondents who reported ≥1 complication was 960.

Table 3.4. Number and percentage of complications reported at any time since procedure.

The frequency of ever reporting a complication was significantly higher amongst female than male respondents (90.8% vs 85.9%, p=0.014); respondents who had surgery five years or more ago compared to more recently (90.8% & 89.3% vs 82.4%, p=0.002); those who had an ileal conduit for a benign cause rather than cancer (93.0% vs 86.5% p=0.006); and those who found difficulty accessing stoma nurses compared to those who found access easy (94.5% vs 87.9%, p=0.015) (Table 3.5). Frequency did not differ by age or whether the respondent had been discharged from hospital follow-up.

When all variables were fitted simultaneously in a logistic regression model, only having surgery 5-10 ago (OR=1.93, 95%CI 1.15-3.24, p=0.012) and difficulty accessing a stoma nurse (OR=2.15, 95%CI 1.06-4.38, p=0.034) remained significantly associated with ever reporting a complication following ileal conduit surgery (Table 3.6).

Category	Ever reported a complication(n)	Total (N)	Ever reported a complication (%)	P
Gender				
Male	546	636	85.9	0.014
Female	414	456	90.8	
Age				
<60	110	121	90.9	0.528
60-74	464	528	87.9	
≥ 75	386	443	87.1	
Time since surgery				
<5	253	307	82.4	
5-10	364	401	90.8	0.002
>10	343	385	89.3	
Indication for surgery				
Benign	225	242	93.0	0.006
Cancer	735	850	86.5	
Discharged				
Yes	369	415	88.9	0.426
No	591	677	87.3	
Access to stoma nurse				
Easy / Very easy	723	822	88.0	0.015
Difficult / Very difficult	154	163	94.5	

Table 3.5. Frequency of ‘Ever reported a complication’ among different patients groups, numbers (n), percentages (%) and p values.

	Odds Ratio	95% CI	P
Gender			
Male	1	-	-
Female	1.22	0.77- 1.97	0.392
Age			
≥ 75	1	-	-
60-74	0.95	0.61-1.49	0.824
<60	1.12	0.50-2.52	0.775
Indication for surgery			
Cancer	1	-	-
Benign	1.80	0.90-3.60	0.096
Time since surgery			
<5	1	-	-
5-10	**1.93**	**1.15-3.24**	**0.012**
>10	1.47	0.85-2.55	0.169
Discharged			
No	1	-	-
Yes	0.92	0.58-1.49	0.763
Difficult access to stoma nurse			
No	1	-	-
Yes	**2.15**	**1.06-4.38**	**0.035**

Table 3.6. Multivariable logistic regression identifying patient characteristics significantly associated with ‘Ever reporting a complication’, odds ratios (OR), 95% confidence intervals (CI) and p values.

3.3.3. Reporting three or more complications

35.2 % of respondents reported ≥3 complications. This was significantly higher amongst the following categories of respondents: females (43.9%), <60 years old (54.6%), time since surgery 5-10 yrs. (35.9 %), time since surgery >10 yrs. (41.9%), benign indication for surgery (52.5%) (p<0.001) and difficulty accessing a stoma nurse (47.9%, p=0.002) (Table 3.7).

Using multivariable logistic regression, there was a significant positive association between benign indication for surgery (OR=1.65,95% CI 1.14-2.41, p=0.008), age <60 years (OR=1.99, 95%CI 1.25-3.21,p=0.004), 5 years or more post-surgery (OR=1.95, 95% CI 1.36-2.80, p<0.001), difficult access to stoma nurse (OR 1.55, 95% CI 1.10-2.22p= 0.015) and reporting at least 3 reported complications. Patients who had been discharged were significantly less likely to report 3 or more complications. (OR=0.67, 95% CI 0.50-0.91, p=0.011) (Table3.8).

Category	Reporting ≥3 complications (n)	Total (N)	Reporting ≥3 complications (%)	P
Gender				
Male	184	636	28.9	<0.001
Female	200	456	43.9	
Age				
≥ 75	136	443	30.7	<0.001
60-74	182	528	34.5	
<60	66	121	54.6	
Time since surgery				
<5	79	307	25.7	<0.001
5-10	144	401	35.9	
>10	161	385	41.9	
Indication for surgery				
Benign	127	242	52.5	<0.001
Cancer	257	850	35.2	
Discharged				
Yes	138	415	33.3	0.300
No	246	677	36.3	
Access to Stoma nurse				
Easy / Very easy	288	822	35.0	0.002
Difficult / Very difficult	78	163	47.9	

Table 3.7. Frequency of reporting three or more complications at different patients groups, numbers (n), percentages (%) and p values.

	Odds Ratio	95 % CI	P
Gender			
Male	1	-	-
Female	1.24	0.918-1.70	0.157
Age			
≥ 75	1	-	-
60-74	1.09	0.81-1.48	0.555
<60	**1.99**	**1.25-3.21**	**0.004**
Indication for surgery			
Cancer	1	-	-
Benign	**1.65**	**1.14-2.41**	**0.008**
Time since surgery			
< 5	1	-	-
5-10	**1.95**	**1.36-2.80**	**<0.001**
>10	**2.45**	**1.67-3.62**	**<0.001**
Discharged			
No	1	-	-
Yes	**0.67**	**0.50-0.91**	**0.011**
Difficult access to stoma nurse			
No	1	-	-
Yes	**1.55**	**1.10-2.22**	**0.015**

Table 3.8. Multivariable logistic regression identifying patient characteristics significantly associated with reporting three or more complications, odds ratios (OR), 95 % confidence intervals (CI) and p values.

3.3.4. Number of ‘Ever reported’ Complications:

The mean number (SD) of reported complications was 2.10 (1.42) while the median was 2 (5%-95% range: 0-5).The mean number of ever reported complications was higher amongst respondents younger than 60 years (2.66, P <0.001), those who had their surgery 5-10 years ago (2.11, p<0.001) and more than 10 years (2.34, p<0.001) and respondents who found it difficult to access a stoma nurse (2.66, p<0.001) (Table 3.9). Within the gender and indication for surgery categories, the median number of ever reported complications was higher amongst female respondents (2, 0-5) and those who had surgery for benign indication (3, 0-6) (p<0.001), but did not differ according to whether the individual had been discharged from hospital follow-up (Table 3.10).

Category	Mean (SD)	P
Age		
<60	2.66 (1.53)	<0.001
60-74	2.07 (1.44)	
≥ 75	1.95 (1.32)	
Time since surgery		
<5	1.75 (1.31)	<0.001
5-10	2.11 (1.34)	
>10	2.34 (1.53)	
Access to stoma nurse		
Easy / Very easy	2.06 (1.38)	<0.001
Difficult / Very difficult	2.66 (1.54)	

Table 3.9. Mean number of reported complications by age, time since surgery and access to stoma nurse, with p values from one-way anova.

Category	Median (5%-95% range)	P
Gender		
Male	2 (0-4)	<0.001
Female	2 (0-5)	
Indication for surgery		
Benign	3 (0-6)	<0.001
Cancer	2 (0-4)	
Discharged		
Yes	2 (0-4)	0.915
No	2 (0-5)	

Table 3.10. Median (5%-95%) number of reported complications by gender, indication for surgery and discharge from secondary care, with p values from Kruskall-Wallis test.

3.3.5. Patient reported frequency of complications

Ever reported a frequent complication and associated characteristics

493 (45.2%) of respondents reported at least one frequent complication. The frequency was significantly higher amongst females (53.7%), those aged less than 60 years (65.3%), those being long after surgery (5-10yrs.; 48.6%, > 10yrs.; 51.3%), those who had a benign indication for surgery (59.92%) (p<0.001) and those who found difficulty accessing a stoma nurse (57.1%) (p=0.004) (Table 3.11).

In multivariable analysis, age <60 yrs. (OR=2.52, 95% CI 1.56-4.08, p<0.001) & 60-74 yrs. (OR=1.36, 95% CI 1.02-1.81, p=0.034), time since IC operation more than 5 years (OR=2.33, 95% CI 1.65-3.28, p<0.001) and difficult access to a stoma nurse (OR=1.44, 95%CI 1.01-2.05, p=0.043) were all significantly associated with reporting at least one frequent complication(Table 3.12).

Hernia (21.3%), UTI (17.6%), bowel (11.8%) and appliances problems (11.2%) were the complications most commonly reported as frequent (Table 3.13).

Category	Ever reported a frequent complication(n)	Total (N)	Ever reported a frequent complication (%)	P
Gender				
Male	248	636	39.0	<0.001
Female	245	456	53.7	
Age				
≥ 75	173	443	39.1	<0.001
60-74	241	528	45.6	
<60	79	121	65.3	
Time since surgery				
<5	101	307	32.9	<0.001
5-10	195	401	48.6	
>10	197	385	51.3	
Indication for surgery				
Benign	145	242	59.9	<0.001
Cancer	348	850	40.9	
Discharged				
Yes	193	415	46.5	0.480
No	300	677	44.3	
Access to stoma nurse				
Easy / Very easy	368	822	44.8	0.004
Difficult / Very difficult	93	163	57.1	

Table 3.11. Frequency of ‘Ever reported a frequent complication’ by patient groups, numbers (n), percentages (%) and p values.

	Odds Ratio	95 % CI	P
Gender			
Male	1	-	-
Female	1.33	0.99-1.79	0.058
Age			
≥ 75	1	-	-
60-74	**1.35**	**1.02-1.81**	**0.039**
<60	**2.52**	**1.56-4.08**	**<0.001**
Indication for surgery			
Cancer	1	-	-
Benign	1.26	0.87-1.83	0.222
Time since surgery			
< 5	1	-	-
5-10	**2.32**	**1.65-3.28**	**<0.001**
>10	**2.41**	**1.66-3.5**	**<0.001**
Discharged			
No	1	-	-
yes	0.88	0.66-1.18	0.400
Difficult access to stoma nurse			
No	1	-	-
Yes	**1.44**	**1.01-2.05**	**0.043**

Table 3.12. Multivariable logistic regression identifying patient characteristics significantly associated with ‘Ever reported a frequent complication’, odds ratio (OR), 95% confidence intervals (CI) and p values.

	Reported frequency			
Type of complication	Frequently N(%)	Sometimes N(%)	Rarely N(%)	Never N(%)
Bowel	129 (11.8)	128 (11.7)	90 (8.2)	745 (68.2)
Kidney	88 (8.2)	75 (6.9)	80 (7.3)	849 (77.8)
UTI	192 (17.6)	229 (21.0)	187 (17.1)	484 (44.3)
Stones	14 (1.3)	14 (1.3)	28 (2. 6)	1036 (94.9)
Hernia	233 (21.3)	95 (8.7)	85 (7. 8)	679 (62.2)
Stoma stenosis	19 (1.7)	20 (1.8)	30 (2.8)	1023 (93.7)
Appliances	122 (11.2)	292 (26.7)	209 (19.1)	469 (43.0)

Table 3.13. Patient reported frequency of experiencing different types of complications.

Of those who reported at least one frequent complications, 57.8 % and 26.8% reported one and two frequent complications respectively (Table 3.14). On average patients reported a mean (SD) of 0.72(0.99) frequent complications; the median (5%-95% range) was 0(0-3). The median number of reported frequent complications was significantly higher (1(0-3), <0.001) amongst female respondents, those who were younger (< 60 yrs.) and those who had surgery more than >10 years ago. Similarly, it was significantly higher for respondents who had surgery for benign cause (1(0-3), p<0.001), and those who found difficulty accessing a stoma nurse (1(0-3), p=0.003) (Table 3.15).

No. of frequent complications	Frequency	Percentage of all	Percentage of those reporting ≥ 1 frequent complication*
0	599	54.9	-
1	285	26.1	57.8
2	132	12.1	26.8
3	65	5.9	13.2
4	6	0.5	1.2
5	2	0.2	0.4
6	2	0.2	0.4
7	1	0.1	0.2

*The total number of patients reporting ≥ 1 frequent complication was 493

Table 3.14. Number (%) of frequent complications reported, among all respondents and among those who reported at least one frequent complication.

Category	Median (5%-95%)	P
Gender		
Male	0 (0-2)	<0.001
Female	1(0-3)	
Age		
<60	1 (0-3)	<0.001
60-74	0 (0-3)	
≥ 75	0 (0-2)	
Indication for surgery		
Benign	1 (0-3)	<0.001
Cancer	0 (0-2)	
Time since surgery		
<5	0 (0-2)	<0.001
5-10	0 (0-3)	
>10	1 (0-3)	
Discharged		
Yes	0 (0-2)	0.929
No	0 (0-3)	
Access to stoma nurse		
Easy / Very easy	0 (0-3)	0.003
Difficult / Very difficult	1 (0-3)	
All patients	0 (0-3)	

Table 3.15. Median number (5%-95% range) of frequent complications reported at different patients groups with p values from Kruskall-Wallis test.

3.3.6 Characteristics associated with reporting different types of complications

Using multivariable logistic regression, the patients and clinical characteristics significantly associated with ‘Ever reported’ and ‘Ever reported as frequent’ for each individual complication were as follows. Ever reporting bowel problems was associated with female gender (OR=1.51, 95% CI 1.80-2.11, p=0.016) and difficulty accessing a stoma nurse (OR= 1.62, 95% CI 1.11-2.36, p=0.012) (Table 3.16). Reporting frequent bowel problems was significantly associated with female gender (OR=1.73, 95% CI 1.09-2.74, p=0.02), benign indication for surgery (OR=1.83, 95% CI 1.11-3.02, p=0.018), age less than 60 years old (OR=2.32, 95% CI 1.23-4.38, p=0.01) discharged status (OR= 0.56, 95% CI 0.36-0.89, p=0.013). Report frequent bowel complications was not affected by access to stoma nurse (Table 3.17).

Ever reporting kidney problems was significantly associated with benign indication for surgery (OR= 2.13, 95% CI 1.36-3.36, p=0.001), more than 10 years after surgery (OR=2.37, 95% CI 1.47-3.85, p<0.001) and less across discharged patients (OR= 0.65, 95% CI 0.45-0.95, 0.024) (Table 3.18). Reporting frequent kidney complications was significantly associated with benign indication for surgery (OR= 2.02, 95% CI1.11-3.67, p=0.022), more than 10 years after surgery (OR=2.97, 95% CI 1.45-6.09, p=0.003) and difficult access to stoma nurse (OR= 1.83, 95% CI 1.07-3.1, p=0.029) (Table 3.19).

Ever reporting UTI was associated with benign indication for surgery (OR=1.88, 95% CI 1.29-2.74, p=0.001), 5-10 yrs. after surgery (OR= 1.64, 95% CI 1.17-2.30, p=0.004) and >10 yrs. after surgery (OR=2.80, 95% CI 1.93-4.07, p=<0.001) (Table 3.20). Reporting frequent UTI was significantly associated with benign indication for surgery (OR=2.04, 95% CI 1.31-3.16, p=0.001), age 60-74 yrs.(OR=1.55, 95% CI 1.05-2.30, p=0.029) & <60years (OR= 2.07, 95% CI1.17-3.66, p=0.012), 5-10 yrs. after surgery (OR=3.53, 95% CI 2.03- 6.14,p< 0.001), and more than 10years after surgery (OR=5.01, 95% CI 2.85-8.81,p< 0.001) (Table 3.21).

	Odds Ratio	95%CI	P
Gender			
Male	1	-	-
Female	**1.51**	**1.08-2.11**	**0.016**
Age			
≥ 75	1	-	-
60-74	1.19	0.85-1.68	0.295
<60	1.58	0.96-2.62	0.073
Indication for surgery			
Cancer	1	-	-
Benign	1.19	0.8-1.79	0.385
Time since surgery			
< 5	1	-	-
5-10	1.03	0.71-1.53	0.847
>10	1.08	0.72-1.64	0.709
Discharged			
No	1	-	-
Yes	0.79	0.57-1.11	0.173
Difficult access to stoma nurse			
No	1	-	-
Yes	**1.61**	**1.11-2.36**	**0.012**

Table 3.16. Multivariable logistic regression identifying patient characteristics significantly associated with ever reporting bowel complication, odds ratios (OR), 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	**1.73**	**1.09-2.74**	**0.020**
Age			
≥ 75	1	-	-
60-74	1.56	0.96-2.53	0.074
<60	**2.32**	**1.23-4.38**	**0.010**
Indication for surgery			
Cancer	1	-	-
Benign	**1.83**	**1.11-3.02**	**0.018**
Time since surgery			
< 5	1	-	-
5-10	1.43	0.84-2.41	0.184
>10	1.42	0.81-2.48	0.217
Discharged			
No	1	-	-
Yes	**0.56**	**0.36-0.89**	**0.013**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.54	0.95-2.5	0.083

Table 3.17. Multivariable logistic regression identifying patient characteristics significantly associated with reporting bowel complication as frequent, odds ratios (OR), 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	0.88	0.59-1.31	0.520
Age			
≥ 75	1	-	-
60-74	1.11	0.76-1.63	0.590
<60	1.25	0.7-2.23	0.455
Indication for surgery			
Cancer	1	-	-
Benign	**2.13**	**1.36-3.36**	**0.001**
Time since surgery			
< 5	1	-	-
5-10	1.48	0.92-2.38	0.107
>10	**2.37**	**1.47-3.85**	**<0.001**
Discharged			
No	1	-	-
Yes	**0.65**	**0.45-0.95**	**0.024**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.39	0.91-2.12	0.131

Table 3.18. Multivariable logistic regression identifying patient characteristics significantly associated with ever reporting kidney complication, odds ratios (OR), 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.41	0.8-2.46	0.235
Age			
≥ 75	1	-	-
60-74	1.32	0.75-2.33	0.331
<60	1.45	0.66-3.19	0.356
Indication for surgery			
Cancer	1	-	-
Benign	**2.02**	**1.11-3.67**	**0.022**
Time since surgery			
< 5	1	-	-
5-10	1.61	0.77-3.36	0.210
>10	**2.97**	**1.45-6.09**	**0.003**
Discharged			
No	1	-	-
Yes	0.77	0.46-1.28	0.315
Difficult access to stoma nurse			
No	1	-	-
Yes	**1.83**	**1.07-3.15**	**0.029**

Table 3.19. Multivariable logistic regression identifying patient characteristics significantly associated with reporting kidney complication as frequent, odds ratios (OR), 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.00	0.74-1.35	0.989
Age			
≥ 75	1	-	-
60-74	1.33	0.99-1.77	0.056
<60	**2.31**	**1.42-3.74**	**0.001**
Indication for surgery			
Cancer	1	-	-
Benign	**1.88**	**1.29-2.74**	**0.001**
Time since surgery			
< 5	1	-	-
5-10	**1.64**	**1.17-2.3**	**0.004**
>10	**2.80**	**1.93-4.07**	**<0.001**
Discharged			
No	1	-	-
Yes	0.85	0.64-1.14	0.288
Difficult access to stoma nurse			
No	1	-	-
Yes	1.28	0.9-1.83	0.172

Table 3.20. Multivariable logistic regression identifying patient characteristics significantly associated with ever reporting UTI complication, odds ratios (OR), 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.19	0.8-1.77	0.385
Age			
≥ 75	1	-	-
60-74	**1.55**	**1.05-2.3**	**0.029**
<60	**2.07**	**1.17-3.66**	**0.012**
Indication for surgery			
Cancer	1	-	-
Benign	**2.04**	**1.31-3.16**	**0.001**
Time since surgery			
< 5	1	-	-
5-10	**3.53**	**2.03-6.14**	**<0.001**
>10	**5.01**	**2.85-8.81**	**<0.001**
Discharged			
No	1	-	-
Yes	0.91	0.63-1.3	0.604
Difficult access to stoma nurse			
No	1	-	-
Yes	1.08	0.7-1.68	0.716

Table 3.21. Multivariable logistic regression identifying patient characteristics significantly associated with reporting UTI complication as frequent, odds ratios (OR), 95% confidence intervals (CI) and p values.

Ever reporting stone problems was associated with time from surgery 5-10 yrs. and >10 years (OR=2.93, 95% CI1.14-7.57, p=0.026, OR=4.43, 95% CI1.71-11.45, p=0.002) (Table 3.22). Reporting frequent stone problems was associated significantly with age category 60-74 years old (OR=4.95, 95% CI1.03 -23.8, p=0.047) (Table 3.23).

Ever reporting hernia problems was less associated with younger age (<60 years: OR=0.41, 95% CI 0.25-0.68, p<0.001; 60-74 years: OR= 0.65, 95% CI 0.49-0.86, p=0.003) and discharge from secondary care (OR=0.70, 95%CI 0.53-0.94, p=0.019). It was associated with time since surgery (5-10 yrs.: OR=2.00, 95% CI 1.41-2.83, p< 0.001>10 years: OR= 2.32, 95% CI 1.59-3.37, p< 0.001) (Table 3.24). Reporting frequent hernia complications was associated with female gender (OR=1.50, 95% CI 1.06-2.12, p=0.021), time since operation categories of 5-10 years (OR=2.13, 95% CI 1.38-3.29, p=0.001) and >10 years (OR=2.68, 95%CI 1.69-4.25, p<0.001). It was negatively associated with discharged status (OR=0.70, 95% CI 0.50-0.99, p=0.043) (Table 3.25).

Ever reporting stoma stenosis was significantly associated with benign indication for surgery (OR=3.10, 95% CI 1.44-6.64, p=0.004) and age <60 yrs. (OR= 3.59, 95% CI 1.46 -8.80, p=0.005) (Table 3.26). Reporting frequent stenosis was associated with age<60 yrs. (OR=4.94, 95% CI 1.02-23.87, p=0.047) (Table 3.27).

Ever reporting appliances problems was associated with age < 60 years (OR=1.67, 95%CI 1.05-2.65, p=0.031) and difficulty accessing stoma nurse (OR=2.13, 95% CI 1.50-3.01, p<0.001) (Table 3.28). No association was identified between reporting appliances complications frequently and patients ‘characteristics (Table 3.29).

None of the characteristics were significantly associated with reporting skin problems- ever or frequent (Tables 3.30 & 3.31).

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.01	0.52-1.97	0.967
Age			
≥ 75	1	-	-
60-74	0.73	0.38-1.42	0.360
<60	1.74	0.75-4.02	0.197
Indication for surgery			
Cancer	1	-	-
Benign	1.99	0.96-4.11	0.063
Time since surgery			
< 5	1	-	-
5-10	**2.93**	**1.14-7.57**	**0.026**
>10	**4.43**	**1.71-11.45**	**0.002**
Discharged			
No	1	-	-
Yes	0.56	0.31-1.03	0.062
Difficult access to stoma nurse			
No	1	-	-
Yes	1.80	0.94-3.41	0.074

Table 3.22. Multivariable logistic regression identifying patient characteristics significantly associated with ever reporting stone complications, odds ratios (OR), 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.61	0.47-5.46	0.447
Age			
≥ 75	1	-	-
60-74	**4.95**	**1.03-23.87**	**0.047**
<60	5.00	0.62-40.49	0.131
Indication for surgery			
Cancer	1	-	-
Benign	0.44	0.1-2.01	0.288
Time since surgery			
< 5	1	-	-
5-10	5.72	0.66-49.63	0.113
>10	6.89	0.74-64.28	0.090
Discharged			
No	1	-	-
Yes	1.15	0.36-3.64	0.813
Difficult access to stoma nurse			
No	1	-	-
Yes	1.18	0.31-4.46	0.811

Table 3.23. Multivariable logistic regression identifying patient characteristics significantly associated with reporting stone complications as frequent, odds ratios (OR) 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.18	0.88-1.6	0.273
Age			
≥ 75	1	-	-
60-74	**0.65**	**0.49-0.86**	**0.003**
<60	**0.41**	**0.25-0.68**	**<0.001**
Indication for surgery			
Cancer	1	-	-
Benign	0.95	0.65-1.39	0.807
Time since surgery			
< 5	1	-	-
5-10	**2.00**	**1.41-2.83**	**<0.001**
>10	**2.32**	**1.59-3.37**	**<0.001**
Discharged			
No	1	-	-
Yes	**0.70**	**0.53-0.94**	**0.019**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.12	0.78-1.59	0.545

Table 3.24. Multivariable logistic regression identifying patient characteristics significantly associated with ever reporting hernia complications, odds ratios (OR) 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	**1.50**	**1.06-2.12**	**0.021**
Age			
≥ 75	1	-	-
60-74	0.82	0.59-1.15	0.252
<60	0.56	0.31-1.01	0.055
Indication for surgery			
Cancer	1	-	-
Benign	0.77	0.5-1.2	0.257
Time since surgery			
< 5	1	-	-
5-10	**2.13**	**1.38-3.29**	**0.001**
>10	**2.68**	**1.69-4.25**	**<0.001**
Discharged			
No	1	-	-
Yes	**0.70**	**0.5-0.99**	**0.043**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.07	0.71-1.61	0.763

Table 3.25. Multivariable logistic regression identifying patient characteristics associated with reporting hernia complications as frequent, odds ratios (OR) 95% confidence intervals and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.20	0.57-2.5	0.632
Age			
≥ 75	1	-	-
60-74	1.07	0.49-2.37	0.861
<60	**3.59**	**1.46-8.8**	**0.005**
Indication for surgery			
Cancer	1	-	-
Benign	**3.10**	**1.44-6.64**	**0.004**
Time since surgery			
< 5	1	-	-
5-10	0.75	0.32-1.78	0.519
>10	1.99	0.91-4.31	0.083
Discharged			
No	1	-	-
Yes	**0.37**	**0.19-0.75**	**0.006**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.23	0.59-2.57	0.573

Table 3.26. Multivariable logistic regression identifying patient characteristics significantly associated with ever reporting stoma stenosis, odds ratios (OR) 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	2.02	0.6-6.75	0.255
Age			
≥ 75	1	-	-
60-74	1.79	0.44-7.25	0.414
<60	**4.94**	**1.02-23.87**	**0.047**
Indication for surgery			
Cancer	1	-	-
Benign	1.16	0.34-3.9	0.811
Time since surgery			
< 5	1	-	-
5-10	0.92	0.22-3.86	0.905
>10	2.02	0.53-7.72	0.304
Discharged			
No	1	-	-
Yes	0.69	0.23-2.03	0.497
Difficult access to stoma nurse			
No	1	-	-
Yes	2.41	0.85-6.85	0.099

Table 3.27 Multivariable logistic regression identifying patient characteristics significantly associated with reporting stoma stenosis as frequent, odds ratios (OR) 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	0.99	0.73-1.34	0.947
Age			
≥ 75	1	-	-
60-74	1.26	0.93-1.69	0.131
<60	**1.67**	**1.05-2.65**	**0.031**
Indication for surgery			
Cancer	1	-	-
Benign	1.29	0.88-1.87	0.188
Time since surgery			
< 5	1	-	-
5-10	1.26	0.89-1.76	0.188
>10	0.82	0.57-1.19	0.302
Discharged			
No	1	-	-
Yes	0.98	0.73-1.31	0.877
Difficult access to stoma nurse			
No	1	-	-
Yes	**2.13**	**1.5-3.01**	**<0.001**

Table 3.28. Multivariable logistic regression identifying patient characteristics significantly associated with ever reporting appliances complications, odds ratios (OR) 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	0.99	0.73-1.34	0.947
Age			
≥ 75	1	-	-
60-74	1.26	0.93-1.69	0.131
<60	**1.67**	**1.05-2.65**	**0.031**
Indication for surgery			
Cancer	1	-	-
Benign	1.29	0.88-1.87	0.188
Time since surgery			
< 5	1	-	-
5-10	1.26	0.89-1.76	0.188
>10	0.82	0.57-1.19	0.302
Discharged			
No	1	-	-
Yes	0.98	0.73-1.31	0.877
Difficult access to stoma nurse			
No	1	-	-
Yes	**2.13**	**1.5-3.01**	**<0.001**

Table 3.29. Multivariable logistic regression identifying patient characteristics significantly associated with reporting appliances complications as frequent, odds ratios (OR) 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.24	0.92-1.68	0.159
Age			
≥ 75	1	-	-
60-74	1.06	0.79-1.42	0.711
<60	1.11	0.7-1.77	0.665
Indication for surgery			
Cancer	1	-	-
Benign	1.30	0.9-1.89	0.165
Time since surgery			
< 5	1	-	-
5-10	1.20	0.85-1.69	0.302
>10	0.92	0.63-1.34	0.663
Discharged			
No	1	-	-
Yes	1.09	0.81-1.46	0.557
Difficult access to stoma nurse			
No	1	-	-
Yes	1.20	0.84-1.7	0.322

Table 3.30. Multivariable logistic regression identifying patient characteristics significantly associated with ever reporting skin complications, odds ratios (OR) 95% confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.72	0.55-5.32	0.348
Age			
≥ 75	1	-	-
60-74	2.54	0.74-8.7	0.138
<60	2.49	0.4-15.54	0.330
Indication for surgery			
Cancer	1	-	-
Benign	0.39	0.09-1.68	0.208
Time since surgery			
< 5	1	-	-
5-10	4.45	0.51-38.73	0.177
>10	4.55	0.49-42.13	0.183
Discharged			
No	1	-	-
Yes	2.63	0.83-8.28	0.099
Difficult access to stoma nurse			
No	1	-	-
Yes	1.91	0.62-5.85	0.258

Table 3.31. Multivariable logistic regression identifying patient characteristics significantly associated with reporting Skin complications as frequent, odds ratios (OR) 95% confidence intervals (CI) and p values.

3.4. Discharge and satisfaction with follow-up

3.4.1. Discharge from hospital follow-up

Of the respondents, 415 (38.0%) reported that they had been discharged from hospital follow up. The frequency of reporting discharge was significantly higher across those aged ≥ 75yrs (45.6%, p<0.001), who were longer since operation (5-10 yrs. 39.7% & >10 yrs.56.8%, p<0.001) and had a benign indication for surgery (44.2%, p=0.024) (Table 3.32). In multivariable logistic regression, reporting discharge from secondary care was significantly associated with longer time since surgery y (p<0.001), but was negatively associated with age 60-74 (p=0.002) with no effect from gender or indication for surgery (Table 3.33).

Category	Discharged (N)	Total (N)	Discharged (%)	P
Gender				
Male	241	636	37.9	0.929
Female	174	456	38.2	
Age				
<60	44	121	36.4	<0.001
60-74	165	528	31.3	
≥ 75	206	443	45.6	
Time since surgery				
<5	38	307	12.4	<0.001
5-10	159	401	39.7	
>10	218	385	56.8	
Indication for surgery				
Benign	107	242	44.2	0.024
Cancer	308	850	36.2	

Table 3.32. Discharge from secondary care by different patient characteristics, numbers (n), percentages (%) and p values of Chi-square test.

	Odds Ratio	95% CI	P
Gender			
Male	1	-	-
Female	0.83	0.61-1.13	0.238
Age			
≥ 75	1	-	-
60-74	**0.63**	**0.47-0.84**	**0.002**
<60	0.84	0.52-1.36	0.467
Indication for surgery			
Cancer	1	-	-
Benign	1.22	0.84-1.77	0.288
Time since surgery			
<5	1	-	-
5-10	**4.40**	**2.96-6.56**	**<0.001**
>10	**8.56**	**5.70-12.86**	**<0.001**

Table 3.33. Multivariable logistic regression identifying patient characteristics significantly associated with reporting discharge from secondary care, odds ratios, 95% Confidence intervals (CI) and p values.

Of discharged patients, 138 (33.2%) reported they had been seen regularly by their GP to follow-up their stoma. One-third of discharged patients (32.3%; n=134) said they had been referred back to hospital following their discharge. 120 of these respondents gave a cause for referral back to secondary care. Parastomal hernia (35%) was the most common cause for re-referral followed by UTIs (15.8 %) then skin problems (15%) (Table 3.34 & Figure 3.2).

Referral back to hospital was significantly associated only with reporting a frequent complication (OR=4.33, 95% CI 1.48-12.70, p=0.008), and not with any other characteristics including stoma nurse access or the presence of regular GP follow-up (Table 3.35).

Reasons for re-referral	Frequency	Percentage
Hernia	42	35.00
UTI	19	15.83
Skin	18	15.00
Stoma	15	12.50
Bowel	8	6.67
Renal	5	4.17
Cancer recurrence	4	3.33
Haematuria	3	2.50
Other reasons	6	5.00
Total	120	100%

Table 3.34. Reasons for referral back to secondary care.

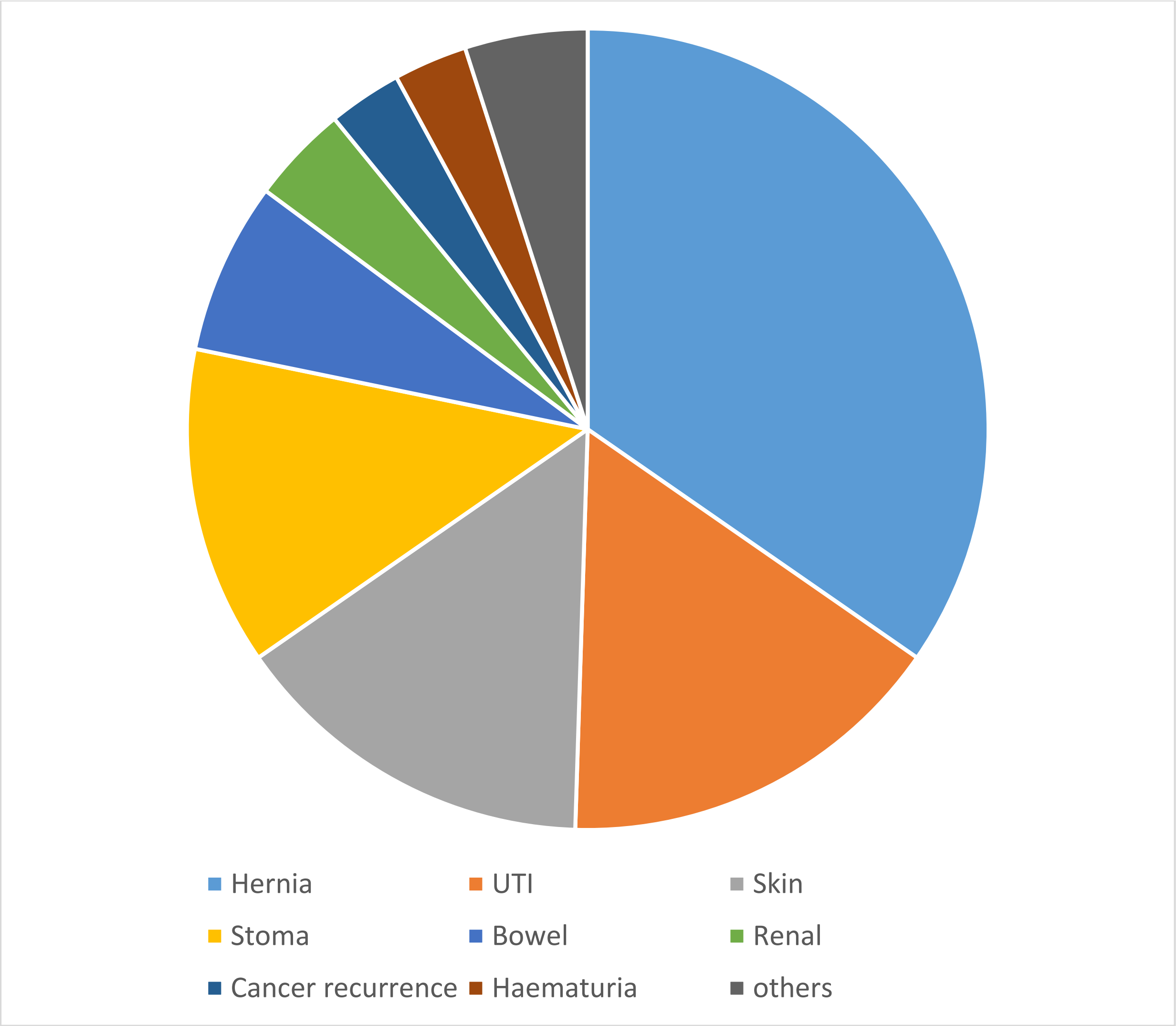

Figure 3.2. Reasons for referral back to secondary care.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.09	0.64-1.85	0.744
Age			
≥ 75	1	-	-
60-74	1.00	0.61-1.65	0.997
<60	1.04	0.47-2.3	0.923
Indication for surgery			
Cancer	1	-	-
Benign	1.44	0.79-2.62	0.231
Time since surgery			
< 5	1	-	-
5-10	0.96	0.41-2.25	0.919
>10	1.37	0.6-3.13	0.455
Difficult access to stoma nurse			
No	1	-	-
Yes	1.32	0.78-2.23	0.304
GP follow up			
No	1	-	-
Yes	0.96	0.59-1.55	0.870
Report ≥1 frequent complication			
No	1	-	-
Yes	**4.33**	**1.48-12.70**	**0.008**

Table 3.35. Multivariable logistic regression identifying patient characteristics significantly associated with reporting referral back to secondary care after discharge, odds ratios, 95% Confidence intervals (CI) and p values.

3.4.2. Patient satisfaction

Only 171 respondents (15.7 %) were dissatisfied with their follow-up. The frequency of dissatisfaction was significantly higher amongst patients who had surgery for benign indication, those who had been discharged and those who found difficulty accessing a stoma nurse ($p<0.001$) (Table 3.36).

Running a multivariable logistic regression including patient characteristics, benign indication for surgery (OR=2.86, 95% CI 1.71-4.7, $p<0.001$), discharge from secondary care (OR=2.23, 95% CI 1.48-3.37, $p<0.001$) and difficult access to stoma nurse (OR=7.92, 95%CI 5.27-11.89, $p<0.001$) all remained positively associated with reporting dissatisfaction with follow up (Table 3.37). Risk of reporting dissatisfaction was significantly lower in two groups: 5-10 years since operation (OR=0.59, 95% CI 0.36- 0.98, p= 0.041) and >10 years from operation (OR=0.47, 95% CI 0.28-0.80, p=0.006). After re-running the model adding two additional independent variables (Ever reported a complication and Ever reporting a frequent complication), reporting a frequent complication was also significantly associated with reporting dissatisfaction (OR=1.73, 95% CI 1.16-2.58, p=0.007) (Table3.38).

Category	Dissatisfied with Follow up (n)	Total (N)	Percentage	P value
Gender				
Male	94	636	14.8	0.345
Female	77	456	16.9	
Age				
≥ 75	68	443	15.4	0.024
60-74	74	528	14.0	
<60	29	121	24.0	
Time since surgery				
<5	47	307	15.3	0.681
5-10	59	401	14.7	
>10	65	385	16.9	
Indication for surgery				
Benign	65	242	25.2	<0.001
Cancer	110	850	12.9	
Discharged				
Yes	93	415	22.4	<0.001
No	78	677	11.5	
Access to stoma nurse				
Easy / Very easy	84	822	10.2	P<0.001
Difficult / Very difficult	76	163	46.6	

Table 3.36. Dissatisfaction with follow up by patients’ characteristics, numbers (n), percentages (%) and p values from chi-square test.

	Odds Ratio	95% CI	P
Gender			
Male	1	-	-
Female	0.64	0.4-1	0.051
Age			
≥ 75	1	-	-
60-74	0.70	0.45-1.08	0.110
<60	1.20	0.64-2.24	0.555
Indication for surgery			
Cancer	1	-	-
Benign	**2.85**	**1.7-4.77**	**<0.001**
Time since surgery			
< 5	1	-	-
5-10	**0.59**	**0.35-0.97**	**0.041**
>10	**0.47**	**0.27-0.8**	**0.006**
Discharged			
No	1	-	-
Yes	**2.23**	**1.48-3.37**	**<0.001**
Difficult access to stoma nurse			
No	1	-	-
Yes	**7.91**	**5.27-11.88**	**<0.001**

Table 3.37. Multivariable logistic regression identifying patient characteristics significantly associated with reporting dissatisfaction with follow up, odds ratios (OR), 95% Confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	**0.60**	**0.38-0.96**	**0.033**
Age			
≥ 75	1	-	-
60-74	0.67	0.43-1.03	0.074
<60	1.04	0.55-1.97	0.891
Indication for surgery			
Cancer	1	-	-
Benign	**2.81**	**1.68-4.72**	**<0.001**
Time since surgery			
< 5	1	-	-
5-10	**0.52**	**0.31-0.87**	**0.013**
>10	**0.41**	**0.24-0.71**	**0.002**
Discharged			
No	1	-	-
Yes	**2.29**	**1.51-3.47**	**<0.001**
Difficult access to stoma nurse			
No	1	-	-
Yes	**7.62**	**5.06-11.48**	**<0.001**
Report ≥1 complication			
No	1	-	-
Yes	1.52	0.70-3.31	0.288
Report ≥1 frequent complication			
No	1	-	-
Yes	**1.73**	**1.16-2.58**	**0.007**

Table 3.38. Multivariable logistic regression identifying patient characteristics significantly associated with reporting dissatisfaction with follow up, adding 2 more variables (Ever reported a complication and Ever reported a frequent complication), odds ratios(OR), 95% Confidence intervals (CI) and p values.

Of the 921 patients who were satisfied with care, 645 provided further information about the reason for this. Among these respondents, the most commonly endorsed reason for satisfaction was the follow up they had received and the investigations they had during it: 33.0% (213 patients) reported this. The care received from the stoma nurse (181 patients, 28.06%) was the second most common reason for satisfaction, followed by the care provided by the surgeon (109, 16.9%) (Table 3.39).

Reason of satisfaction	Number	Percentage
Follow up	213	33.0
Stoma nurse	181	28.1
Surgeon	109	16.9
Team	52	8.1
Communication	23	3.6
Access to care	37	5.7
GP	5	0.8
Total	645	100

*645 respondents gave answer to this question.

Table 3.39. Reasons for satisfaction with follow up reported by patients.

Of the 171 patients who were not satisfied, 128 provided further information on the reasons for this. Inadequate follow up (64, 50%) was the most commonly endorsed reason for dissatisfaction, followed by care of the stoma nurse (33, 25.78%), then complications (14, 10.1%) and communication (13, 10.1%). (Figure 3.3).

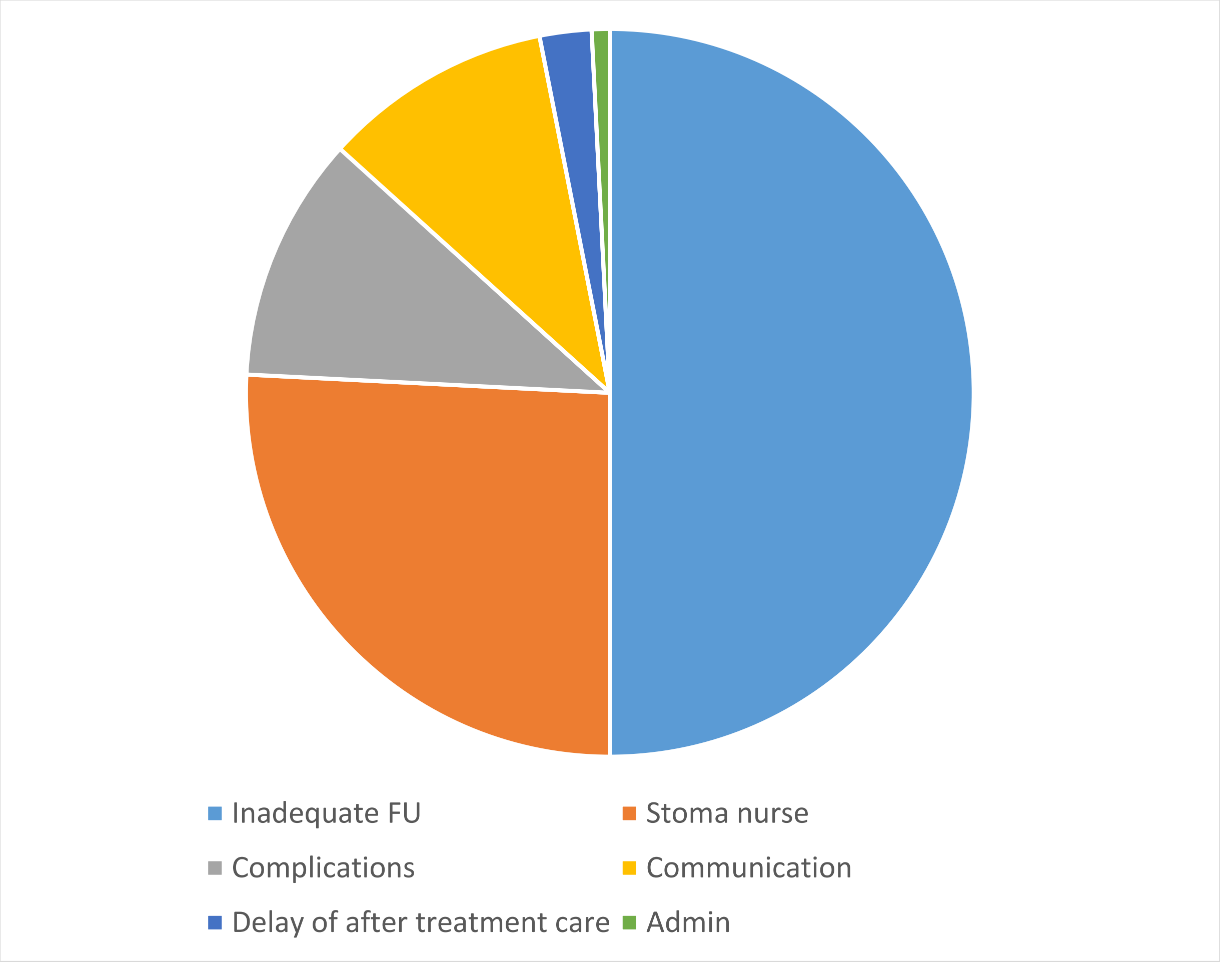

Figure 3.3. Reasons of dissatisfaction reported by patients.

3.5. Patients' preferences for follow up

3.5.1. First two years following surgery

When asked about the first 2 years following IC, the most commonly chosen schedule for surgeon review was 6 monthly (551; 52.4%); this was followed by 3 monthly (311; 29.6%). For stoma nurse review, patients chose 3 monthly (395; 40.0%), not routinely (257; 26.0%) then 6 monthly (245; 24.8%) (Table3.40).

	Surgeon review*		Stoma nurse review**	
Chosen frequency	Number	Percentage	Number	Percentage
3 monthly	311	29.6	395	40.0
6 monthly	551	52.4	245	24.8
12 monthly	133	12.7	70	7.1
3m/ 6m	10	0.1	6	0.6
6m/12m	1	0.1	0	0
3m/12m	1	0.1	2	0.2
Monthly	0	0	13	1.3
Not routinely	44	4.0	257	26.0
Total answered	1051	100	988	100

*41 (3.8%) respondents gave no answer to this question

**104(9.5%) respondents gave no answer to this question

Table 3.40. Patients' preferences for surgeon and stoma nurse follow up schedule during the first 2 years post-surgery.

3.5.2 Length of follow up in secondary care after 2 years

When patients were asked of their views on the length of follow up in secondary care after the first 2 years, 40.6% (n=425) chose lifelong follow-up as their preferred option. 18.6% of respondents chose review when problems develop, while only 4.5 %(n=47) opted for no more follow up after 2 years. The remainder opted for variable periods of follow up (Table 3.41).

Being 5-10 years postoperative (OR= 1.87, 95% CI 1.31-2.65, p=0.001) or>10 years postoperative (OR= 2.17, 95% CI 1.47-3.22 p<0.001) were significantly associated with choosing lifelong follow up in multivariable analysis. Patients who had been discharged from secondary care were less likely to choose lifelong follow up schedule (OR= 0.15, 95% CI 0.11-0.21, p<0.001) (Table 3.42). None of the other variables (age, gender, indication for surgery and access to stoma nurse) were significantly associated with preferring lifelong follow-up, although being female was borderline statistically significantly (OR=1.37, 95%CI 1-1.88, p=0.053).

Similar results were obtained on repeating the analysis adding ‘Ever reported a complication’ and ‘Ever reported a frequent complication’ as two additional independent variables (Table 3.43).

Patient choices of length of secondary care	Number	Percentage
Lifelong	425	40.6
When problems develop	195	18.6
5 yrs.	141	13.6
1-4 yrs.	146	13.9
6-10 yrs.	87	8.3
No more	47	4.5
11-20 yrs.	6	0.6
Total	1047	

*45 (4.1%) respondents gave no answer to this question

Table 3.41. Patients’ preferences for length of secondary care follow up after first 2 years.

	Odds Ratio	95% CI	P
Gender			
Male	1	-	-
Female	1.37	1-1.88	0.053
Age			
≥ 75	1	-	-
60-74	1.29	0.95-1.76	0.105
<60	1.11	0.67-1.83	0.681
Indication for surgery			
Cancer	1	-	-
Benign	1.35	0.9-2.02	0.141
Time since surgery			
< 5	1	-	-
5-10	**1.87**	**1.31-2.65**	**0.001**
>10	**2.17**	**1.47-3.22**	**<0.001**
Discharged			
No	1	-	-
Yes	**0.15**	**0.11-0.21**	**<0.001**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.40	0.96-2.05	0.081

Table 3.42. Multivariable logistic regression identifying patient characteristics significantly associated with lifelong preference of follow up, odds ratios (OR), 95% Confidence intervals (CI) and p values.

	Odds ratio	95% CI	P
Gender			
Male	1	-	-
Female	1.37	1-1.88	0.052
Age			
≥ 75	1	-	-
60-74	1.30	0.95-1.77	0.102
<60	1.12	0.68-1.85	0.668
Indication for surgery			
Cancer	1	-	-
Benign	1.34	0.9-2.01	0.150
Time since surgery			
< 5	1	-	-
5-10	**1.86**	**1.3-2.66**	**0.001**
>10	**2.18**	**1.46-3.25**	**<0.001**
Discharged			
No	1	-	-
Yes	**0.15**	**0.11-0.21**	**<0.001**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.39	0.95-2.04	0.089
Report ≥1 complication			
No	1	-	-
Yes	1.23	0.77-1.97	0.380
Report ≥1 frequent complication			
No	1	-	-
Yes	0.95	0.70-1.28	0.723

Table 3.43. Multi variable logistic regression identifying patient characteristics significantly associated with lifelong preference of follow up, adding 2 more variables (Ever reported a complication and Ever reported a frequent complication), odds ratios (OR), 95% Confidence intervals (CI) and p values.

3.5.3. Patients' preferences for follow up 2-5 years after surgery

When asked about the postoperative period of between 2 and 5 years , the most commonly chosen schedules for surgeon review were 12 monthly (61.3%) followed by 6 monthly (23.8%). For stoma nurse review, patients selected 'Not routinely' (44.1%) and 12 monthly (29.8%) as the most preferred regimens (Table 3.44).

	Surgeon review*		Stoma nurse review**	
	Number	Percentage	Number	Percentage
Monthly	0	0	3	0.4
3 monthly	17	1.8	48	5.6
6 monthly	222	23.8	170	19.9
12 monthly	571	61.4	255	29.8
6m/12m	2	0.2	0	0
2 yrs.	4	0.4	1	0.1
2-5 yrs.	1	0.1	1	0.1
Not routinely	115	12.3	377	44.1
Total answered	932	100	855	100

*160 (14.7%) respondents gave no answer to this question.

**237(21.7%) respondents gave no answer to this question.

Table 3.44. Patients' preferences for surgeon and stoma nurse follow up schedule between 2 and 5 years post-surgery.

3.5.4. Patients preference for follow up five years after surgery

After 5 years, the most commonly chosen schedules for the surgeon review were 12 monthly (58.7%), and 'Not routinely' (34.8%). For stoma nurse review, patients chose 'Not routinely' (59.0%), 12 monthly (32.1%) as the most preferred regimens (Table 3.45).

	Surgeon review*		Stoma nurse review**	
	Number	Percentage	Number	Percentage
3 monthly	4	0.4	16	2.0
6 monthly	41	4.8	53	6.6
12 monthly	505	58.7	258	32.1
2yrs	9	1.1	2	0.2
5yrs	2	0.2	1	0.1
Not routinely	300	34.8	474	59.0
Total	861	100	804	100

*231(21.2%) respondents gave no answer to this question.

**288(26.4%) respondents gave no answer to this question.

Table 3.45. Patients' preferences for surgeon and stoma nurse follow up schedule 5 years post-surgery.

3.5.5. GP Follow up

Every patient was asked to choose her/his preference of local doctor follow up schedule <u>if she/ he felt community follow up is appropriate</u>, 441 (40.4%) patients gave no answer and 37. 4 % felt that follow up with local doctor should be only 'when needed'(Table 3.46). Patients were asked to give a reason if they thought GP follow up was inappropriate and 486 (43.5%) did so. Answering this question was assumed to imply patient lack of preference for community follow-up. Of these 486 patients, 427 (87.9%) stated they did not prefer their local doctor to look after their IC because of lack of knowledge or experience (Table 3.47).

The frequency of answering this question (i.e not preferring GP follow-up) was higher across female patients (45.6%, p=0.004) and lower among patients who had their surgery < 5 years ago (38.4%, p=0.032) and those who had already been discharged (32.3%, p<0.001) (Table 3.48). In a multivariable model, lack of preference of community based care was significantly associated with being longer since surgery (5- 10 years: OR= 1.83, 95% CI 1.30-2.57; >10 years: OR= 2.41, 95% CI 1.66-3.49) and negatively associated with being already discharged from secondary care (OR= 0.35, 95% CI 0.26-0.48) (Table 3.50). Similar results were obtained when running the model adding two extra variables of 'Ever reported a complication' and 'Ever reported a frequent complication' (Table 3.49); neither complication variable was associated with lack of preference for community-based follow-up.

	Number	Percentage
No answer	441	40.4
3 monthly	20	1.8
6 monthly	97	8.9
12 monthly	126	11.5
when needed	408	37.4
Total	1092	100

Table 3.46. Patients' preferences for GP follow up schedule if appropriate.

	Number	Percentage
No experience/ No knowledge	427	87.9
Busy/ No attention	33	6.8
No consistency	8	1.7
Cancer can recur	3	0.6
No facilities (i.e. scans)	6	1.2
Prefer Stoma nurse	4	0.8
Prefer surgeon	5	1.0
Total answered	486	100

*606(55.5%) respondents gave no answer to this question.

Table 3.47. Reasons stated by patients for why they believe GP follow up is inappropriate.

Category	Frequency of stating a reason (n)	Total (N)	Percentage	P
Gender				
Male	260	636	40.9	0.004
Female	266	456	45.6	
Age				
≥ 75	59	121	48.8	0.270
60-74	242	528	45.8	
<60	185	443	41.8	
Time since surgery				
<5	118	307	38.4	0.032
5-10	183	401	45.6	
>10	185	385	48.2	
Indication for surgery				
Benign	117	242	48.4	
Cancer	369	850	43.4	0.173
Discharged				
Yes	134	415	32.3	<0.001
No	352	677	52.0	
Access to stoma nurse				
Easy / Very easy	371	822	45.1	0.226
Difficult / Very difficult	82	163	50.3	

Table 3.48. Frequency of stating a reason for lack of preference of community follow up at different respondents groups, numbers (n), percentages (%) and p values.

	Odds Ratio	95% CI	P
Gender			
Male	1	-	-
Female	1.28	0.95-1.73	0.103
Age			
≥ 75	1	-	-
60-74	1.18	0.88-1.57	0.276
<60	1.29	0.81-2.06	0.281
Indication for surgery			
Cancer	1	-	-
Benign	0.89	0.61-1.3	0.552
Time since surgery			
< 5	1	-	-
5-10	**1.83**	**1.3-2.57**	**<0.001**
>10	**2.41**	**1.66-3.49**	**<0.001**
Discharged			
No	1	-	-
Yes	**0.35**	**0.26-0.48**	**<0.001**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.31	0.92-1.86	0.138

Table 3.49. Multivariable logistic regression identifying patient characteristics significantly associated with lack of preference of community follow up, odds ratios (OR), 95% Confidence intervals (CI) and p values.

	Odds Ratio	95 %CI	P
Gender			
Male	1	-	-
Female	1.26	0.93-1.7	0.136
Age			
≥ 75	1	-	-
60-74	1.16	0.86-1.55	0.328
<60	1.23	0.76-1.97	0.398
Indication for surgery			
Cancer	1	-	-
Benign	0.87	0.6-1.27	0.466
Time since surgery			
< 5	1	-	-
5-10	**1.72**	**1.22-2.42**	**0.002**
>10	**2.27**	**1.56-3.31**	**<0.001**
Discharged			
No	1	-	-
Yes	**0.35**	**0.26-0.48**	**<0.001**
Difficult access to stoma nurse			
No	1	-	-
Yes	1.26	0.88-1.8	0.204
Report ≥1 complication			
No	1	-	-
Yes	1.36	0.87-2.11	0.175
Report ≥1 frequent complication			
No	1	-	-
Yes	1.26	0.95-1.66	0.108

Table 3.50. Multivariable logistic regression identifying patient characteristics significantly associated with lack of preference of community follow up, adding 2 more variables (Ever reported a complication and Ever reported a frequent complication), odds ratios (OR), 95% Confidence intervals (CI) and p values.

3.6. Summary of patients’ survey results

These results represent the responses of 1092 patients who were surveyed through the Urostomy Association. The response rate to the questionnaire was 59.5%. The respondents included males and females, of a range of ages, and times since surgery, and who were treated for cancer or benign indications.

87.9% of respondents reported at least one complication since surgery, and 45.2% reported a frequent complication. Urinary tract infections (48.2%), parastomal hernia (39.3%) and appliances (36.6%) problems were the most common reported complications.

Using multivariable logistic regression, certain patient characteristics were identified to be significantly associated with reporting complications. These were female gender, age < 60 years, benign indication for surgery, 5-10 yrs. & > 10 yrs. since surgery.

Reporting difficulty in accessing a stoma nurse was associated with a higher risk of reporting complications. This variable was also strongly negatively associated with patient satisfaction with their postoperative care after adjusting for other factors (OR=7.92, 95%CI 5.27-11.89, p<0.001).

The overwhelming majority of patients (84.3%) were satisfied with their follow up. Benign indications for surgery (OR=2.86, 95% CI 1.71-4.7, p<0.001), discharge from secondary care (OR=2.23, 95% CI 1.48-3.37, p<0.001) and difficult access to stoma nurse were all significantly associated with dissatisfaction.

Of the respondents, 415 (38%) reported that they had been discharged from hospital follow up. One-third of the discharged patients said they had been referred back to hospital following their discharge. 38.9% of respondents favored lifelong hospital follow up. A longer time since surgery was associated with choosing lifelong hospital follow up. After adjusting for other factors, patients who had been discharged from secondary care were significantly less likely to prefer lifelong hospital follow up (OR= 0.15, 95% CI 0.11-0.21, p<0.001).

43.5% patients gave a reason why they felt GP follow up is inappropriate for IC cases; the predominant reason (87.9%) was lack of knowledge or experience. Lack of preference of community based care was significantly positively associated with being long from surgery (OR= 1.83, 95% CI 1.30-2.57) and > 10 yrs. (OR= 2.41, 95% CI 1.66-3.49). Those who had already been discharged from secondary care were significantly less likely to think GP follow-up is inappropriate (OR= 0.35, 95% CI 0.26-0.48, p≤0.001).

Chapter 4. Study B results: Current practice & alternative models of surveillance for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process Theory

4.1. Introduction

The main aim of this study was to explore the implementation of current practices of follow up for IC patients and to understand why and how a “new” (alternative) model of surveillance for IC patients could be successfully developed and implemented, whether in the community or secondary care. The introduction and implementation of an alternative model of surveillance up for ileal conduit patients would require the involvement of multiple stakeholders across both primary and secondary care. A qualitative method (semi-structured interviews with secondary care health professionals) guided by the Normalization Process Theory was used to conduct this part of the study. The theory has identified four main domains that promote or inhibit the kinds of co-operative work that is needed to implement service innovations in complex organizational contexts, the NHS for example. Those four domains are Coherence, Cognitive Participation, Collective Action, and Reflexive Monitoring (Chapter 1)(May and Finch, 2009) .

4.2. Study sites and participants

4.2.1. Study sites

The interviews took place at 3 centres - designated A, B and C to protect participants’ identifies - in three different areas in England. The centres were at the North, Yorkshire and the Midlands. The centres’ characteristics are summarised in Table 4.1.

Centre	Region	Type	Approx. catchment Population	Type of relevant Urology service
A	Midlands	Teaching hospital	800,000	Cancer
B	North	Teaching hospital	1,000,000	Cancer and reconstruction
C	Yorkshire & the Humber	District General	500,000	Cancer and reconstruction

Table 4.1. The characteristics of the centres involved in the study.

4.2.2 Follow up models

As described earlier (Chapter1), the differences in the local follow up schedules between centre A and centre B were known before the start of the study. The follow up protocol at the site C emerged during the interviews. The three centres had different models for long-term follow up for IC patients in terms of length, settings and involved health professionals. Nevertheless, there was a great similarity in the investigations arranged on hospital visits for surveillance.

Centre A. At this site the follow up was mainly a consultant led service. Following the initial few post-operative years, the patients are followed up annually at a consultant led clinic. There is no departmental written protocol for the length of follow-up, however most of the consultants tend to keep the surveillance lifelong. There was no Urology nurse specialist involvement in follow up due to workforce shortages, however there was a plan to introduce this role. [After the end of recruitment to study B, AA learned that a nurse specialist had been appointed to take on the role of following up bladder cancer patients who had IC at a joint clinic with the consultant]. The stoma nurses on this site are employed by an appliances company but hold an honorary contract with the Trust. Their role involves solely providing stoma care support for patients when required. The patient accesses them via phone and an appointment is arranged if required.

Centre B. At this site there is a uniform- but unwritten - local protocol for long term follow up. Following the initial postoperative years of consultant led follow up, patient surveillance is transferred to a Urology stoma nurse or a nurse specialist led clinic. A well-structured annual review takes place at this nurse-led clinic where patients are reviewed and have a set of bloods and a scan. Patients always have access to stoma nurses by phone, and they can be booked into a drop-in nurse-led clinic if required.

Centre C. On this site there is a uniform - but again unwritten - protocol for follow up for 5 years after surgery. During that period patients are seen simultaneously at 2 different clinics led by consultant and nurse specialists, respectively, for the first 2 years. Following the initial 2 years, patients are discharged from the consultant led clinic and follow up continues with the specialist nurse where they are followed up for further three years then discharged back to community. They keep access via phone to the hospital based stoma nurse clinic for stoma care support, and appointments are arranged if required.

4.2.3. Participants

Of 20 health professionals approached, 17 agreed to participate and were interviewed. These were 8 consultant Urological surgeons (U), 4 nurse specialists (NS) and 5 stoma nurses (SN). The participants' average (range) experience in their current role was 13 yrs. (2.5-35). The participants' characteristics are detailed at table 4.2. The average (range) interview length was 29 minutes and 46 seconds (12:24 -50:58).

NO	Centre	Code	Job title	Years of experience in current role
1.	X	X/U/01	Consultant Urologist	27
2.	X	X/U/02	Consultant Urologist	4
3.	X	X/U/03	Consultant Urologist	17
4.	X	X/U/04	Consultant Urologist	27
5.	X	X/SN/01	Stoma nurse	14
6.	X	X/SN/02	Stoma nurse	30
7.	Y	Y/NS/01	Nurse specialist	10
8.	Y	Y/NS/02	Nurse specialist	35
9.	Y	Y/SN/03	Stoma nurse	4
10.	Y	Y/NS/04	Nurse specialist	16
11.	Y	Y/U/01	Consultant Urologist	13
12.	Y	Y/U/02	Consultant Urologist	11
13.	Z	Z/U/01	Consultant Urologist	8
14.	Z	Z/SN/01	Stoma nurse	2.5
15.	Z	Z/SN/02	Stoma nurse	9
16.	Z	Z/U/02	Consultant Urologist	4
17.	Z	Z/NS/03	Nurse specialist	3

Table 4.2. Participants' characteristics.

The three groups of health professionals were represented across all three centres except for centre X where no nurse specialists were involved into IC care during the study period. Hence, no nurse specialist could be interviewed from that site.

4.3. Themes and Sub-themes

Seven main themes emerged from the interviews: (1) current practice and alternative models; (2) role of surgeon & secondary care; (3) role of stoma nurse & urology nurse specialist; (4) community follow up; (5) General Practitioner role; (6) patients' involvement and (7) resources. Tables (4.3-4.9) shows the main seven themes and the relevant subthemes

Theme(1)	**Current practice and alternative models**
Sub-Themes	Awareness of ileal conduit complications
	Defining complications
	Valuing of follow up
	Need for change
	No agreement on length of follow up
	Advocacy for a standard protocol
	Existing local protocols
	Defining the aims of follow up
	Accommodating benign and cancer cases
	Accommodating different types of bladder cancer follow up
	Knowledge of guidelines
	Ideas proposed for long term follow up

Table 4.3. Theme 1: Current practice and alternative models.

Theme(2)	**Role of surgeon & secondary care**
Sub-Themes	Role of surgeons at follow up
	Willingness to teach or organise
	Engagement of stakeholders
	Audit and research

Table 4.4. Theme 2: Role of surgeon & secondary care.

Theme(3)	**Role of stoma nurse & Urology nurse Specialist**
Sub-Themes	Role of SN/NS at follow up
	SN/NS coordinating role
	Valuing SN/ NS role
	Individualised care & holistic approach to care from SN/NS
	Work relationship with non-NHS stoma nurse
	Stoma nurse access to investigations
	Lack of stoma nurses experience at non-stomal complications

Table 4.5. Theme 3: Role of stoma nurse & Urology nurse Specialist.

Theme (4)	**Community follow up**
Sub-Themes	Support for community based follow up
	Awareness of implications of community FU
	Similar successful models
	Communication between primary and secondary care

Table 4.6. Theme 4: Community follow up.

Theme(5)	**General practitioner role**
Sub-Themes	Uncertainty about GP willingness to be involved
	GP role at follow up
	Lack of GP knowledge & experience
	Communication with GP
	Support of and work relationship with GP

Table 4.7. Theme 5: General practitioner role.

Theme (6)	Patients' involvement
Sub-Themes	Patients' access to secondary care
	Patients' expectations
	Giving patients the choice
	Patient education
	Patient support groups

Table 4.8. Theme 6: Patients' involvement.

Theme (7)	Resources
Sub-Themes	Investigations required
	Lack of SN in secondary care
	Teaching and training
	Urology workload

Table 4.9. Theme 7: Resources.

In the next section the sub- themes are described in relation to the four constructs of the NPT; the sub-themes are further classified into barriers and facilitators under each construct. The additional subthemes that didn't fall under the NPT framework were separately discussed in a dedicated section (4.5).

4.4. Findings in relation to the four NPT constructs

4.4.1. Coherence

This construct represents the work of making sense of a set of practices, its aims, its value and how it is different from other practices. The participants showed a good coherence of the concept of long term surveillance for IC and of the potential need for introduction of an alternative model. The majority of the interviewees described the long term complications of IC and expressed valuing the role of surveillance. Stoma nurses with no urology background expressed their lack of experience of the non-stoma related complications. Participants considered that there was a need for change in surveillance in order to: reduce the risk of missing complications because of the (current) absence of a standardised protocol; and help to decrease the pressure in secondary care services. They considered that there were some challenges in the introduction of a shared care community pathway, including the need for resources and investment to make it workable. Further barriers to implementation of an alternative follow-up protocol were absence of a shared understanding of the length of follow up needed in secondary care and of how the surveillance scheme could be adjusted to accommodate both benign and cancer cases.

NPT construct	Facilitators	Barriers
Coherence	Valuing follow up	No agreement on length of follow up
	Awareness of ileal conduit complications	Accommodating benign and cancer cases
	Advocacy for a standard protocol	Accommodating different types of bladder cancer follow up
	Knowledge of guidelines	Lack of stoma nurses experience at non stoma complications
	Need for change	
	Awareness of implications of community FU	

Table 4.10. Facilitators and barriers to implementation of an alternative follow-up schedule under ‘Coherence’ construct.

Facilitators

Valuing of follow up and Awareness of ileal conduit complications

Participants expressed that they valued the long term follow up for IC patients. This seemed to arise from their knowledge of the risk of long term complications that are associated with this surgery. Surgeons and nurse specialists showed awareness of the different long term complications, and they described the different adverse effects of the surgery i.e. renal failure, urinary tract infections, hernia etc. They emphasised the role of follow up in detecting these complications early. Participants felt that the importance of long term follow up lies in identifying minor problems before they exacerbate. Surgeons showed more in-depth knowledge of the metabolic complications such as acidosis, folic acid deficiency and the need to monitor those. Most of the stoma nurses considered an additional focus of follow-up should be the on the social and psychological consequences of the surgery and its complications.

X/U/01

'Follow up is very important; apart from the cancer follow up the ileal conduit has its own issues. Bicarbonate upset of blood cause hyper-acidosis or low bicarbonate that needs to be monitored and also local issues of stomal prolapse, parastomal hernia, and stomal stenosis will all need addressing as well'

Z/SN/01

'Recently I had a problem with a patient who had incontinence and problems dealing with the stoma, leakage from the pouch which was affecting him psychologically.'

Advocacy for a standard protocol and Knowledge of guidelines

Almost all the professionals expressed their awareness of the lack of national or international guidelines designed specifically for IC long term follow up, and were advocates of a written protocol. Several advantages of a formal arrangement of follow up were described by interviewees: it would minimise the risks of missing complications and losing patients to follow up, it can improve the communication between secondary and primary care; and it can provide the patient with a formal port of call when required .In addition, it was felt that it could provide greater uniformity of care and allow for auditing and research.

X/U/03

'I think there should be (1) a standard transfer of care form, (2) what to look for, (3) point of contact by the patient. '

X/U/01

'if we can organise their [patients] follow up then we can try our best to make sure we don't lose patients to follow up and that is why the stoma nurse clinic was set up many years before I started here which I think is a good model. A medically-led follow up in a consultant-led clinic with varying degrees of trainee input throws up all sorts of anomalous practices.'

Need for change

The participants considered that there might be a need for change from current practice for two main reasons: first; the risk of non-standardised follow up that is not well supported by evidence or national guidelines; and secondly the mounting pressure on secondary care services. According to the participants', the absence of a standard model of surveillance could result in failure to identify complications, patients being lost in the system and inability of patients to gain access to medical attention when required.

Z/SN/01

'…... the patient should know who to contact if they are having problems.'

X/U/02

'It [Community based follow up]) would free up spaces in your clinic to see other patients'

Z/U/01

'At the moment I suspect it is very hit and miss that they (GPs after patients are discharged from secondary care) don't know what they should be doing which is why patients can incur accidents etc'

Interviewees discussed the pressure in outpatients' clinics and on the work force in secondary care. The increasing numbers of follow up slots in clinics is minimising the space available for new patients who can wait for months for their first appointment. Additional stoma nurses have been appointed at one of the centres just to cope with workload of stoma care and maintaining the local protocol for follow up. Some participants expressed a belief that the increased workload in secondary care could stimulate the introduction of a shared care model which could work for ileal conduit patients as it has worked in other urology areas like prostate cancer. Furthermore, easily accessible and individualised care were seen as additional benefits of community follow up.

Y/NS/04

'The negatives [of Hospital based follow up setting] are probably insufficient time with each patient when they attend the clinics but as we now have additional staff we are trying to accommodate patients who require a longer clinic time slot to deal with their problem on the same day.'

X/SN/01

'I do think it [community follow up] is a safe thing to do as you get to see the patient in their own environment. You get to see their social setting, if they are married or if living on their own, if they are vulnerable, not eating or drinking, we get to see that side quite differently from the hospital setting.'

Awareness of implications of community FU

The majority of participants emphasised the implications of development of a community based follow up model and the challenges that comes with it. Most participants discussed the challenges and barriers of community follow up; for example: lack of GP experience, poor access of stoma nurses to investigations such as upper tract imaging and availability of space for clinics. Participants identified that a range of resources would be required to establish this model including training for GPs and community stoma nurses, financial resources and a formal communication route between primary and secondary care.

Z/SN/01

‘The GP actually asks us to review the patients because sometimes they don’t know how to manage them.”‘

X/SN/02

‘…, the only investigation that I [community stoma nurse] can do is taking a urine sample ‘

X/U/01

‘We [Urologists] will need willing GPs, patient co-operation and excellent communication between us and GP. If GPs are not able to contact us the process could fail.’

Barriers

No agreement on length of follow up, Accommodating benign and cancer cases and Accommodating different types of bladder cancer follow up.

In terms of development of a standardised protocol, participants held very different opinions over the length of follow up that should be offered in secondary care before discharge to community if at all. There was no common view of how long the patients should be reviewed in hospitals before they get discharged for a community follow up. Another area where there were differences in opinion was with whether there was a need to adjust any protocol for cancer and benign cases; this seemed undetermined yet by some participants or viewed differently amongst others. In addition, some surgeons highlighted that even surveillance of different types of bladder cancers can be different as they vary at their prognosis.

X/U/02

‘I [a Urologist] do not know if after ten years whether we should go for discharging them or not; potentially from a cancer point of view we could do’

‘I think it would be a tailored follow up protocol according to the patient but this might complicates things for GPs so I don’t want to start stratifying patients ‘

X/SN/01

‘The follow up plan should be exactly the same [for benign cases] because it is the stoma we are concentrating on;’

Lack of stoma nurses’ experience at non-stoma complications

As might be expected for their current role, it emerged that stoma nurses’ experience of long term complications seemed largely focused on the stoma -related complications such as appliances and skin issues. The stoma nurses without a Urology background expressed their lack of experience and involvement with the monitoring of non-stoma issues. On the other hand, Urology stoma nurse specialists seems to have good knowledge and experience at this areas. In one of the centres, they described their active involvement in the implementation of local protocols, including requesting appropriate investigations and even interpreting the results.

X/SN/01

‘We [stoma nurses] don’t get involved in that [non stoma complications], we just focus on the stoma and the skin. We don’t look at the kidney problems’

Coherence	Sub-Themes	Quotes
Facilitators	Valuing of follow up	X/SN/01 *'We need to keep in contact with them [patients] to make sure that their minor issues do not become bigger problems'*
	Awareness of ileal conduit complications	Y/NS/01 *'I Look at the patient as a whole to see if the patient is coping physically,…… bloods, kidney function which is looked at in the outpatient follow up where they get scans and bloods taken.'*
	Advocacy for a standard protocol	X/U/01 *'I think if you have a firm protocol to make things uniform it would be very useful for audits or research to see how the patient have done nationally because there would be a set pattern for follow-up, and investigations'*
	Knowledge of guidelines	Y/U/01 *'I am not aware of any follow up guidelines.'*
	Need for change	*Y/SN/03* *'I have queried why I am still seeing people 10 years down the line that have never had a problem.'*
	Awareness of implications of community FU	Y/U/02 *'…….; it might be difficult to set up ultrasound scans in the community due to lack of machines.'*

Table 4.11. Additional examples of quotes of facilitators under 'Coherence' construct.

Coherence	Sub-Themes	Quotes
Barriers	No agreement on length of follow up	Z/U/01 *‘Again we haven’t set it [local protocol] in stone, but I would say five years in total and then the patient is discharged.’*
	Accommodating benign and cancer cases	X/U/03 *‘I would look at the stoma [for benign IC cases]3 months later and if it is fine then maybe one more visit 6 months later and that’s it.’*
	Accommodating different types of bladder cancer follow up	Y/U/02 *‘Depending on the type of cancer the imaging would be quite intense for the first couple of years and then after that probably twice a year and then from year 5 once a year only.’*
	Lack of stoma nurses experience at non -stoma complications	Z/SN/01 *‘We review the stoma and if there is a problem we deal with it, be it different pouch, leakage, sore skin. If the problem is more complex, then it is referred to the consultant.’*

Table 4.12. Additional examples of quotes of barriers under ‘Coherence’ construct.

4.4.2. Cognitive participation

This construct represents the ‘relational work’ that the people do towards a set of practices. Successful implementation of an intervention such as IC long term surveillance, would require the engagement of the key professionals and their units and the readiness to invest time or resources into its enacting. In the absence of a standardised protocol or guidelines, all three units have shown proactivity towards establishing a follow up scheme either at the level of the local unit or individual surgeon. Stoma nurses described how they have invested time and underwent training to fulfil the requirements of their role and put extra efforts to meet patients’ needs. There were doubts expressed about GPs’ willingness to be involved in IC long term surveillance and about patients’ response to a community based model of follow up.

NPT construct	Facilitators	Barriers
Cognitive participation	Existing local protocols	Uncertainty about GP willingness to be involved
	Similar successful models	Patients’ expectations
	Role of surgeons at follow up	
	Support of and work relationship with GP	
	Role of SN/ NS at follow up	
	GP role at follow up	

Table 4.13. Facilitators and barriers under ‘Cognitive participation’ construct.

Facilitators

Existing local protocols & Similar successful models

In the absence of national or regional guidelines, two of the three units involved in the study have taken the initiative to develop their own follow-up protocol. While only one of the local protocols covered long term follow up, the description of both protocols by the enacting participants revealed that both of the local protocols were reasonably structured, organised and supported by resources such as clinics and investigations. With the increasing numbers of patients, one of the units had invested further by recruiting additional stoma nurse specialists to support the nurse led surveillance.

Y/U/01

‘..and that is [knowing the IC related complications] why stoma nurse clinic was set up many years before I started here which I think is a good model.’

Y/SN/03

‘…. Following discharge we see ileal conduit patients 3 monthly, 6 monthly and then annually but again in between that they also see the consultant as well. We do ask the patient if they have had recent CT/bloods with the consultant to make sure these investigations are up to date.’

Participants described that all three units were actively engaged into a shared care pathway designed for the long term surveillance of prostate cancer patients in collaboration with their local Clinical Commissioning Groups (CCG), this can demonstrate that urology units could act similarly if an alternative community model of surveillance is developed.

X/U/02

‘We (the unit) have a protocol for stable prostate cancers. We could have a similar protocol for stable bladder cancers or patients with urine diversion’

Y/U/02

‘ We (the unit) did a similar thing for PSA for prostate cancer and it seemed very successful. We were the first people in the country to actually do such a study so it can be done.’

Role of surgeons at follow up

While surgeons showed good coherence of the scope and value of a follow up protocol, they also expressed engagement with the follow up process. When there was no local protocol for surveillance at one of the three units, individual consultants explained that each of them had initiated his own schedule. This involved regular visits to their clinics and a set of investigations to identify any potential complications related to the ileal conduit. In order to overcome the lack of communication channel for patients to secondary care due to shortage of stoma nurses in their unit, some surgeons described how they had provided patients with their secretaries’ phone number to facilitate the contact.

X/U/01

‘In the current practice we see the patient, arrange tests and arrange an appointment for 12 months for example. In the meantime if there are problems the patient has to contact our secretaries and that is working okay’

X/U/03

‘The patients have my point of contact. The GPs can also contact me if they have a problem. In addition the incontinence nurses also help out.’

Support of and work relationship with GP

Surgeons described how they invested time into training and collaborating with GPs on similar shared care pathways for prostate cancer. Most of them expressed willingness to play similar role for the development of a pathway for ileal conduit patients.

Z/U/01

'…., we have a yearly GP meeting[about the prostate cancer shared pathway] ……… and then we will talk about any issues that have come up, we will talk about what they have in terms of issues and it is an educational day as part and parcel of shared care.'

X/U/01

'I would be more than happy to participate in a meeting with the GPs either in the hospital or in GP practice. …..We could have a meeting between the urology department staff and the local GP to teach them the requirements for stoma follow up. A face to face meeting would be ideal to facilitate immediate questions and answers rather than sending protocols by post.'

Role of stoma nurse/ specialist nurse at follow up

Using the existing follow up arrangements, stoma nurses & Urology nurse Specialists described acts of commitment and flexibility to ensure appropriate care is delivered. When there is a local protocol, stoma nurses described how they adhered to the schedule and how they had invested in expanding their role, for example, by requesting the relevant tests and developing the skills to interpret the results. Stoma nurses explained how they worked flexibly to deliver patient care. Time and effort had been invested into consultation phone calls and outreach visits to make the service more accessible to patients and minimise the burden of travel. Stoma nurses without a Urology background expressed their willingness to expand their roles and receive the necessary training to underpin new responsibilities.

X/SN/01

'If the patient requires a second follow up then I [stoma nurse] would do a second week[home] visit but I would do one each week for as long as it takes the patient to feel confident in coping with the stoma bag.'

X/SN/02

'I think that could become an extended role with some training alongside so we can become efficient.'

GP role at follow up

Some participants described active role for some local doctors at the current surveillance process. According to interviewees, some GPs already arranged annual reviews for IC patients, monitored renal function and referred patients back when specialist attention was required.

X/U/02

'….,they [GPs] are very good at picking things up [complications]and sending the patients to the right channel if there is any problem.'

Barriers

Uncertainty about GP willingness to be involved

Most of the participants expressed doubts over GPs' willingness to engage with a shared care community pathway for IC patients. They spoke about a range of issues that they felt could make greater engagement of local doctors in IC follow-up challenging. These included GP workload, lack of GP expertise in this clinical area, GP unwillingness to take the clinical responsibility and financial arrangements.

X/U/02

'I do not know how many GPs would be interested in looking after these[IC] patients long term.'

'I think overall because it [follow up review] is annual it is not very onerous for GPs to do that but it would add to their workload anyway. '

Z/SN/03

'…... when we have bloods that is in the name of the consultant they [GPs] pick up on this stating it is not in their name so there are certain things they won't pick up on.'

Patients' expectations

Some participants expressed their concerns about possible patient lack of confidence in a community based follow up, and that this might affect patient engagement with such model. Interviewees expressed the view that patients might feel that GPs' lack experience or have too heavy workload to be involved in IC follow up.

X/U/01

'When I mention discharge to GP care some patients are disappointed; some patients do not trust their GP'

Y/NS/04

'On the other hand I think there a lot of patients who feel reassured by coming back to secondary care for their follow up because they saw them when they were most vulnerable.'

Cognitive participation	**Sub-Themes**	**Quotes**
Facilitators	Existing local protocols	Z/U/01 *'they [patients] come to see me [urologist] at six weeks, then 3 monthly in the first year and the second year .. . The reason we see them for two years is that they should get a CT scan at 6, 12 and 24 months and then routine bloods in between.'*
	Similar successful models	Z/U/01 *'We have a prostate cancer and renal cancer follow up service out in the community that works very well and so for our other cancers we want to have a similar bladder cancer service'*
	Role of surgeons at follow up	Y/U/01 *'I would certainly have an input into it [Developing a new protocol]'*
	Role of SN/ NS at follow up	Y/SN/03 *'We [stoma nurses] check the results and if there are no changes. If there are of concern we would then speak to the consultant for his input.'*
Barriers	Uncertainty about GP willingness to be involved	Y/NS/04 *'From a GP point of view, I think it would be a lot of extra work for them to take on and from a financial side it would possibly not be beneficial.'*
	Patients' expectations	X/U/04 *'…..patients would be unhappy to be discharged back to primary care.'*

Table 4.14. Additional examples of quotes of facilitators and barriers under 'Cognitive participation' construct.

4.4.3. Collective action

This construct reflects the ability of the staff to operationalise the intervention into their day to day practice. It reflects how people work together to implement the intervention, the use of the skills available to deliver tasks and the work of allocation for available resources to enact certain practice.

The participants discussed the aim of follow up in their view and explained how they regularly requested the investigations required to detect complications. Participants described how stoma nurses in particular were able to interact with patients and the other members of the clinical team to improve communication and enact the follow up. It was highlighted by participants how patients sometimes developed their own skills in IC self-care and founded support groups both of which were felt, by participants, to represent valuable assets to the implementation of the follow up practice. A belief that GPs lack the skills that would make them play a role at the implementation of a community surveillance model was expressed by most participants. Resources, such as lack of clinic slots and trained stoma nurses, were felt to represent a barrier to the existing secondary care models.

NPT construct	Facilitators	Barriers
Collective action	Defining complications	Patients' access to secondary care
	Defining the aims of follow up	Lack of GP knowledge & experience
	SN/NS coordinating role	Work relationship with non-NHS stoma nurse
	Patient education	Resources
	Patient support groups	Communication with GP

Table 4.15. Facilitators and barriers under 'Collective action' construct.

Facilitators

Defining complications & Defining the aims of follow up

The complications encountered by ileal conduit patients were well defined by surgeons and nurse specialists. Participants' responses reflected a clarity of their perception of the aim of the follow up scheme they are currently using and how they are using it to detect potential complications. There was a consistency amongst the participants about the investigations required to diagnose relevant complications, such as upper tract imaging and blood tests to monitor renal function, vitamin B_{12}, etc. This indicates the ability of the participants to operationalise surveillance protocols with clear aims and usage of their tools.

X/U/02

'Blood tests e.g. UE, check vitamin B12, folic acid. For cancer patients we tend to do LFTs, calcium and FBC as well to look for any anaemia and urine culture. Regarding imaging, I would say CT scan potentially but if this is a non-cancer patient I would be happy also with an ultrasound of the kidneys'

Y/U/02

'We know that in the long term they can have metabolic problems; renal failure; also we do look at the psychological and social impact of having even a urinary diversion package.'

Stoma nurse/ Nurse Specialist coordinating role

The role of stoma nurse was considered pivotal by many participants for the successful implementation of a long term surveillance protocol. In addition to their day to day role enacting of the follow up by requesting investigations, and clinic consultation, participants described how stoma nurses play an important coordinating role, liaising between the different parties involved in the provision of care. The participants' described how stoma nurses liaise with patients, community stoma nurse, local doctors and surgeons to arrange simple investigations such as blood tests and urine cultures or more specialised imaging such as CT scans or loopograms. They are seen as a contact person for patients or GPs when a specialist advice or consultation is required because of their direct communication with the consultants of the unit. This interactive role in current practice was considered very effective and something that should be maintained in any future arrangements for an alternative model.

X/SN/01

'We [stoma nurses] might say [to the patient] attend your GP and get a urine sample checked to make sure there are no underlying infections…………….. ; if we feel this [a blood test] is required then we would write to the GP.'

Z/SN/01

'If the problem is more complex then it is referred to the consultant. We could do blood tests for renal function; if infection we can do swabs at that clinic appointment and we liaise with the GP for antibiotics. If they have presenting symptoms and are unwell I could get them reviewed in the surgical assessment unit'.

Patient education & Patient support groups

From their experience working with patients, participants described how they noticed patients acquiring skills, gaining experience and learning quickly to manage their condition. Participants described how patients had worked with clinicians to develop patient support groups which represent a platform to exchange experience and tips and to interact with clinicians. Participants emphasised the importance of patient support groups and how they are keen to link their patients to them. The patients' role was seen as a valuable resource that could aid successful implementation of an alternative surveillance protocol.

X/U/02

'They [patients] get actually very experienced with their stomas quickly so they can tell whether there is any problem or not early on and this has been my experience'

X/U/04

'They [patients] will float ideas from each other [using the patients support group] and surprisingly they will have a lot more resource to actually look on the internet. I think the patient focus group for urostomy is good. I know that the urostomy association used to be very proactive and I know that when we started the process here.'

Barriers

Patients' access to secondary care

In a secondary care follow up setting, the burden of travelling to hospitals was seen by some participants as a barrier to implementation of this model. Participants described that patients who are frail, live remotely, and don't drive can struggle to attend their hospital appointments. Added to that, there can be issues with car parking availability and anxiety of coming to hospitals. Therefore, participants felt that attending hospital follow up can be difficult for certain group of patients. Stoma nurses explained their attempts to overcome these hurdles by undertaking home visits, but noted that this was time consuming and costly to hospitals. A community based model of surveillance was felt to be a way to mitigate these problems.

Y/U/02

‘Discharging them [patients] would save a lot of money or time because some of them live a long way from the hospital.’

Y/NS/02

‘……, it just takes away a lot of the anxiety surrounding attendance to the hospital etc. and the problems that go with that, which may seem little problems to us because we are fit and well, but for patients getting to a specialist centre is often a big ordeal and parking so if you can take away all of those layers then they can just focus on the thing that you are actually seeing them for.’

Lack of GP knowledge & experience

Almost all of the interviewees expressed a belief that GPs currently lack the experience and knowledge to follow up IC patients in the community, because of lack of training in this area and the small number of IC cases seen by each GP during his/her work experience. Participants felt that GPs’ current skills are not sufficient to enable them to take on the clinical responsibility of community based follow up. Nevertheless, participants felt that GPs core skills could be built upon with training to enable them to be sufficiently expert to be able to enact a follow up protocol for IC patients.

X/U/04

‘…, but for the upper tract I do not think that primary care is geared to think a lot about the upper tract; I say this because of the NICE guidance that has been released for urothelial cancers last year which stipulates that an average GP is likely to see how many prostate cancers, how many bladder cancers, how many kidney cancers in his working in his working life.’

X/U/01

‘Once educated I am sure the GPs could manage any complications that may arise’

Work relationship with non-NHS stoma nurse

One of the three centres suffered from a shortage of stoma nurses support. In order to solve the problem and maintain the support patients required, the Trust have arranged honorary contracts for two community stoma nurses who are sponsored by an appliance company. It emerged during the interviews that there was a perception of non-NHS stoma nurse as biased towards their company products. One of the appliance company stoma nurses felt that GPs are sceptical of their role if they are employed by a stoma appliances company. This scepticism was also clearly expressed by one of the hospital Nurse specialists in another unit.

X/U/01

‘At the moment we have not got a urology stoma nurse based in the hospital. The current stoma nurse works in different institutions and provides an ambulatory service.’

Y/NS/04

‘Stoma nurses tend to be employed by companies rather than the NHS and I can envisaged patients being followed up by them but of course they would be biased to using their company’s products which might not be the best for the patient whereas NHS community staff would always service the patient’s best interest.’

Resources

It clearly emerged from the interviews that certain resources were felt to be essential to conduct safe and efficient surveillance. These are a standard IC follow up protocol, investigations, clinic capacity and skilled clinicians. As previously discussed apart from local protocols, the literature, national and international guidelines are deficient at the area of long term ileal conduit follow up (chapter1). This was expressed by most of participants.

X/U/04

‘……..particularly for ileal conduit to my knowledge there are no newer guidelines that I have seen.’

Y/NS/04

‘In my opinion I think we follow local guidelines. I have not come across any national or international guidelines.’

The investigations mentioned - such as blood test, urine culture and upper tract imaging - were described as being accessible and available in both primary and secondary care settings. However, community based stoma nurses expressed that they don’t have access to request or review the investigations. Again, many participants discussed how the increasing workload at Urology clinics seem to be a barrier against continued secondary care long term follow up. This was expressed by interviewees irrespective of whether they were in a centre where the current surveillance offered was in a consultant led or a nurse led clinics. The need for skilled stoma nurses was identified as a particular challenge in terms of resources.

X/SN/01

‘Obviously we [community stoma nurses] would have to write to GP to request the forms for the bloods and ultrasound etc. and then to review the results and let us know if there is an issue.’

‘If we are in a GP clinic then obviously we would have access for results but if I am working out in the community on my own, I would have to go to that GP practice to get the results’

X/U/01

‘………to see these patients in the community to take the burden off secondary care. In urology we are inundated with referrals’

Communication with GP

The difficulty of communicating with local doctor was raised as a barrier by many participants. The process of gaining access to GPs and waiting for responses was described as being long and not easy. This barrier was described particularly by stoma nurses and nurse specialists.

X/SN/02

‘I [community stoma nurse]do generally have to go through the GP [to arrange an investigation] and that can take quite a long time to contact them if they are not working that day etc; it can take up to a week to get an answer from a GP.’

Collective action	**Sub-Themes**	**Quotes**
Facilitators	Defining complications	Y/NS/ 02 *'Sometimes I have problems with the stoma itself and perhaps clients' difficulties, skin problems etc.'* *'Our patients can often go onto develop stones, have obstruction at later times, sometimes deterioration in renal function.'*
	Defining the aims of follow up	Y/NS/04 *'To make sure the conduit is functioning well; check their kidney function is not compromised; check they have the correct products.'*
	Investigations required	X/U/01 *'Tests would include conduit urine for microbiology, serum bicarbonate, renal function and to check for upper tracts with ultrasound or CT scan at least twice a year.'*
	SN / NS coordinating role	X/U/03 *'The stoma nurse provides a contact for the patient and she would contact our department should the need arise.'*
	Patient education	Y/U/02 *'Most patients are competent to look after their stoma and do very well.'*
	Patient support groups	Y/NS/01 *'They could be provided with contact numbers of relevant associations so that they don't feel they are out there on their own coping with something on their own.'*

Table 4.16. Additional examples of quotes of facilitators under 'Collective action' construct.

Collective action	**Sub-Themes**	**Quotes**
Barriers	Patients’ access to secondary care	X/SN/01 *‘…, if the patient is elderly with poor mobility then I would do a home visit so there is flexibility.’*
	Lack of GP knowledge & experience	Y/U/01 *‘Discharging directly back to GPs in the current climate is impractical.’*
	Work relationship with non-NHS stoma nurse	X/SN/01 *‘GPs tend to be very sceptical about the[appliances] company, they don’t particularly want company nurses to be involved with the patients; they think we are there to make ways to get more business for the company.’*
	Resources	Y/U/01 *‘The only thing that is imperfect about it [the secondary care follow up] is the capacity for the stoma nurse follow up clinic because of the numbers of patients.’*
	Communication with GP	Z/SN/03 *‘Access in the hospital is easier because we can email the consultant’s secretary for quicker response. In the GP practice this process might take a bit longer.’*

Table 4.17. Additional examples of quotes of barriers under ‘Collective action’ construct.

4.4.4. Reflexive monitoring

The work of appraisal of a practice or intervention is of paramount importance to successful implementation. This work starts by collecting data followed by an evaluation of the outcomes which usually leads to certain measures that might lead to reconfiguration of the service.

According to interviewees, reflexive monitoring was clearly deficient across the three centres. Apart from a few audits which were either done long time ago or were not mainly focused on assessing the effectiveness of IC follow up , most of the participants reported not being involved in, or aware of, any form of evaluation of current practice. One of the participants explained how he relied on an informal ‘chat’ with the patients to get their feedback on their care. No facilitators emerged under this construct.

X/U/02

‘Q. Do you use any method to evaluate your follow scheme for those patients?

A. Not particularly although in the next 4 to 5 months we will be auditing my cystectomies and part of it is ileal conduit to look at various things’

Y/U/02

‘I know X [name of the surgeon] picked out this years ago and he even looked at doing renograms in these patients but this was about 20 years ago’

Reflexive monitoring	**Quotes**
Barriers	X/U/03 *‘Whenever the patients come to clinic we have a good chat and they often come to my office rather than the clinic to have a long chat about their care.’* Y/NS/04 *‘I think a few years ago there was an informal study by our Matron where she was trying to avoid patients having duplicated appointments with the doctors and the nurses but I don’t think very much happened with that maybe due to being too time consuming at that time.’*

Table 4.18. Additional examples of quotes of barriers under ‘Reflexive monitoring’ construct.

4.5. Additional themes

Several additional themes emerged during the analysis process that could not be mapped under the NPT four constructs.

Ideas proposed for long term follow up & Support for community based follow up

Many participants suggested models of follow up different to the ones they are currently following. The majority of these ideas favoured community based surveillance models. Some participants were able to give a comprehensive description of what the model of care might involve. One of the ideas that was repeatedly suggested was the development of a shared care community based surveillance model where the different parties contribute. Under this model, local doctors could provide resources such as the clinic room, taking bloods and, perhaps, ultrasound scans. The Urology department would provide a trained stoma nurse who is well connected to the urology surgical team at the hospital and who would run structured clinics in the GP practice. .The hospital doctors would offer training sessions to patients to improve awareness of their condition and enhance their skills of self-care. Participants felt that this model could have many benefits. It would provide an accessible service to patients by a well-trained clinician who has strong connection to specialist care, and at the same time relieve the pressure on secondary care. Because this theme reflects hypothetical ideas rather than action, it was not mapped under the NPT (which is a theory of actions).

X/SN/02

'I think we [stoma nurses] could run structured clinics in GP practices for these patients; this would also facilitate quicker access to GPs for example requests for bloods/radiology. This would make life easier as any investigations could be dealt with quickly.'

Giving patients the choice

Another interesting theme that emerged was to provide community-based and hospital-based models for surveillance simultaneously and to allow the patient to choose between them. Some participants felt that this would satisfy certain groups of patients, for example, those who only get reassured by hospital visits and those who struggle to travel to hospitals.

Z/SN/03

'…I think it is patients choice because some like to attend the hospital as they feel they get things done better or they can get to us quicker than being seen by the GP.'

Engagement of stakeholders

Participants repeatedly expressed their views that, for the development of a standard surveillance scheme, all stakeholders (including GPs, patients, nurses and surgeons) should be involved. Again, this was hypothetical but reflects participants' beliefs in the importance of involving all those concerned.

X/U/01

'…but it would be worthwhile consulting with the patients, GP and stoma nurses in order to create a strict protocol that we can adhere to which would be useful.'

Valuing SN role

Many surgeons expressed their appreciation of the role the stoma nurses play. They described the effort and the flexibility shown by SN to help patients. They valued stoma nurses' co-ordination role between primary and secondary care and role as a contact person for patients to facilitate delivery of care. This expression of appreciation to another team member didn't entirely fall under any constructs of the theory, although it reflects good work relationships.

X/U/02

'.., we have a very accessible stoma nurse who sees these patients regularly.'

X/U/03

'I found that the stoma nurse is provides a vital service post cystectectomy in assisting the patient to cope with the stoma bag.'

4.6. Summary of results

17 professionals from 3 different centres were interviewed over the period of one year. The participants represented 3 different groups of health care professionals involved into IC patients care; surgeons, stoma nurses and specialist nurses. Following the analysis of data guided by NPT, facilitators and barriers were identified under the four main constructs of the theory.

On the facilitators' side, participants described good understanding of the scope, value and aim of an IC follow up protocol. They expressed their views of the need for change in current practice due to lack of guidelines and the service workload. Participants considered the implications associated with embedding a new model of surveillance that is based in the community. Participants described the engagement of stakeholders in the current process of follow up. Surgeons described putting effort into developing local protocols; nurses explained how they invested into their training; and participants highlighted how patients established support group to facilitate their own teaching. The stoma nurses were regarded to play an eminent role in making the follow up workable by coordinating between all stakeholders and putting extra effort to make the service accessible to patients.

Several barriers were found on all four areas of the theory. There was a lack of agreement over the length of the follow up and the need to adjust follow-up care to different patients groups. Based on their working experience, participants raised concerns regarding GPs' willingness to be part of an IC follow-up protocol. Most of our sample considered that GPs lack the experience and knowledge that would enable them to provide postoperative care at the community. Resources - such as trained stoma nurses, clinic times, - were seen as a barrier against successful implementation of any surveillance model whether in primary or secondary care. Audits were lacking according to the interviewees, making the appraisal work deficient at the process of embedding a surveillance protocol.

One of the themes that emerged strongly but didn't fall under any NPT construct was the idea of development of a shared care community-based surveillance model where all the different parties involved contribute to the surveillance.

Chapter 5. Discussion

5.1. Key Findings of study A: Patient national survey

1. Frequency of reporting complications

In this study the vast majority (87.9%) of the 1092 respondents reported at least one complication since surgery; almost half of them (45.2%) reported a frequent complication; and about a third (35.2 %) reported three or more complications.

2. Commonly reported complications

Urinary tract infections (48.2%), parastomal hernia (39.3%) and appliances (36.6%) problems are the most common reported complications, both ‘Ever’ and ‘Frequent’. When comparing patients’ answers about the first 2 years post-surgery to those about five years after surgery, the frequency of reporting UTIs remains stable but there is a notable decrease for reporting appliances problems and an increase of parastomal hernia. Hernia (21.3%), UTI (17.6%), bowel (11.8%) and appliances complications (11.2%) were the most commonly reported as occurring frequently. Parastomal hernia (35.0%) was the most common cause for re-referral back to secondary care followed by UTIs (15.8 %) and skin problems (15.0%).

3. Patient characteristics and reporting complications:

Using multivariable logistic regression analysis, certain patient characteristics were significantly associated with reporting complications. These were age <60yrs, benign indication for surgery, female gender and 5-10yrs. or >10yrs. after surgery.

Being younger than 60yrs was significantly associated with reporting ≥3 complications, ‘Ever reported a frequent complication’ and higher numbers of ‘Ever reported’ and ‘Ever reported as frequent’ complications. It was also significantly associated with reporting stoma stenosis, appliances problems, frequent UTIs and bowel problems.

Benign indication for surgery was significantly associated with reporting ≥3 complications, higher number of ‘Ever reported as frequent’ complications, kidney, UTIs, stoma stenosis and frequent UTIs, bowel and kidney complications.

Female gender was significantly associated with higher number of both ‘Ever reported’, ‘Ever reported as frequent’ complications, and with bowel complications and frequent bowel and hernia complications.

Being more than 10 years after surgery was significantly associated with reporting ≥3 complications, ’Ever reported a frequent complication’, higher number of ‘Ever reported’ &’ Ever reported as frequent’ complications, and with kidney, UTI, stone and hernia complications.

4. Access to stoma nurse and frequency of reporting complications

Less than 15% of our respondents reported that access to stoma nurse was difficult or very difficult. This was significantly associated with ‘Ever reported a complication’, ≥3 complications, ‘Ever reported a frequent complication’ and higher numbers of ‘Ever reported’ and ‘Ever reported as frequent’ complications. It was also associated with reporting bowel, kidney and appliances related problems.

5. Patients’ satisfaction and preferences for follow up

Most of the respondents (84%) were satisfied with their follow up. The adequacy of the follow up scheme, and stoma nurse care were the main reasons stated by patients to explain their satisfaction. Inadequate follow up, stoma nurse care and complications were the main reasons for dissatisfaction. In multivariable analysis, benign indication for surgery, difficult access to stoma nurse, discharge from secondary care and reporting a frequent complication were all significantly associated with dissatisfaction.

39% of respondents favoured lifelong hospital follow up. Interestingly, this option was significantly less popular amongst patients who had already been discharged but was favored by those who had their surgery for 5 years or longer ago. 44% of respondents reported they would not prefer follow up with their local doctor and 88% of these attributed this to GP lack of knowledge and experience.

5.2. Strength and limitations of study A

Current literature lacks PROM series where IC patients report on the long term different physical complications of this surgery. In the absence of a standard protocol for long term follow up for IC patients, the data obtained from more than one thousand respondents to this survey could be of great value to inform the development of a standardized alternative follow up scheme. The additional value of these results is that most of the respondents (785, 71.9%) had their operation for five years or more and more than a third (384, 35.2%) had it for more than a decade ago. Literature on long-term consequences is especially limited.

The response rate to the survey was 60%. This is reasonably comparable to national patient surveys such as National Cancer Patient Experience Surveys for the years 2015 and 2016 (NHS-England, 2017). For this survey, the overall response rate over the 2 years was about 66% out of more than116, 000 cancer patients on each survey. Patients were asked to evaluate the care they received after being diagnosed with cancer by answering a questionnaire of 59 questions (NHS-England, 2017).

One of the limitation of the survey is the potential for selection bias. Those invited to take part were all members of the Urostomy Association. This group of patients might be generally more involved in their self-care and possibly receiving extra support from the association in the form of advice and tips regarding the management of their condition. They could have also joined the UA because they had experienced complications. This could possibly impact on the frequency of experiencing complications, satisfaction with follow-up and preferences for follow-up found in the survey. In addition, and like any survey, it is possible that survey respondents and non-respondents differ in ways that impact on the reporting of the outcomes of interest.

The characteristics of the survey respondents were broadly comparable to those of patients included in the BAUS national cystectomy audit covering the 2 years of 2014 and 2015 ,except for gender distribution (Jefferies *et al.*, 2018). The median age of the survey group was 72 yrs. compared to 69 yrs. for the national audit. The indication for surgery was cancerous for 78% of the respondents compared to 86% on the audit. The distribution of gender (Male: Female) was 58%:42% in this study compared to 74%:26% on the cystectomy audit. This comparison need to be interpreted with care, given that not all (86%) of the patients in the audit had IC as a method of UD and, for 14% of patients in the audit, information on IC indication was either not clear or missing. Moreover, benign cases can have IC surgery without cystectomy so will not be included in the audit.

Another limitation of this part of the study was that it relies on patients' recall of previous events which can affect the accuracy of reporting. Moreover, it is possible that some of the complications attributed by the patients to the surgery are not actually a consequence of the surgery. In addition, the pre-test sample might not have been representative as the majority had their surgery more than 10 yrs. ago and the group who had surgery <5 yrs. ago was not represented. Had a more representative group been included, the feedback on the questionnaire may have differed. However, since relatively few changes needed to be made to the survey following pre-testing, it seems unlikely that this will have had a major impact on the study.

The development of the questionnaire as a patient reported outcome measure followed several, but not all, of the steps described in literature (Coyne *et al.*, 2006). The need for the questionnaire was established based on the lack of similar measures for IC complications in literature. The purpose of questionnaire, and the initial draft, took into account the views expressed by patients through a group discussion at their support group. Face/ content validity was assessed by pretesting the questionnaire amongst patients and refining the questionnaire accordingly. Choosing a self-administered mode allowed for involvement of a larger number of patients reaching more than one thousand and possibly minimized the bias that could had been created with interviewer-administered survey. Reproducibility to check that the measure will produce similar results if repeated was not tested. Criterion validity could not be tested as there was no gold standard measure to compare to. This was also the case for responsiveness, as the questionnaire was not designed to produce a final score. Nor was it designed to contain subscales meaning reliability was not assessed.

5.3. Key findings of study B: Current practice & alternative models of surveillance for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory

By conducting interviews at three hospitals in different areas in England, it was evident that current IC follow-up care differs. Three different models were seen across the three units:

- Long term consultant led model

- Long term nurse led model.
- Short term combined consultant and nurse led model

Variation was also seen in the resources availability to each unit; while one was able to recruit additional nurse specialists to cover stoma care, another was struggling to have stoma nurses at all and had to rely on company sponsored community stoma nurses.

The key findings from the qualitative study were as follows:

1. Coherence (make sense): Participants expressed clear understanding of the rationale for long term surveillance for IC patients. Their awareness of the long term complications of IC reported in literature and the need to identify these problems throughout regular investigations made them value follow up. Most participants expressed the view that there was a need for change from current practice to a standardised evidence based protocol in order to alleviate the risk of missing complications and to a more shared community based follow up to decrease the pressure of secondary care. Participants highlighted the implications of the development of a new model of surveillance that is more community based. They discussed the challenges that could face the implementation of such model such as lack of skills, access to resources, GPs' workload and patients' concerns. On the other hand, they described the benefit of such approach as freeing more spaces at hospital clinics and taking away the burden of travel from patients. Views varied about the length of follow up required at secondary care (i.e. whether 5yrs, 10 yrs. or lifelong). Another area where opinions differed was whether tailoring of any new follow up protocol was required according to the indication for IC surgery and different types of bladder cancer.
2. Cognitive participation (engagement): Participants described the engagement of themselves and their units with the current IC surveillance process and with any attempts to formalise it. Two of the three units and individual surgeons in the third one described development of their own protocols. Stoma /specialist nurses discussed how they engaged with local protocols and some of them described how they invested time and training to make it work. Nurses

developed their skills to enable themselves to interpret investigations such as ultrasound reports and request further advice when required. Some participants raised concerns regarding the readiness and willingness of GPs to be involved in follow up and patients' possible frustrations if care is transferred from secondary to primary care.

3. Collective action (implementation): Participants were able to define the aims of their units' local protocol and how they enact them day to day. Investigations required were requested on a regular basis as planned. Stoma nurses played a pivotal coordinating role between patients, GPs, consultants and even on call team when patients were acutely ill. According to participants, patients developed their personal skills at stoma self-care and worked to establish support groups to help each other. Resources were considered a barrier to the secondary care model with the lack of sufficient stoma nurses and clinic spaces. Participants constantly expressed their belief that GPs lack the skills to provide the care for stoma patients, and this was seen as a hurdle for implementation of a shared care community based pathway. Difficulties in communicating with local doctors was seen as another barrier to a community-based model of surveillance.
4. Reflexive monitoring (evaluation): The work of appraisal of the current practice for surveillance was deficient across all three centres and there are no formal audits that was conducted recently to assess the used protocols and reflect on the outcomes. A few participants thought that the standardisation of surveillance would create a good opportunity for audit and research, especially for the comparison of surgical outcomes between units.

5.4. Strengths and limitations of study B

This appears to be the first qualitative study to explore the area of Urology practice dealing with the long-term follow up for ileal conduit patients. The use of qualitative methods allowed knowledge and understanding to be obtained from the participants' perspectives. This could help to understand 'Why' and 'How' an alternative model of surveillance could be implemented; these types of questions cannot usually be answered by conventional quantitative methods. The NPT provided a generalised framework that was beneficial for the analysis of the implementation process and allowed for exploration of different areas that can influence the implementation of the current practice and the development of a new follow-up model.

One of the potential limitations of the study is the limited number of centres involved. However, the 3 units had three different models of IC surveillance, resulting in a diversity of participant experiences and views. Another potential limitation of the study is that it was restricted to England; if the results were to be used to inform the development of national (i.e. UK) or international guidelines then more areas and countries may need to be included to ensure representativeness of themes and issues.

The study recruited different types of health professionals involved into the follow up care of IC (Lincoln and Guba, 1985)patients. This was a strength, as the results represented multidisciplinary perspectives. Nurse specialists were not represented at one of the three centres simply because there were none employed. Interestingly, after the end of the study, this unit started introducing the nurse specialist role at post cystectomy follow up clinics. 17 out of 20 invited health professionals agreed and participated in the study; however, there is always a possible limitations that different themes could emerge from the health professionals who declined to take part. A further a limitation of the study was that it did not, for reasons of time, recruit GPs, whose views and opinions would be crucial in the implementation of any community-based follow up.

The use of NPT framework to guide the analysis could have restricted the emergence of different themes outside the framework of the theory. That is why an initial thematic analysis was conducted before mapping emerging themes onto the theory constructs. The themes that didn’t fall under the NPT framework were separately discussed in a dedicated section on the results chapter (chapter 4). In terms of quality assurance, several actions were taken (Lincoln and Guba, 1985). In terms of credibility, the topic guide was designed to stimulate the participants to express their views about their current practice and to propose alternative models of surveillance. The interviewees were given the opportunity to comment on any area of discussions and to add any further comments toward the end of the interviews on anything they felt they wanted to raise (Appendix 10). The topic guide was revised several times before the start of the interviews following discussions between AA and LS and once the interviews started, any new themes were raised by interviewees were added to the guide for subsequent interviews. During the analysis process participants' comments were compared; for example participants' views of the length of follow up at secondary care were compared and the comparison revealed significant variation at their opinions. One of the limitations was the single coding of the transcripts by AA. However LS and TF reviewed the transcripts of the initial three interviews and the initial coding framework and their comments guided subsequent analysis. In terms of transferability, the recruitment of the participating sample, the participants, and their centres' characteristics were clearly described in the methodology and results sections (Chapters 2 & 4).

5.5. Comparison with literature

In terms of reporting long term IC complications, the largest series in the literature have relied on hospital records and indicate that 45%-66% of patients will develop at least one complication (Madersbacher *et al.*, 2003; Shimko *et al.*, 2011; Gilbert *et al.*, 2013). The findings here indicate that 88% of patients reported at least one complication. This could demonstrate the value of patient-reported outcomes to record patient experiences that could be missed by relying only on hospital records. It is possible that some patients reported complications which were less serious than those recorded in hospital records. However it might be argued that these "less serious" complications are also important to patients and any alternative model of surveillance should be aware of these in order to ensure that it meets patients' needs.

There is a growing evidence of the cumulative nature of IC related complications and how they can develop decades after surgery (Shimko *et al.*, 2011).This agrees with the finding here of a significant association between reporting complications and being >10yrs post-surgery. It could possibly also explain the higher frequency of complications reported by the survey respondents than seen in other studies (Hautmann *et al.*, 2011) as more than the third of them had their IC surgery more than a decade ago.

In the current study urinary tract infections (48.2%), parastomal hernia (39.3%) and appliances (36.6%) were the most commonly reported complications. This does not correspond with the literature reports where renal and bowel complications are amongst the top three, although previous reports on infections were of similar frequency to the survey results (Madersbacher *et al.*, 2003; Shimko *et al.*, 2011; Gilbert *et al.*, 2013). Clearly, bowel and renal side effects could be of greater concern from the clinical perspective, but the survey findings may suggest that they possibly not the most bothersome from the perspective of the patient.

This study has highlighted the association of reporting complications with certain groups such as younger age (<60) and benign indications for surgery. Interestingly, Wood et al reported that stoma complications are significantly higher in females with intractable urinary incontinence who received IC (Wood *et al.*, 2004). The mean age of the patients on Wood's series was 48 years old. This could draw attention towards the quality of life that patients experience after such a major surgery for the treatment of intractable benign bladder conditions and raise questions about whether a different counselling approach is required for this group.

In the current study, there was a significant association between difficult access to a stoma nurse and reporting complications and satisfaction with follow-up. This concept is supported by several studies which highlighted the role of specialist nursing care; some even showed more favourable patient satisfaction rating for nurse led follow up for cancer patients when compared to the traditional physician led model (Lewis *et al.*, 2009a; Leahy *et al.*, 2013). In addition, there have been no proven advantage in terms of recurrence detection rate in both models (Howell *et al.*, 2012).

About 60% of the respondents in the current study did not prefer lifelong hospital follow-up. This could indicate a level of acceptability of different follow-up models based at the community. Nevertheless, GP lack of experience and knowledge was a concern to most of the group (88%) who did not favour local doctor surveillance. These findings broadly agree with those of a qualitative study that explored cancer patients' views of follow-up; while patients appreciated having their care locally, they emphasised the need for further training to GPs to fulfil this role (Hall *et al.*, 2011).

To our knowledge, the qualitative part of this study represents the first report in literature to explore, using NPT, the facilitators and challenges that face the implementation of IC follow up schedule, both in terms of current practices and at any potential alternative models. Most of the themes that emerged could be mapped onto the four constructs of the theory: coherence; cognitive participation; collective action and reflexive monitoring (May and Finch, 2009; Murray *et al.*, 2010). The participants' coherence of the value of follow-up was driven by their understanding of the complications, and their knowledge did match mostly what has been reported in literature about IC related complications (Hautmann *et al.*, 2011). The findings revealed a lack of experience among community stoma nurses when it comes to metabolic complications; this type of complications is evident in literature reports (Roth and Koch, 2018). The participants were aware of the lack of guidelines designed specifically to IC follow up and the review of the current urology guidelines (Chapter 1) confirm this (The National Institute for Health and Care Excellence 2015; Alfred Witjes *et al.*, 2017; Chang *et al.*, 2017).

A review of qualitative studies exploring patients' and health professionals' views about cancer follow-up found that the participants felt that secondary care appointments were limited in terms of dedicated time and that psychological support need by patients was not provided due to the pressure on the service (Lewis et al., 2009b). In addition, there is a growing tendency towards the development of a community based shared care pathway at different medical specialities (Davies and Batehup, 2011). A similar theme emerged from analysis in the current study where participants highlighted the pressure on the secondary care service and how a community based care could help to solve this problem. In addition in the current study participants raised concerns about local doctors' knowledge and experience and the lack of skills to follow up IC patients, which agrees with the results from a qualitative study that explored cancer patients views (Hall et al., 2011).

The Urology specialist nurses participating in the current study described how they were able to engage successfully with the local protocols, in keeping with current evidence that supports the possibility of providing a successful nurse led follow up (Howell *et al.*, 2012; Leahy *et al.*, 2013). Moreover, the interviewees believed that patients are very keen on acquiring skills and that their education could facilitate their care. Similarly, several studies in the literature, in cancer patients and those with other conditions, have shown a growing support for patient empowerment and supporting patients to self-manage their condition and even self-refer to specialist care (Davies and Batehup, 2011; de Silva, 2011; Foster and Fenlon, 2011).

5.6. Implications of the study for future research and future follow-up

This study has highlighted the high occurrence of complications following IC surgery. It has emphasised the need to take into consideration the less risky but perhaps more bothering side effects of this operation such as parastomal hernia, appliance issues and infections. The current study did not assess side-effect bother directly and future research might usefully investigate bother and impact on life associated with each complication.

The results also draw attention toward the higher frequency of dissatisfaction within follow-up and reporting of complications among certain groups, such as females and those who has surgery for benign conditions. This might also drive future research, for example focussed on options for the surgical management of young females with benign bladder symptoms not responding to medical treatment.

In terms of follow-up, the findings broadly support the idea of the development of a community based shared care pathway. There was a reasonable acceptance from patients (60%) and health professionals for a greater role for primary care in follow-up. To add to the data generated in this study, it would be valuable to conduct future qualitative research projects to explore the views of the primary care health professionals and patients on shared-care community-based follow-up.

The results obtained from both the patient survey and the health professional interviews demonstrated the pivotal role of stoma nurses in the care of this group of patients and how they plays a coordinating role between all parties involved in patient care. This should be considered in the future in any development of alternative models of surveillance in order to ensure that the valuable role of stoma nurses is maintained.

The ultimate goal of this project was to inform the need for and development of an alternative follow-up schedule for IC patients. In terms of moving this forwards, the results of this study could stimulate health experts to work with patient representatives to co-design a standard long term follow up schedule that meets the patients' needs and is equally capable of early identification of serious medical complications of this surgery. This would be in keeping with the national cancer strategy for England 2015 -2020 which emphasizes the value of patient involvement and feedback to help to improve the care provided for cancer patients across the country (NHS-England, 2015). As suggested by participants in the qualitative interviews, follow-up could be conducted in the community by a stoma / Urology specialist nurse who is appropriately trained and possesses strong links with the secondary care. However, while the survey findings suggests that patients value stoma nurse access in current follow up, it would be essential to ensure that they would find nurse-led follow up in the community acceptable. This new follow up protocol might also include a supported self-management programme to empower patients to participate more actively in their care. How best to deliver such a programme, and what it might contain, could be the focus for future research.

5.7. Conclusion

The high and cumulative incidence of IC related complications suggest the development of a standardised, evidence based long term surveillance protocol. A shared care community based nurse led scheme could be a suitable model that can be successfully implement after further evaluation.

Appendices

Appendix 1. Patient 'Ileal conduit experience questionnaire' (ICE-Q).

Section 1: About yourself

1. Your gender Male ☐ Female ☐

2. Your age .... years

3. In which year did you have your ileal conduit urinary diversion operation? …………

4. Why did you have to have an ileal conduit urinary diversion?

- ☐ Bladder cancer
- ☐ Urinary incontinence
- ☐ Bladder Pain
- ☐ Urgency and frequent urination
- ☐ Other please state ....

Section 2

A. The first 2 years after the operation

5**. In the first 2 years after the operation,** approximately how frequently were you seen?

	By your **surgeon**	By your **stoma nurse**?
Every 3 months	☐	☐
Every 6 months	☐	☐
Every 12 months	☐	☐
Not routinely	☐	☐
Other, please state	………	………

6.Did you develop any of the following problems during **the first 2 years** after your operation? (You may choose more than one answer)

☐ Bowel problems

☐ kidney problems

☐ water infection

☐ Kidney stones

☐ hernia or bulging around the stoma

☐ narrowing of the stoma

☐ Problems with the skin around the stoma

☐ Problems with getting the stoma appliance to stick to the skin

☐ Any other problems. Please state ……………………………………………………………………………

<u>B. The period between 2 and 5 years after the operation</u>

7. Thinking about **the period between 2 and 5 years** after your operation, approximately how frequently were you seen?

	By your **surgeon**	By your **stoma nurse**?
Every 3 months	☐	☐
Every 6 months	☐	☐
Every 12 months	☐	☐
Not routinely	☐	☐
Other, please state	………	………

8. Did you develop or continue to suffer from any of the following problems during **the period between 2 and 5 years** after your operation? (You may choose more than one answer)

☐ Bowel problems

☐ kidney problems

☐ water infection

☐ Kidney stones

☐ hernia or bulging around the stoma

☐ narrowing of the stoma

☐ Problems with the skin around the stoma

☐ Problems with getting the stoma appliance to stick to the skin

Any other problems. Please state …………………………………………………………………………

C. More than 5 years after the operation

9. Thinking about **the period starting from 5 years** after your operation, approximately how frequently were you seen?

	By your **surgeon**	By your **stoma nurse**?
Every 3 months	☐	☐
Every 6 months	☐	☐
Every 12 months	☐	☐
Not routinely	☐	☐
Other, please state	....	....

10. Did you develop or continue to suffer from any of the following problems during **the period starting from 5 years** after your operation? (You may choose more than one answer)

☐ Bowel problems

☐ kidney problems

☐ water infection

☐ Kidney stones

☐ hernia or bulging around the stoma

☐ narrowing of the stoma

☐ Problems with the skin around the stoma

☐ Problems with getting the stoma appliance to stick to the skin

Any other problems. Please state ………………………………………………………………………….

Section 3: Discharge arrangements from hospital care

11. Have you been discharged from routine regular hospital care?

- ☐ Yes,
    - a. After how many years of follow up following your operation were you discharged from regular hospital care?........years
- ☐ No

If you answered No, please go to Question 14.

12. If you have been discharged, have you had to go back to the hospital for problem (s) related to your stoma/operation?

- ☐ Yes
    - a. What was the problem (s)? ....
- ☐ No

13. If you have been discharged, have you been seen by the local doctor (GP) regularly to check on your stoma or your kidney function?

- ☐ Yes
    - a. Approximately how frequently? every............months
- ☐ no

14. Looking back, have you been satisfied with the follow up you had since your operation?

- ☐ Yes
- ☐ No

If **no** what would like to have been done differently (if anything)?
…….........

If **yes** what aspects of your care were particularly helpful to you?

…….

15. Overall how easy have you found it to get help from a stoma therapist or nurse when you required it?

- ☐ Very easy
- ☐ Quite easy
- ☐ Quite difficult
- ☐ Very difficult

Section 4: Your opinion

Based on your own personal experience what do you think is the best way to follow up people who have had an ileal conduit diversion (Urostomy) operation? Please give your opinion by answering the following questions.

15. How often should people be seen in **the first 2 years** after urostomy?

	By the **surgeon**	By the **stoma nurse**?
Every 3 months	☐	☐
Every 6 months	☐	☐
Every 12 months	☐	☐
Not routinely	☐	☐
Other, please state	....	....

16. **After the first 2 years following the operation**, for how many more years do you think people with a Urostomy should be seen regularly at the hospital before the care is transferred to their local doctor (GP)?

- ☐ No further follow up needed
- ☐ For .... years (please state)
- ☐ People should only be reviewed when they develop problems with the Urostomy
- ☐ People should continue to be seen regularly at the hospital for the rest of their life

17. If you feel people should be seen regularly after the first 2 years, approximately how often should they be seen?

a. From between 2 and 5 years after the operation

	By the **surgeon**	By the **stoma nurse**?
Every 3 months	☐	☐
Every 6 months	☐	☐
Every 12 months	☐	☐
Not routinely	☐	☐
Other, please state	....	....

b. From 5 years after the operation

	By the **surgeon**	By the **stoma nurse**?
Every 3 months	☐	☐
Every 6 months	☐	☐
Every 12 months	☐	☐
Not routinely	☐	☐
Other, please state	………	………

18. If you feel that transfer of peoples' care concerning their Urostomy to their local doctor (GP) is appropriate, approximately how frequently do you think people should be seen by their GP?

☐ Every 3 months

☐ Every 6 months

☐ Every 12 months

☐ When needed

☐ other, please state ……………………………………………………………………………………….

19. If you feel that transfer of peoples' care concerning their Urostomy to their local doctor (GP) is <u>not</u> appropriate, please explain your reasons here

……
……

Section 5: Complications related to your ileal conduit operation (Urostomy)

19. Please give a score to each of the following problems according to how often **you** have experienced them since **your** operation.

Please use the following scoring system to tell us how often you experienced any of these problems. Please write the appropriate number in the box.

Score	Frequency
0	Never
1	Rarely
2	Sometimes
3	Frequently

☐ Bowel problems

☐ Kidney problems

☐ Urine infection

☐ Urinary stones

☐ Hernia/bulging around stoma

☐ Narrowing of the stoma (stenosis)

☐ Problems with appliance

☐ Other, please state ……………………………………………………………………………………………

The End!

Thank you for taking the time completing the questionnaire. We will collect all the results anonymously and publish the findings. The NHS can then use the results to plan the best care for people with Urostomy.

If you would like to be contacted regarding any follow up questions please give a contact detail such as telephone number, email address or postal address below.

Your Contact (only complete if you wish): ………………….…………………………………………………………………..

Robert Pickard and Ather Abdelbaky

Department of Urology, Freeman Hospital, Newcastle upon Tyne, NE7 7DN.

0191 213 7139,Robert.pickard@nuth.nhs.uk

Appendix 2. Participant information sheet (Study A)

UROSTOMY
ASSOCIATION

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Care for people with urinary diversion: patient questionnaire

Dear Madam/Sir,

Thank you for taking the time to answer this questionnaire. This survey aims to record the care people currently get after having an ileal conduit urinary diversion operation (Urostomy) and find out the opinions of people with urostomy regarding the follow up arrangements they feel would be best in the future. It has been organised by Professor Robert Pickard and Dr Ather Abdelbaky from the Department of Urology, Freeman Hospital, Newcastle upon Tyne in collaboration with the Urostomy Association. Your participation is entirely voluntary and you do not have to include any details that may identify you. Please use the enclosed freepost envelopes to return the completed questionnaire.

Please tick the box that corresponds to the appropriate answer or write your answer in the box or next to each question.

Appendix 3. Research protocol (Study B)

“Implementation of a long term follow up schedule for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory”

Chief investigator:

Mr Ather Abdelbaky
Consultant Urologist & MD student
Heart of England NHS Foundation Trust
Birmingham B9 5SS
Email: ather.abdelbaky@heartofengland.nhs.uk
Phone: 0121 424 1138

Principal investigators at other sites:

Chris Harding
Consultant Urologist
Freeman Hospital
Trust
Newcastle upon Tyne
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Phone: 0191 233 6161 ext 37597

Ased Ali
Consultant Urologist
The Mid Yorkshire Hospitals NHS

Wakefield
WF14DG
Email:ased_ali@hotmail.com
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MD Supervisor:

Prof Linda Sharp
Professor of Cancer Epidemiology
Institute of Health & Society
Newcastle University
Newcastle upon Tyne
NE2 4AX
Email: linda.sharp@ncl.ac.uk
Phone: 0191 208 6275

Institution(s) responsible for the running of the study

Heart of England NHS Trust
Newcastle University
Newcastle upon Tyne NHS Trust
The Mid Yorkshire Hospitals NHS Trust

Sponsor of the study

Heart of England NHS Foundation Trust

Contents

Abstract

Ileal conduit (IC) is the most frequent urinary diversion procedure performed following radical cystectomy and for patients with intractable lower urinary tract symptoms, particularly incontinence (1). Several reviews have highlighted the high rates of long term complications but the best schedule of surveillance care remains undecided (2-13). In the absence of guidelines, there has been a great variation at the long term follow-up practice amongst different units.

The aim of this study is to understand how and why a “new” (alternative) model of surveillance for IC patients can be successfully implemented. The study will use an implementation theory known as the Normalization Process Theory (NPT). The NPT specifies four constructs relating to collective action in a new service implementation: Coherence, Cognitive Participation, Collective Action, and Reflexive Monitoring (14). The study will use a qualitative methodology of semi-structured interviews with approximately 20 healthcare professionals who are involved in the care for IC patients at 3 different areas in England. The interview will aim to describe current practice of follow-up for these patients and what influences this; the participant’s views of the ideal follow up schedule; the barriers and facilitators to ideal follow-up; and what needs to be in place for successful implementation. Interviews will be audio-recorded, transcribed, and anonymized. An inductive thematic analysis will be conducted, and findings interpreted with respect to the domains of the NPT.

Abbreviations

Abbreviation	**Definition**
IC	Ileal conduit
NPT	Normalisation process theory
HEFT	Heart of England NHS Foundation Trust
UTI	Urinary tract infection
NHS	National health system
GP	General practitioner

Background

Ileal conduit (IC) is the most frequent urinary diversion procedure performed following radical cystectomy and for patient with intractable lower urinary tract symptoms particularly incontinence or bladder pain. Several reviews have highlighted the high rates of long term complications following this surgery but the best schedule of surveillance care remains undecided. Among the national and international health and urology associations there is no clear guidelines for the length, setting or modality of long term care for IC patients.(15, 16).With the current pressure on the NHS, a community based follow up might need to be explored as an option.

The data relating to long-term complications is summarized in table 1. Incidence of complications in most series is at least 66% and in subgroup of patients who had IC for >15 years it could reach to 94%. Long term follow up has been recommended, however the length and the settings have not been specified.

Table1. Series with more than 50 patients and at least 4 years of follow up (2-4, 11-13)

				Incidence of complications (%)						
Author	Year	Patients no.	Median FU (m)	Renal	Bowel	UTI	Hernia	Stoma	Urolithiasis	Metabolic
Madersbacher	2003	131	98	27	24	23		24	9	
Wood DN	2004	93	63.4				16.5	9.2		
Samuel	2005	178	48	29						
Shimko	2010	1057	75.6	20.0	20.0	16.5	13.9	2.1	15.3	12.8
Jin	2011	50	120	36						
Gilbert	2013	544	60	4.0		45.4	7.35	6.25	4.6	31.3

This high rate of long term complications justifies the need for the development of a more standardized long term follow up schedule. The schedule could facilitate the prevention, early detection and treatment for such complications. At the moment, IC patients return to secondary care for follow-up. Consistent with moves in other areas of the health service (and in cancer follow-up), there may be possibilities to involve primary care more in the follow-up of these patients. The potential role of primary care – and barriers and facilitators to their involvement - has not previously been examined.

The aim of this study is to understand how and why a “new” (alternative) model of surveillance for IC patients can be successfully implemented, whether in the community or secondary care.

The implementation of interventions is increasingly being studied using theory-led research designs. This study will be guided by the Normalization Process Theory. This theory regards implementation as a social process which requires collective actions of participants. The theory has identified four main domains that promote or inhibit the kinds of co-operative work that is needed to implement service innovations in complex organizational contexts, the NHS for example.

Objectives

- To describe current practice with regard to follow-up of IC patients and any associated problems/challenges/limitations.
- To explore health professionals’ views regarding “ideal” long-term follow-up, including the best setting and the appropriate investigations.
- To identify barriers and facilitators to implementing long term follow up schedule for IC patients

Study Methodology

- **Study design**
    - This is a qualitative research study, with a semi-structured interview design.
    - The study will attempt to recruit approximately 20 health professionals.

  - The participants will be interviewed at their place of work or another location convenient for them.
  - The chief investigator has received training in conducting qualitative interviews for research.

- **Study intervention**
  - The CI will conduct a face to face semi structured interview with the participants; this is likely to last 30- 60 minutes.
  - The interview will be will be guided by a topic guide and audio recorded.
  - The guide will be divided into 3 major areas: Area (1) will explore participants' views of the purpose of long-term follow-up. Area (2) will discuss participants' current practice in following up IC patients. Area (3) will explore the views of the participants of the best follow up scheme and the potential barriers and facilitators to implementation of this.
  - The topic guide will be used flexibly and allowed to evolve as the interviews progress; if new issues are raised by interviewees these will be added to the guide for subsequent interviews, so that sufficient depth is reached.

Study population

- **Source of participants**
  Potential participants will be identified through the clinical lead of bladder cancer at the 3 participating sites. They will be approached initially by the CI via work email or phone call. Those potentially interested in being interviewed will be sent a study information sheet, which they will have time to review before deciding to take part.

- **Inclusion criteria**

Healthcare professionals who are involved in the follow up of ileal conduit patients. This will include urological surgeons, urology nurse specialists, and renal specialists.

- **Exclusion criteria**
  Healthcare professionals who have no experience or knowledge of follow up of ileal conduit patients.

Study procedure

- A study information leaflet will be sent by email prior to the interview to participants explaining the aim and the methods of the project. Once the participant expresses his/her interest by email or phone call, a hard copy of the PIS will be sent to him/her. Participants will be given 24 hours to consider the information once the PIS is sent.The chief investigator will then obtain a written informed consent from the participant. The consent will confirm that participants understand that their participation is voluntary and that they are willing to let the project researcher include anonymous quotations from them in the write up of the study. Participants will also have had adequate chance to ask questions, which will have been answered to the participant's satisfaction prior to giving written informed consent.
  Participants will be assured of confidentiality; whether or not they take part in the study and, if they do, their views and opinions will not be revealed to the senior colleague who nominated them, nor anyone outside of the research team. Furthermore, no interviewees will be identified in the CI's thesis or any publications arising from the study.

- **Data collection**
  - Each participant will be allocated a personal identity code which will ensure their anonymity on the study.
  - Interviews will be audio-recorded, transcribed, and anonymized, prior to analysis.
  - The transcription will be carried by a medical secretary at the Urology department at Heart of England NHS Trust (Verdelle Stewart).

  - Transcripts will be coded. A thematic analysis will be used to identify emerging themes. These will be interpreted with respect to the NPT domains.
  - The participant job title, years and area of experience will be among the data.

- **Study timelines:**
  - Expected duration of the study 6 months (interviews: 3 months; coding, analysis and write-up: 3 months).
  - Start time: 1/04/2016.

- **Risk**:
    - No potential risks to the participants have been identified.
    - If the participant felt distressed during the interview, the interview will be stopped and only restart after confirming that the participant is happy to continue.

Benefit

- The only direct benefit to participants is knowing that contributing to this study might eventually help improve follow-up of their future patients.

Data Management

- Interviews will be audio-recorded and will be copied anonymised to the CI’s password protected laptop. Once transcribed and checked, the recordings will be moved onto a blank encrypted CD and archived.

- As part of the data management, each participant will be allocated a personal identity code for the study. Using this code a separate database will be saved removing all personal identifying data creating a pseudonymised data set. The interviews collected data will be anonymised when the results are written up. The research team (MD student and supervisors) have signed a confidentiality agreement as per Newcastle University http://www.ncl.ac.uk/res/assets/documents/PGRPolicyv10111114FINALClean.pdf.

Statistical Analysis

- Data will be imported into the qualitative data analysis software NVivo. An abductive analysis will be conducted. This will be done by coding data inductively using a thematic analysis and examined for relevance to implementation. To relate the data to Normalization Process Theory, codes will be transposed onto the four main constructs of the theory.
- Recruitment and analysis will be simultaneous, so that issues that emerge from preliminary analysis of early interviews can inform later interviews).
- Ather Abdelbaky will carry out the analysis under the supervision of Professor Sharp, who is experienced in the conduct of qualitative research. Interpretation of the findings with respect of the NPT will be discussed with Dr Tracey Finch, of Newcastle University; Dr Finch was one of the developers of the NPT.

Quality assurance, monitoring & safety

The methodology was agreed with both of the educational supervisors, Prof. Robert Pickard and Prof. Linda Sharp of Newcastle University. Further internal Newcastle University review of the MD project was carried out by Dr Catherine Haighton Lecturer in Public Health Research of Institute of Cellular Medicine, and by Mr Tahseen Hasan Lecturer of Urology and consultant urological surgeon.

Ethical Issues

The study has been approved by Newcastle university ethics committee. Ref: 3550/2016. The study did not require REC review as it is a qualitative study recruiting only health professionals.

Finance and resource use

The study is self-funded as part of the MD thesis of the CI; this will cover as well any travel expenses if required.

Dissemination of Results and Publication policy

The data collected will be used for conference abstracts and a scientific paper. The CI will be using data to write up part of his MD thesis.

References of study B protocol

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12. Jin XD, Roethlisberger S, Burkhard FC, Birkhaeuser F, Thoeny HC, Studer UE. Long-term renal function after urinary diversion by ileal conduit or orthotopic ileal bladder substitution. Eur Urol. 2012 Mar;61(3):491-7. doi: 10.1016/j.eururo.2011.09.004. Epub 2011 Sep 15.

13. Wood DN, Allen SE, Hussain M, Greenwell TJ, Shah PJ. Stomal complications of ileal conduits are significantly higher when formed in women with intractable urinary incontinence. J Urol. 2004 Dec;172(6 Pt 1):2300-3.

14. Biblography of studies and the theory demonstration is available on http://www.normalizationprocess.org/

15. http://uroweb.org/wp-content/uploads/EAU-Guidelines-Muscle-invasive-and-Metastatic-Bladder-Cancer-2015-v1.pdf

Appendices of study B protocol

A. Topic guide

Introduction

Purpose of interview. Confidentiality.

Can you tell me a bit about yourself – how long you've been in practice, etc

1-Participant's perspective of follow-up and long term complications

How important is it to provide follow up for patients with ileal conduit? Why?

What do you want to achieve? [What is a good outcome of follow-up for you/the patient?]

Ideally, how long -Should follow-up last for? Why? [Is/should length of follow-up be different for different patients?]

What kind of complications have you seen? How serious?

2-Partcipant's current practice

What is your current practice of follow up for IC patients?

How do you decide what follow-up a particular patient will get?

Are you using any national or international guidelines?

When? (Frequency)

What Investigations? (Scans, blood test, others)

Who? (Professionals involved)

What is the role of stoma nurse in your current practice?

Where? (Setting)

How long? (Length) How do you decided when to stop follow-up (if ever)]

Do you ever discharge patient to primary care? At what point?

+/-what arrangement do you use on discharge ensure that GP are comfortable with taking that care over from secondary care? (Feedback, meetings, letters)

What is good/ bad about current follow-up practice? [What works well/ what doesn't work well?

Do you do any evaluation of whether current follow-up "works" ? How can it get better?

3- Do you feel a need to change follow up schedule

What are the options?

Discuss each - Where; Who; How; Setting

Do you think these would be better or worse than current follow-up? Why?

Would anything need to be in place to allow changes to follow-up? (e.g. safety net to ensure discharged patients don’t fall through crack in service; training of health professionals; rapid route back into hospital clinic; more patient education]

Would there be a need to evaluate any “new” follow-up strategy?

4-Discharge to primary care

How safe it is to discharge patient to community? Why? Which patients could be discharged?

What benefits (if any) the secondary care would get from transferring the care to primary care? [Would there be any benefits for primary care?]

How much skills/ knowledge do GPs have to look after those patients? How can it be improved? What role can you personally play?

Which complications you think the GP will need to deal with frequently? (UTIs, hernia)

What could be missed with community-based follow-up? How to avoid this? (Renal function)

What investigations? How frequent? Do GP have sufficient resources in the community to undertake follow-up?

What role could stoma nurses play?

How can patient education help?

What would be the indications to refer patient back to hospital?

What might make community follow up difficult? (e.g. Communications with specialists, guidelines, GP knowledge, access to SN, patients preference. Etc)

What would help/been need to make community FU work well? (e.g. Communications with specialists, guidelines, GP knowledge, access to SN, patients preference. Etc)

5. Close

Is there anything else you would like to discuss, or tell me, about follow-up of these patients, either now or in the future?

Thank you for your help.

Appendix 4. Letter of sponsorship for single site (Study B)

Heart of England NHS
NHS Foundation Trust

Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
B9 5SS

Tel: 0121 424 2000
Web: www.heartofengland.nhs.uk

21/11/2016

Dear Ather Abdelbaky,

Study Title: Implementation of a long term follow up schedule for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory
IRAS ID: N/A
R&D Code: 2016061GS
Sponsor: Heart of England NHS Foundation Trust

I am writing to confirm that Heart of England NHS Foundation Trust will undertake the duties of Sponsor for the above referenced study, in line with the Research Governance Framework for Health and Social Care (2nd Edition).

As a single site, single sponsored study, it does not require a formal assessment of capacity and capability, as this has previously been undertaken as part of our decision to Sponsor the study. As agreed with June de la Rue and myself, this study was not required to go through IRAS, and therefore there are no REC or HRA approvals. There is, however, university ethics approval from Newcastle University.

Should you wish to make any amendments to the study, as Sponsor, these will have to be notified to us for our approval prior to implementing them.

Please accept this letter as confirmation that the study can proceed at Heart of England NHS Foundation Trust. We would like to wish you well on your project and look forward to hearing the progress on this.

Best wishes

Liz Adey
Head of Research

Appendix 5. Letter of sponsorship for multiple sites (Study B)

midru
idea. reality. linked

HEART of ENGLAND
NHS Foundation Trust

19/05/2017

Dear Ather,

Confirmation of Heart of England NHS Foundation Trust Sponsorship:
“Implementation of a long term follow up schedule for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory”

You submitted your project for consideration for HEFT Sponsorship in 2016. Your proposal was reviewed by the R&D Management Team and the Heart of England NHS Foundation Trust confirmed that they were able to take on the duty and responsibility of Sponsor for the above named study on 21/11/2016.

You have since submitted an amendment to add additional sites to the study, meaning that the current study will no longer be a single-site study. Please take this letter as confirmation that we have agreed to this change.

Heart of England NHS Foundation Trust will fulfil its Sponsorship duties in accordance with the legislative requirements as detailed in the HEFT Sponsorship of a Research Study standard operating procedure (SOP), which is available from the Trust policies and procedures intranet site:
http://sharepoint/policies/Office%20Documents/Forms/Research.aspx .

As part of our processes, we have nominated Nick Denyer, who will work directly with you as our Sponsor representative for the duration of your project. Please refer to section 7.3.2 in the "HEFT Sponsorship of a Research Study" SOP for further details on the role of the link person and the support they will provide you during the study.

We would like to wish you all the best for your project and we look forward to hearing of your progress in the near future.

Yours sincerely

Nick Denyer

On behalf of the R&D Management Team

Appendix 6. Participant information sheet (Study B)

Heart of England NHS Trust

Urology Department

Participant information leaflet

Study Title: *Implementation of a long term follow up schedule for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory*

Investigator: Ather Abdelbaky

Consultant Urological surgeon Heart of England NHS Trust & MD Student Newcastle University

Introduction:

Dear colleague you are invited to participate in this research study about the best schedule for follow up of ileal conduit patients. Ileal conduit (IC) is the most frequent urinary diversion procedure performed following radical cystectomy and for patient with intractable lower urinary tract symptoms particularly incontinence. Several reviews have highlighted the high rates of long term complications but the best schedule of surveillance care remains undecided. In the absence of guidelines, there has been a great variation at follow up practice amongst different units.

What is the aim of this study?

The purpose of this research is to understand how and why a “new” (alternative) model of surveillance for IC patients can be successfully implemented. The study will use an implementation theory known as the **Normalization Process Theory (NPT)**. This is a theory that studies the collective action in a new service implementation.

What is the Normalization Process Theory?

This is a social science theory that specifies four constructs relating to collective action in a new service implementation: Coherence, Cognitive Participation, Collective Action, and Reflexive Monitoring. The theory has identified four main domains that promote or inhibit the kinds of co-operative work that is needed to implement service innovations in complex organizational contexts, the NHS for example. You can read more about the theory at this link www.**normalizationprocess.org**.

The theory has been used to understand the dynamics of implementing, and integrating some new healthcare technology or complex intervention at different medical specialities. The results have been published at many peer reviewed journal. http://www.normalizationprocess.org/bibliography/.

What happens if I agree to participate?

You will be interviewed by the researcher for 30-60 minutes.

Do I have to participate?

Your participation is voluntary. We will describe the study further and based on that you can decide to join or not. If you agree to participate you will be asked to sign a consent form to say that you have agreed to take part. You can withdraw your consent at any time without giving a reason.

Is there any disadvantages/risks of taking part of the study?

No risks identified; the participant will only provide the time needed for the interview which is about 30-40 minutes. You can be interviewed at your work place or any convenient place for you.

What are the possible benefits of taking part of the study?

The main benefit to participants is knowing that contributing to this study might eventually help improve follow-up of your current or future patients.

Expenses and payments

No expenses or payments are made to participants.

Is my participation confidential?

Your participation is totally confidential; whether or not you take part in the study and, if you do, your views and opinions will not be revealed to the colleague who nominated you. No interviewees will be identified in the CI's thesis or any publications arising from the study.

Who is organizing and funding the study?

The study is part of the MD thesis of the CI and it is sponsored by the Heart of England NHS Trust. The MD is self-funded by the researcher who is a consultant employed by the trust at the Urology department.

How is the data collected and managed?

Each participant will be allocated a personal identity code.Interviews will be audio-recorded, transcribed, and anonymized, prior to analysis. As soon as possible after the interview they will be copied to the CI's laptop which is password protected, and wiped from the audio-recording device. Once transcribed and checked, the recordings will be moved onto a blank encrypted CD and archived.

Using the personal identity code of each participant a separate database will be saved removing all personal identifying data creating a pseudonymised data set. The interviews collected data will be anonymised when the results are written up. The research team (MD student and supervisors) have signed a confidentiality agreement as per Newcastle University http://www.ncl.ac.uk/res/assets/documents/PGRPolicyv10111114FINALClean.pdf

Has the study design been reviewed?

The methodology was agreed with both of the educational supervisors, Prof. Robert Pickard and Prof. Linda Sharp of Newcastle University. Further internal Newcastle University review of the MD project was carried out by Dr Catherine Haighton Lecturer in Public Health Research of Institute of Cellular Medicine, and by Mr Tahseen Hasan Lecturer of Urology and consultant urological surgeon.

The protocol has been reviewed as well by the research and development department at Heart of England NHS Trust

What will happen to the data and results at the end of the study?

Data will be retained for minimum of 1 year till the MD thesis submitted .At the end of this period any paper documentation will be destroyed using confidential shredding service and any electronic data will be deleted form personal computer, trust or university server.

What if I need more information or want to participate?

If you want to know more or want to join the study, please contact

Ather Abdelbaky

Consultant Urological surgeon Heart of England NHS Trust & MD Student Newcastle University

ather.abdelbaky@heartofengland.nhs.uk / Tel: 0121 424 1138

What if I have a complaint?

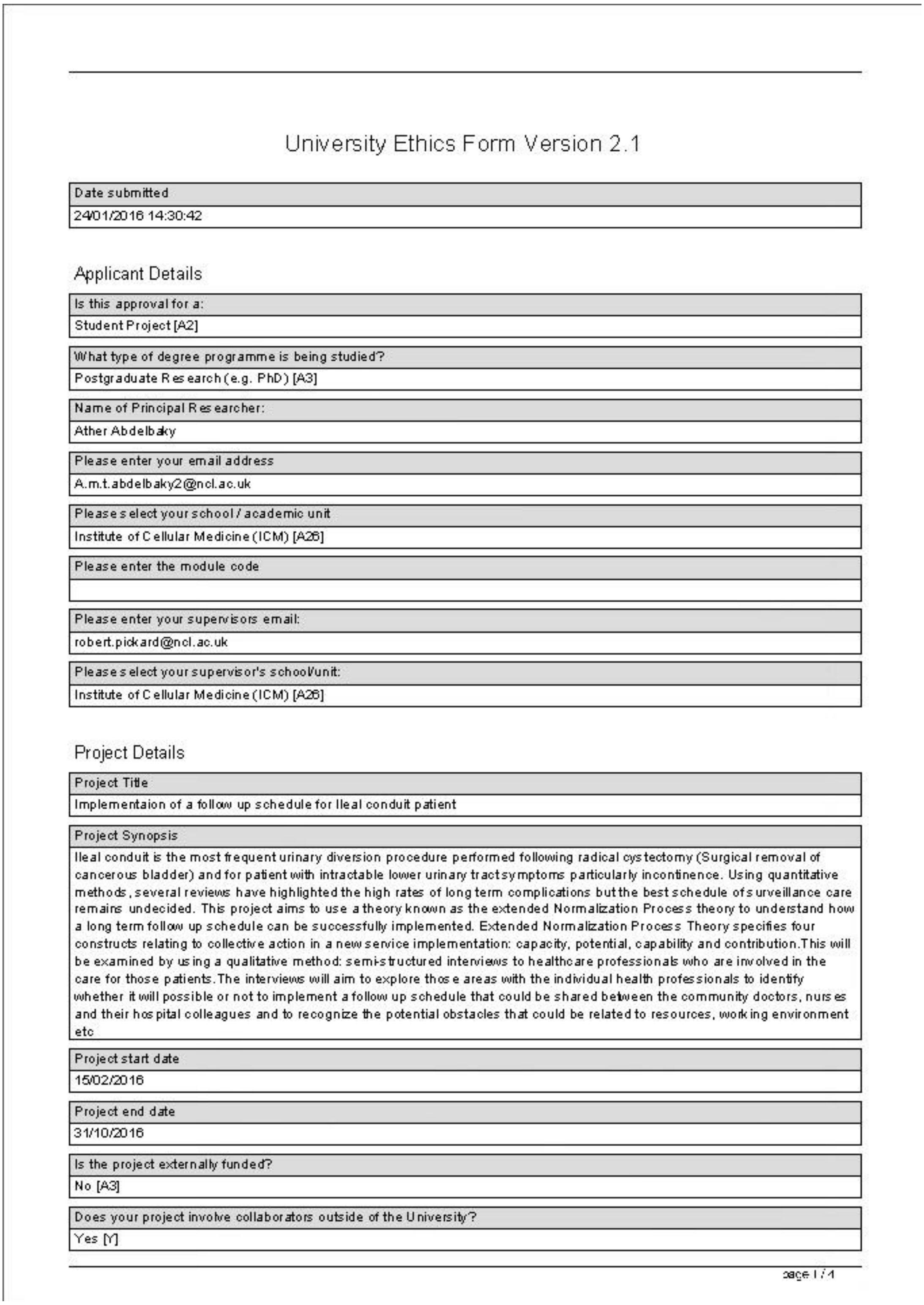
If you have any complaint regarding the study or your involvement, please contact:

Prof. Linda Sharp

Institute of Health & Society
Newcastle University
Baddiley Clark Building
Richardson Road
Newcastle upon Tyne NE2 4AX

Telephone: +44 (0)191 208 6275
email: linda.sharp@ncl.ac.uk

Appendix 7. University ethics form (Study B)



University Ethics Form Version 2.1

Date submitted

24/01/2016 14:30:42

Applicant Details

Is this approval for a:

Student Project [A2]

What type of degree programme is being studied?

Postgraduate Research (e.g. PhD) [A3]

Name of Principal Researcher:

Ather Abdelbaky

Please enter your email address

A.m.t.abdelbaky2@ncl.ac.uk

Please select your school / academic unit

Institute of Cellular Medicine (ICM) [A26]

Please enter the module code

Please enter your supervisors email:

robert.pickard@ncl.ac.uk

Please select your supervisor's school/unit:

Institute of Cellular Medicine (ICM) [A26]

Project Details

Project Title

Implementaion of a follow up schedule for Ileal conduit patient

Project Synopsis

Ileal conduit is the most frequent urinary diversion procedure performed following radical cystectomy (Surgical removal of cancerous bladder) and for patient with intractable lower urinary tract symptoms particularly incontinence. Using quantitative methods, several reviews have highlighted the high rates of long term complications but the best schedule of surveillance care remains undecided. This project aims to use a theory known as the extended Normalization Process theory to understand how a long term follow up schedule can be successfully implemented. Extended Normalization Process Theory specifies four constructs relating to collective action in a new service implementation: capacity, potential, capability and contribution.This will be examined by using a qualitative method: semi-structured interviews to healthcare professionals who are involved in the care for those patients.The interviews will aim to explore those areas with the individual health professionals to identify whether it will possible or not to implement a follow up schedule that could be shared between the community doctors, nurses and their hospital colleagues and to recognize the potential obstacles that could be related to resources, working environment etc

Project start date

15/02/2016

Project end date

31/10/2016

Is the project externally funded?

No [A3]

Does your project involve collaborators outside of the University?

Yes [Y]

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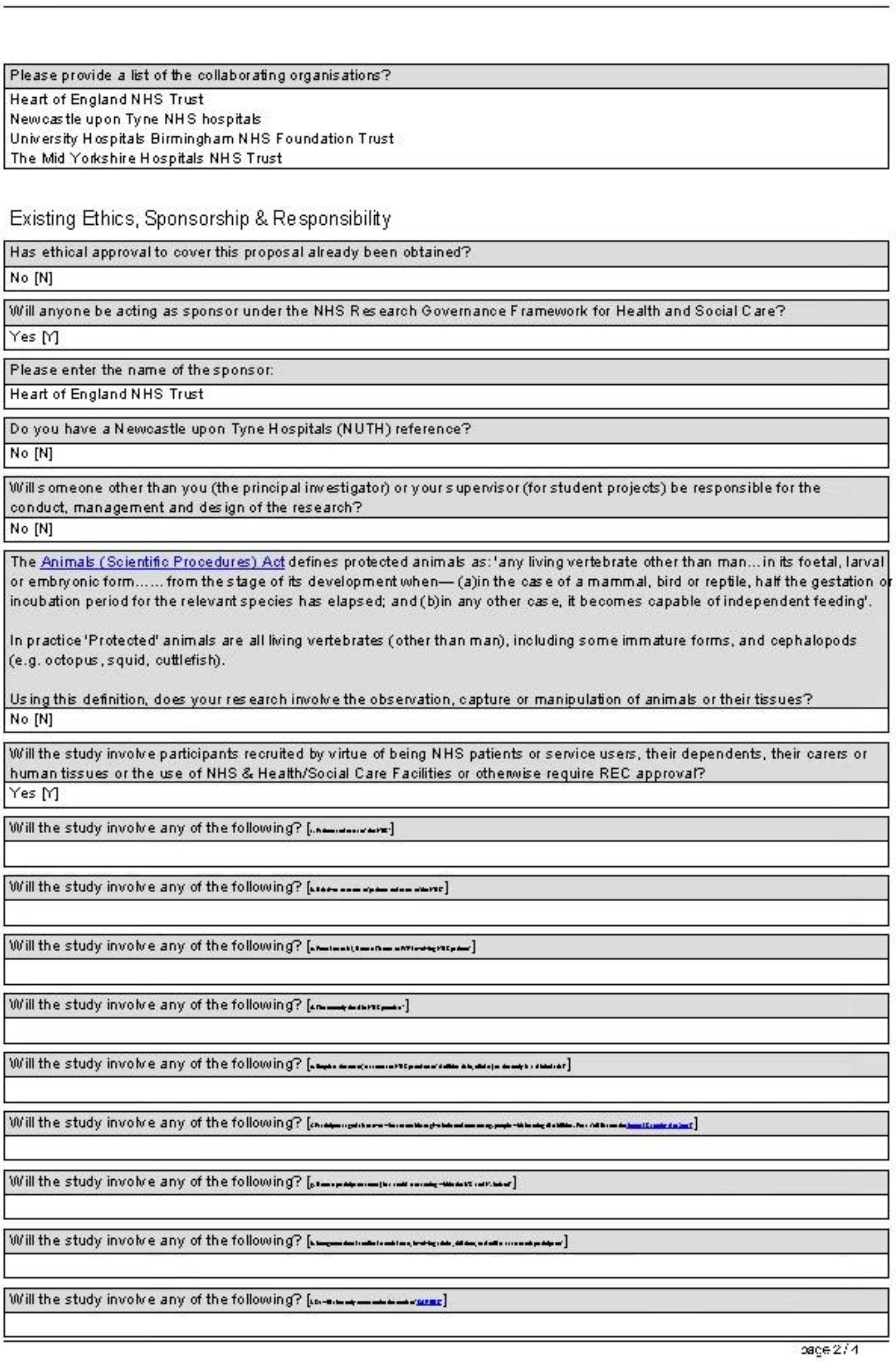

Please provide a list of the collaborating organisations?

Heart of England NHS Trust
Newcastle upon Tyne NHS hospitals
University Hospitals Birmingham NHS Foundation Trust
The Mid Yorkshire Hospitals NHS Trust

Existing Ethics, Sponsorship & Responsibility

Has ethical approval to cover this proposal already been obtained?

No [N]

Will anyone be acting as sponsor under the NHS Research Governance Framework for Health and Social Care?

Yes [Y]

Please enter the name of the sponsor:

Heart of England NHS Trust

Do you have a Newcastle upon Tyne Hospitals (NUTH) reference?

No [N]

Will someone other than you (the principal investigator) or your supervisor (for student projects) be responsible for the conduct, management and design of the research?

No [N]

The Animals (Scientific Procedures) Act defines protected animals as: 'any living vertebrate other than man... in its foetal, larval or embryonic form...... from the stage of its development when— (a)in the case of a mammal, bird or reptile, half the gestation or incubation period for the relevant species has elapsed; and (b)in any other case, it becomes capable of independent feeding'.

In practice 'Protected' animals are all living vertebrates (other than man), including some immature forms, and cephalopods (e.g. octopus, squid, cuttlefish).

Using this definition, does your research involve the observation, capture or manipulation of animals or their tissues?

No [N]

Will the study involve participants recruited by virtue of being NHS patients or service users, their dependents, their carers or human tissues or the use of NHS & Health/Social Care Facilities or otherwise require REC approval?

Yes [Y]

Will the study involve any of the following? [[illegible]]

Will the study involve any of the following? [[illegible]]

Will the study involve any of the following? [[illegible]]

Will the study involve any of the following? [[illegible]]

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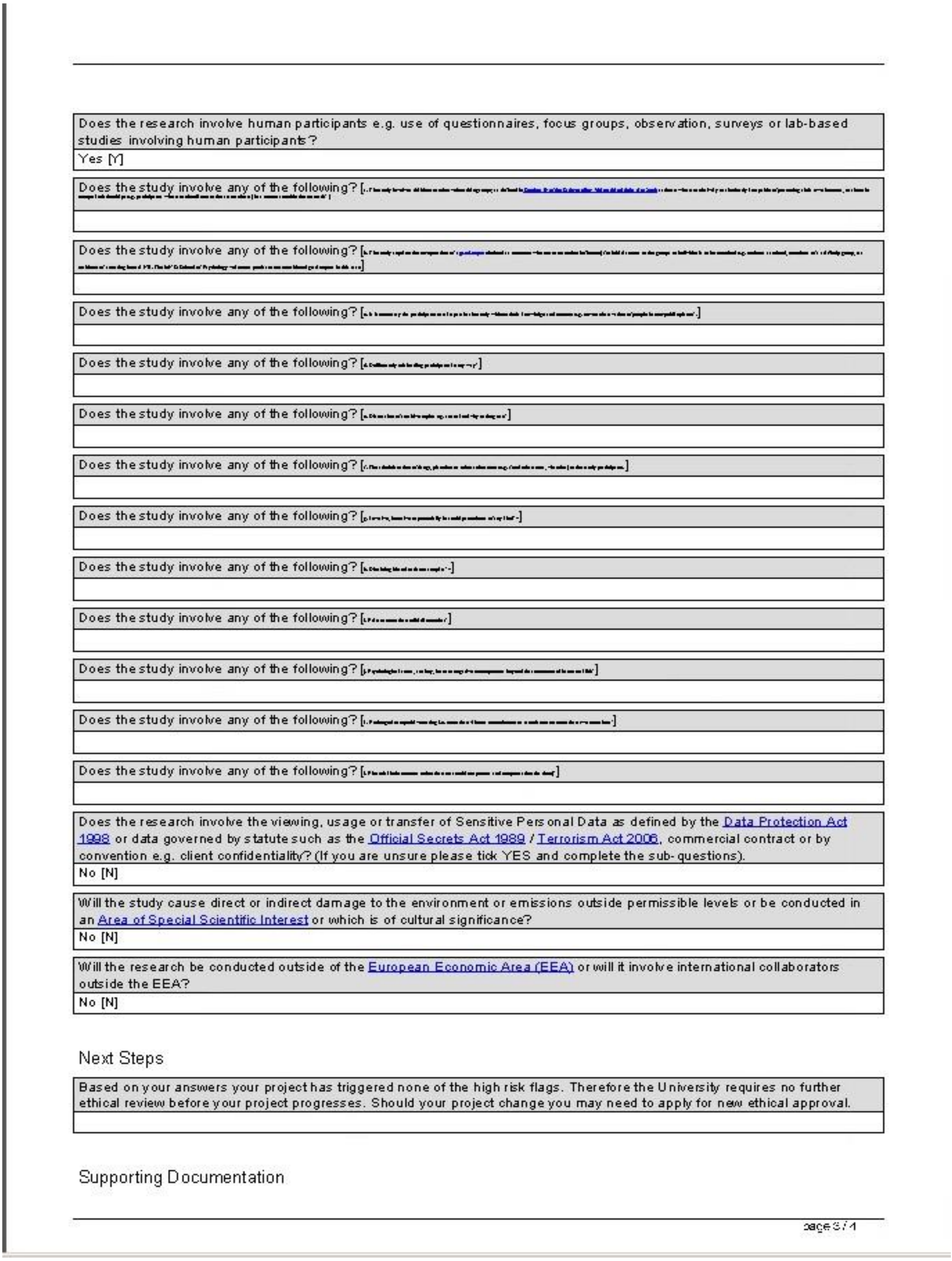

Does the research involve human participants e.g. use of questionnaires, focus groups, observation, surveys or lab-based studies involving human participants?
Yes [Y]

Does the study involve any of the following? [[illegible]]

Does the study involve any of the following? [[illegible]]

Does the study involve any of the following? [[illegible]]

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Does the study involve any of the following? [[illegible]]

Does the study involve any of the following? [[illegible]]

Does the study involve any of the following? [[illegible]]

Does the research involve the viewing, usage or transfer of Sensitive Personal Data as defined by the Data Protection Act 1998 or data governed by statute such as the Official Secrets Act 1989 / Terrorism Act 2006, commercial contract or by convention e.g. client confidentiality? (If you are unsure please tick YES and complete the sub-questions).
No [N]

Will the study cause direct or indirect damage to the environment or emissions outside permissible levels or be conducted in an Area of Special Scientific Interest or which is of cultural significance?
No [N]

Will the research be conducted outside of the European Economic Area (EEA) or will it involve international collaborators outside the EEA?
No [N]

Next Steps

Based on your answers your project has triggered none of the high risk flags. Therefore the University requires no further ethical review before your project progresses. Should your project change you may need to apply for new ethical approval.

Supporting Documentation

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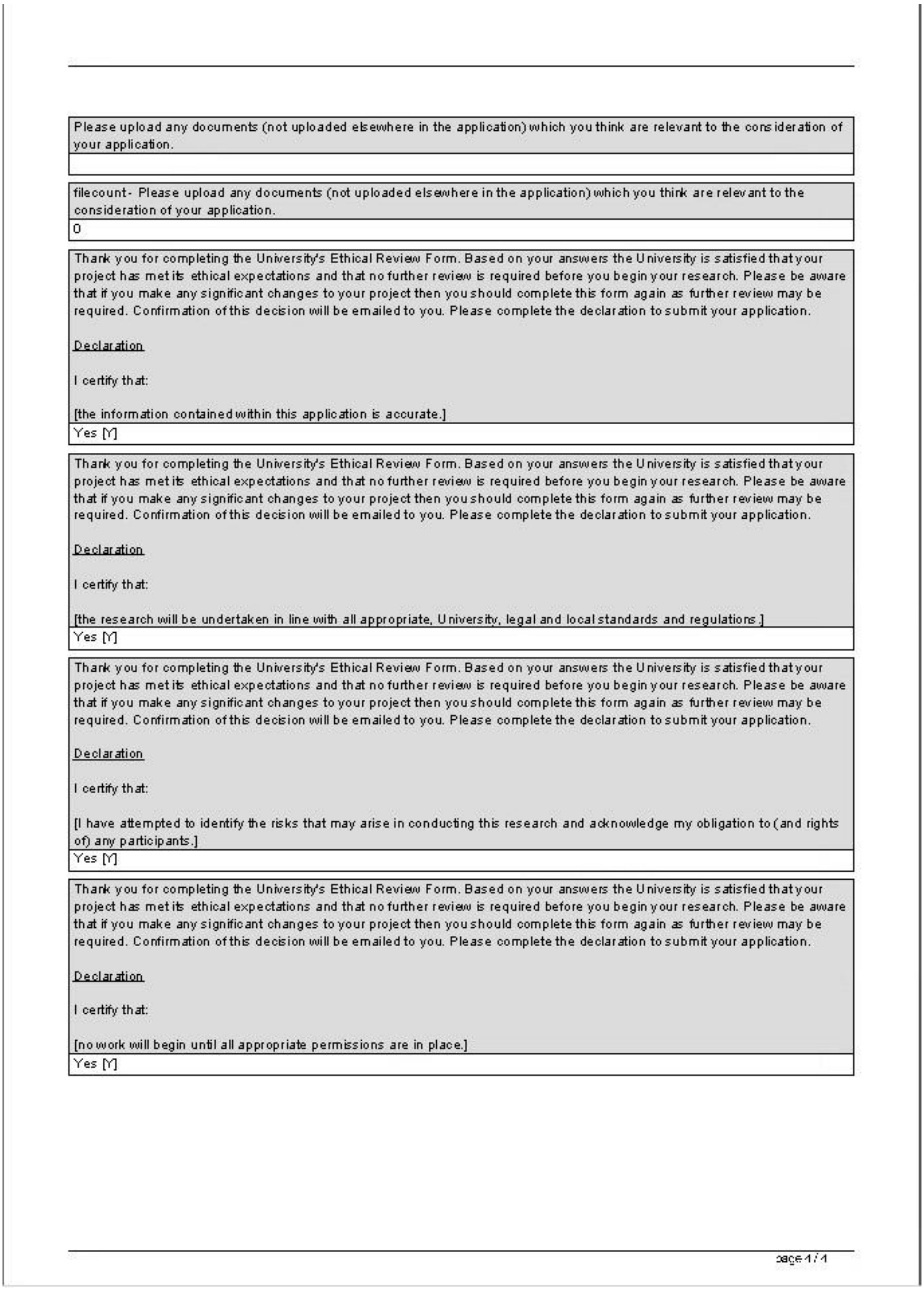

Please upload any documents (not uploaded elsewhere in the application) which you think are relevant to the consideration of your application.

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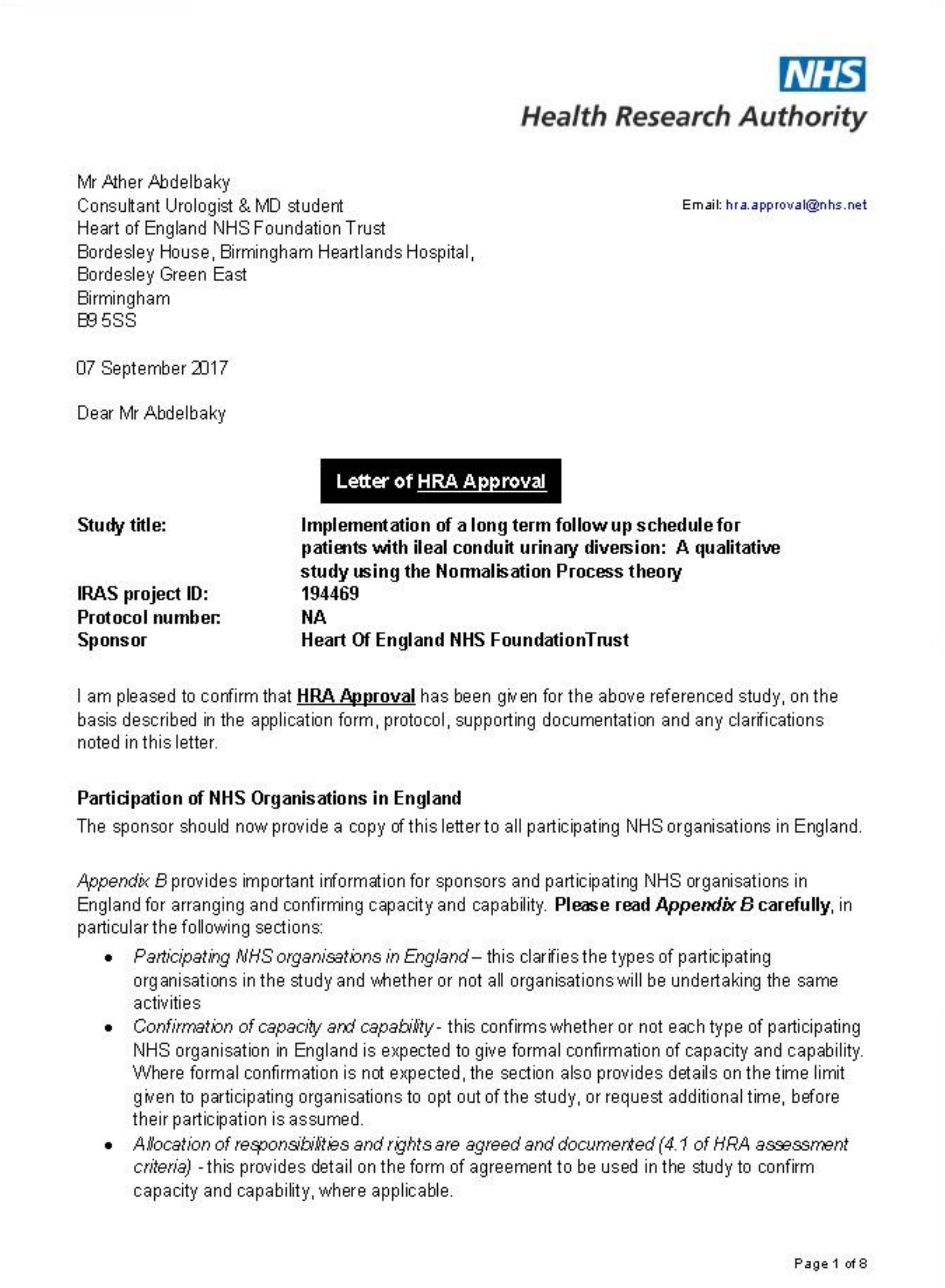
Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and that no further review is required before you begin your research. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you. Please complete the declaration to submit your application. Declaration I certify that: [the information contained within this application is accurate.]
Yes [Y]

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and that no further review is required before you begin your research. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you. Please complete the declaration to submit your application. Declaration I certify that: [the research will be undertaken in line with all appropriate, University, legal and local standards and regulations.]
Yes [Y]

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and that no further review is required before you begin your research. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you. Please complete the declaration to submit your application. Declaration I certify that: [I have attempted to identify the risks that may arise in conducting this research and acknowledge my obligation to (and rights of) any participants.]
Yes [Y]

Thank you for completing the University's Ethical Review Form. Based on your answers the University is satisfied that your project has met its ethical expectations and that no further review is required before you begin your research. Please be aware that if you make any significant changes to your project then you should complete this form again as further review may be required. Confirmation of this decision will be emailed to you. Please complete the declaration to submit your application. Declaration I certify that: [no work will begin until all appropriate permissions are in place.]
Yes [Y]

Appendix 8. Letter of HRA ethical approval (Study B)



NHS
Health Research Authority

Mr Ather Abdelbaky
Consultant Urologist & MD student
Heart of England NHS Foundation Trust
Bordesley House, Birmingham Heartlands Hospital,
Bordesley Green East
Birmingham
B9 5SS

Email: hra.approval@nhs.net

07 September 2017

Dear Mr Abdelbaky

Letter of HRA Approval

Study title:	**Implementation of a long term follow up schedule for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory**
IRAS project ID:	**194469**
Protocol number:	**NA**
Sponsor	**Heart Of England NHS FoundationTrust**

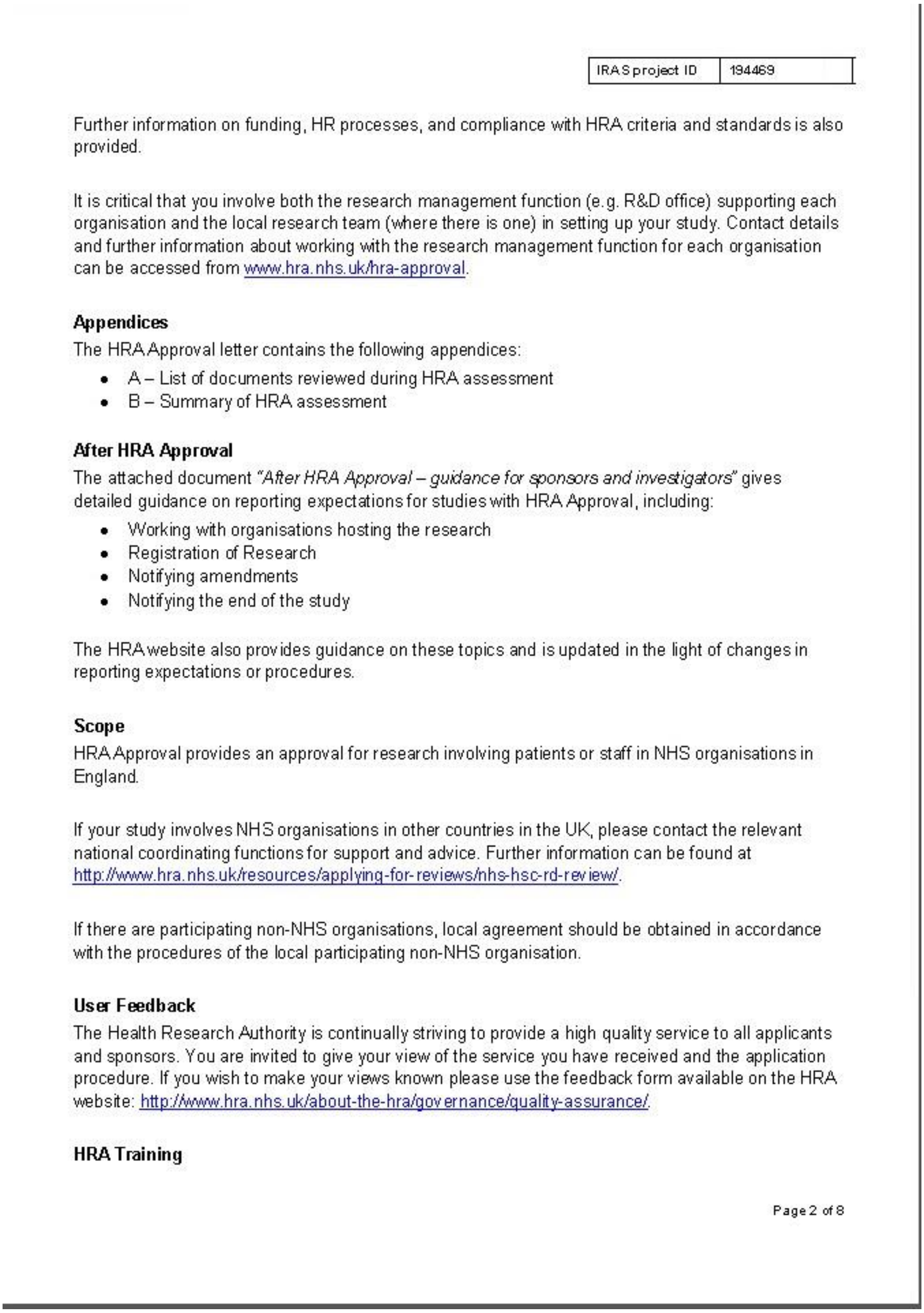
I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.



Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The attached document *"After HRA Approval – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

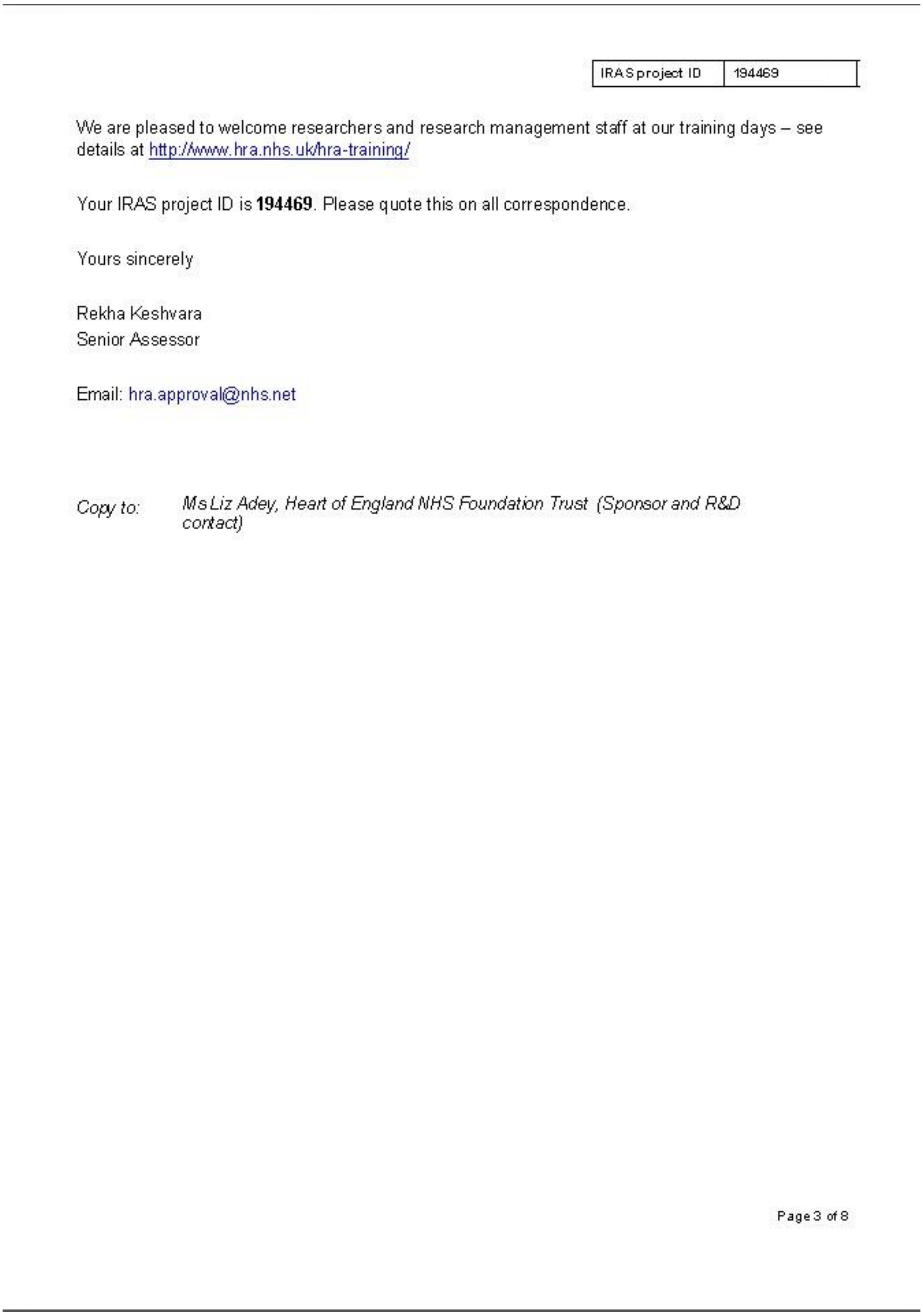
If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training



We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **194469**. Please quote this on all correspondence.

Yours sincerely

Rekha Keshvara
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Liz Adey, Heart of England NHS Foundation Trust (Sponsor and R&D contact)*

Appendix 9. Participant consent form (Study B)

Heart of England NHS Trust

Urology Department

IRAS ID: 194469

Centre Number:

Participant Identification Number for this trial:

CONSENT FORM

Title of Project: ***Implementation of a long term follow up schedule for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory***

Name of Researcher: Ather Abdelbaky

Please initial box

1. I confirm that I have read the information sheet dated 10/08/17 (version 4.2.) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐
3. I understand that my participation is fully confidential.
4. I understand that the interviews collected data will be anonymised when the results are written up. ☐
5. I agree to the use of anonymised direct quotations from my interview in publications. ☐
6. I agree to take part in the above study ☐

____________________	____________________	____________________
Name of Participant	Date	Signature
____________________	____________________	____________________
Name of Person taking consent	Date	Signature

Appendix 10. Interviews topic guide (Study B)

"Implementation of a long term follow up schedule for patients with ileal conduit urinary diversion: A qualitative study using the Normalisation Process theory"

Topic guide

Introduction

Purpose of interview. Confidentiality.

Can you tell me a bit about yourself – how long you've been in practice, etc

1-Participant's perspective of follow-up and long term complications

How important is it to provide follow up for patients with ileal conduit? Why?

What do you want to achieve? [What is a good outcome of follow-up for you/the patient?]

Ideally, how long -Should follow-up last for? Why? [Is/should length of follow-up be different for different patients?]

What kind of complications have you seen? How serious?

2-Partcipant's current practice

What is your current practice of follow up for IC patients?

How do you decide what follow-up a particular patient will get?

Are you using any national or international guidelines?

When? (Frequency)

What Investigations? (Scans, blood test, others)

Who? (Professionals involved)

What is the role of stoma nurse in your current practice?

Where? (Setting)

How long? (Length) How do you decided when to stop follow-up (if ever)]

Do you ever discharge patient to primary care? At what point?

+/-what arrangement do you use on discharge ensure that GP are comfortable with taking that care over from secondary care? (Feedback, meetings, letters)

What is good/ bad about current follow-up practice? [What works well/ what doesn’t work well?

Do you do any evaluation of whether current follow-up “works” ? How can it get better?

3- Do you feel a need to change follow up schedule

What are the options?

Discuss each - Where; Who; How; Setting

Do you think these would be better or worse than current follow-up? Why?

Would anything need to be in place to allow changes to follow-up? (e.g. safety net to ensure discharged patients don’t fall through crack in service; training of health professionals; rapid route back into hospital clinic; more patient education]

Would there be a need to evaluate any “new” follow-up strategy?

4-Discharge to primary care

How safe it is to discharge patient to community? Why? Which patients could be discharged?

What benefits (if any) the secondary care would get from transferring the care to primary care? [Would there be any benefits for primary care?]

How much skills/ knowledge do GPs have to look after those patients? How can it be improved? What role can you personally play?

Which complications you think the GP will need to deal with frequently? (UTIs, hernia)

What could be missed with community-based follow-up? How to avoid this? (Renal function)

What investigations? How frequent? Do GP have sufficient resources in the community to undertake follow-up?

What role could stoma nurses play?

How can patient education help?

What would be the indications to refer patient back to hospital?

What might make community follow up difficult? (e.g. Communications with specialists, guidelines, GP knowledge, access to SN, patients preference. Etc)

What would help/been need to make community FU work well? (e.g. Communications with specialists, guidelines, GP knowledge, access to SN, patients preference. Etc)

5. Close

Is there anything else you would like to discuss, or tell me, about follow-up of these patients, either now or in the future?

Thank you for your help.

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