

Choice of urinary diversion after radical cystectomy: A UK perspective

Volume 1 of 2

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Abstract

Introduction, Aim and Objectives

The central aim of Shared Decision Making (SDM) is to improve the quality of healthcare decisions made, mainly through enhanced collaboration between patients and healthcare professionals. The benefits of applying SDM are particularly pronounced for healthcare choices which are preference-sensitive. Certain types of bladder cancer can be cured by surgical removal of the bladder (radical cystectomy), necessitating diversion of urine (urinary diversion) either via a small bowel segment of an abdominal wall stoma (ileal conduit) or into a substitute bladder constructed from bowels (orthotopic neobladder). The latter is the less established urinary diversion technique but has been promoted by some surgeons as the new 'gold standard' for urinary diversion after radical cystectomy. Individual patient suitability for either of the two diversion options and their relative benefits and risks remain subjects of debate. The choice of urinary diversion after radical cystectomy has therefore become preference-sensitive, where the best choice is usually the one that is best aligned with patient preferences. The work presented in this thesis sought to understand how this choice was reached and reflect the findings against the ideals of SDM, within the current UK healthcare setting. The objectives were 1) To evaluate patient decisional needs in the decision making process and 2) To explore aspects considered most important to patients when they made their choice.

Methodology and Methods

Mixed methodology was adopted and both quantitative and qualitative methods were employed. There were three interlinked studies 1) Secondary analysis of the joint Southwest Public Health Observatory – British Association of Urological Surgeons (SWPHO – BAUS) Cystectomy dataset 2) Needs assessment questionnaire survey of patients and clinicians 3) Qualitative semi-structured interviews with patients and clinicians to provide insights into current practice and to explore how SDM may benefit option selection. The three studies were analysed individually and the results were then cross-interpreted to generate overall findings.

Main Findings

The statistically significant locality-based variation in use of neobladder in the UK NHS appears unwarranted, as it was unexplained by differences in demographic and clinical characteristics.

Patient knowledge, expectation and support to make the choice in accordance to informed preferences were the three main decisional needs. There were instances where patients seemed misinformed about the diversion options, potentially due to the way they were counselled by their clinicians. There were also reported practices by clinicians and the use of certain information materials which appeared to help patients make a choice more aligned with the ideals of SDM. The distinct power imbalance between the consultant surgeons and patients appeared to be the main hindrance to implementing SDM with surgeons excluding or discouraging patients from the neobladder having considered relevant factors or simply their personal 'feeling' on an individual's suitability. The sometimes conflicting inter-professional relationship between surgeons and specialist nurses, with misunderstanding of each other's roles and information sharing techniques seemingly further hampered the application of SDM into this choice. Others such as family and former patients might help have roles to help patients make a more informed, value-based and preference-aligned choice. In the main, patients appeared to choose the diversion option which was anticipated to fit in best with their known normality; the aspects considered by patients before the choice was made included preservation of body image, daily activities and hobbies, minimisation operative risks, as well as avoidance of stigma from urinary leakage and toileting adaptations. Written additional information was valued by both patients and clinicians, and the written format for a future decision support for this choice was favoured. Clinicians and patients were uncertain of key differences of informed as opposed to shared decision making.

Conclusions

This thesis highlights that enhancing patient knowledge, taking into account patients' expectations as well as their values and preferences, and supporting patients to consider and voice their preferences are priorities in the individually appropriate choice of urinary diversion during cystectomy. Enhanced patient knowledge alone

would be insufficient to allow SDM in diversion option selection to become a reality; the power imbalance between surgeons, patients and specialist nurses needs to be addressed. Design and use of a validated decision support package containing quality evidence on relative benefits and risks of each diversion option and features to elicit individual patient (and perhaps surgeon) preferences and values would represent a significant step towards realising SDM as the basis for choice of urinary diversion in radical cystectomy.

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Chapter 1 Introduction

Bladder cancer is a significant healthcare problem in the UK and also globally. Localised high-risk non-muscle invasive and localised muscle invasive bladder cancers are the two specific types which concern this thesis. Surgical excision of the entire bladder, radical cystectomy, has been widely adopted as a curative treatment (BAUS Bladder Cancer MDT 2013) for these two types of bladder cancer, and this procedure is followed by the formation of an artificial urinary drainage channel (urinary diversion) i.e. radical cystectomy is the first part and urinary diversion the second in the same operation. Various methods of urinary diversion exist, with the ileal conduit (conduit) and orthotopic neobladder (neobladder) being the most popular (Hautmann et al. 2012). The process concerning the selection between a conduit and neobladder in the context radical cystectomy represents the research subject central to this thesis.

1.1 Bladder Cancer

1.1.1 *Epidemiological and Pathological Aspects*

According to the World Health Organization (WHO), bladder cancer is the 11th most common type of cancer globally, with the highest incidences in North America, Southern and Western Europe (WHO Globocan 2012); however, high incidences are also noted in some areas of Africa and the Middle East, where the waterborne parasitic infection of Schistosomiasis is endemic (WHO 2014). In 2011 the UK alone there were over 10,300 new cases of bladder cancer reported. The occurrence of bladder cancer is more common in males over the age of 50 (WHO Globocan 2012). In the UK, a diagnosis of bladder cancer in someone under the age of 50 is rare, but thereafter the incidence starts to rise steeply; the current male to female ratio is approximately 5:2 (Cancer Research UK 2014). At least half of all UK patients with high-risk non-muscle invasive or muscle-invasive bladder cancer survive for five years after their diagnosis, with men demonstrating a slight survival advantage over

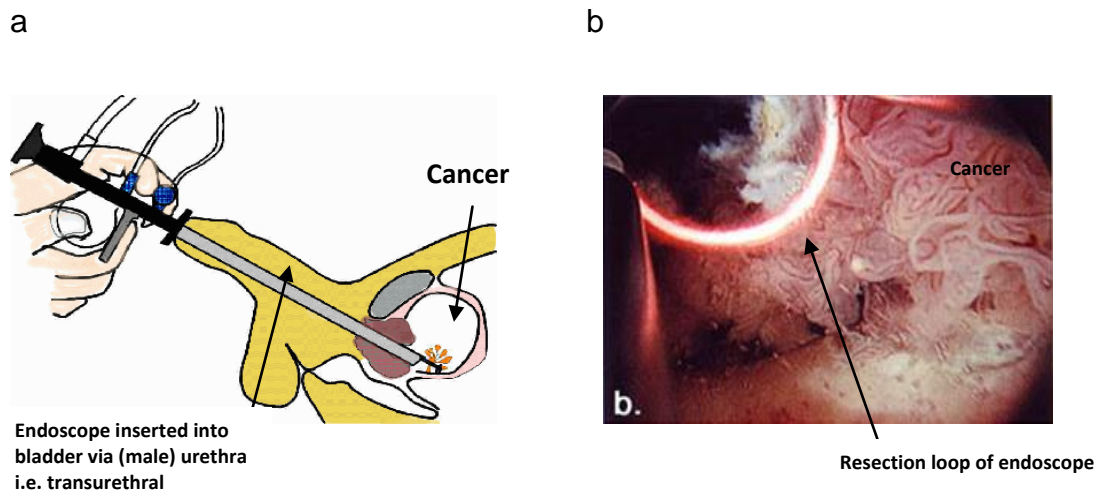
women (men: 58.2%; women: 50.2, Cancer Research UK 2014); this trend is also found in other European populations (Sant et al 2009).

Aside from geography, age and gender, the development of bladder cancer is also associated with cigarette smoking and exposure to aromatic amines, which is an occupational hazard frequently encountered in the paint, textile, steelworks and mining industries (Kogevinas 2003; Zeegars et al 2001).

Bladder cancer can be categorised by its cellular type, depth of invasion into the bladder wall, and the degree of maturity of the cancer cells identified. In developed countries, the predominant cellular type is transitional cell carcinoma (TCC), whilst other types found include squamous cell carcinoma (SCC), adenocarcinomas and lymphomas. However, in areas endemic for Schistosomiasis, most bladder cancers are SCCs. The depth of cancer invasion and degree of cancer cell maturity are classified by the Tumour-Node-Metastasis (TNM) staging system and the WHO 1973 system, respectively (Sobin et al. 2002; Stenzl et al. 2009). Within the TNM system, 'T' denotes the depth of cancer invasion and contains the sub-stages Tis, Ta, and then T1 through to T4. Bladder cancers which are staged as Tis, Ta or T1 are 'non-muscle invasive' bladder cancers, involving the inner lining and/or the connective layers of the bladder wall only. In contrast, those staged as T2 or above are 'muscle-invasive' bladder cancers which have invaded into and/or through the muscle layer of the bladder wall. The WHO 1973 system grades bladder cancer from 1 to 3, with the higher grade cancers containing less matured cells, which tend to proliferate more quickly and have a higher tendency to invade deeper into the bladder wall, i.e. they are more aggressive. With specific reference to Tis bladder cancer, this contains carcinoma-*in-situ* cancer cells which are high grade and therefore can rapidly evolve into muscle-invasive bladder cancer and spread outside the bladder.

Accurate staging and grading of bladder cancer requires the combined efforts of appropriate history taking and clinical examination, imaging interpretation, and examination of specimens obtained from the initial surgical removal of bladder cancer via transurethral resection (TUR; **Error! Reference source not found.**).

Figure 0.1 a and b: Transurethral resection of a bladder tumour



(Sources: Images via Google Image Search with term ‘transurethral resection of a bladder tumour’; figure 1.1a from <http://www.montereybayurology.com/urocond/BladderCancerTreatment.htm>; figure 1.1b from <http://www.urologyassociates.com.au/WeTreat/BC/BladderCancer-2.php>)

The TNM system helps categorising bladder cancer into non-muscle and muscle invasive disease, thus informing the potential management strategies. Non-muscle invasive bladder cancer can be further considered as being low, intermediate or high risk, where high is 3 cm or greater and multiple in nature, with grade 2, 3 or CIS cells, or recurring frequently despite bladder instillation of chemotherapeutic agents (e.g. Mitomycin-C and Bacille Calmette–Guérin) following TURBT (Sylvester et al. 2004; BAUS Bladder Cancer MDT 2013). The management strategy for a patient with bladder cancer may change over time following the initial diagnosis in response to surveillance findings and a patient’s changing needs (BAUS Bladder Cancer MDT 2013; Babjuk et al. 2013; Hautmann et al. 2012; Stenzl et al. 2011)

1.1.2 Management of Localised High Risk Superficial and Localised Muscle-Invasive Bladder Cancer

The management strategies for bladder cancer in the UK are largely linked with the European clinical guidelines (BAUS Bladder Cancer MDT 2013; Stenzl et al. 2009, 2011, 2012). Radical cystectomy is currently the recommended curative treatment

for localised muscle-invasive bladder cancer (i.e. no cancer spread to other organs), but can also be considered for localised high-risk non-muscle invasive bladder cancer which has not been well controlled in terms of recurrence frequency and upstaging (Hautmann et al. 2007; Stein et al. 2001). An alternative curative treatment to radical cystectomy is radical radiotherapy with preservation of the bladder, but there is no evidence to-date demonstrating its superiority to radical cystectomy (Shelley et al. 2002).

Radical cystectomy entails the surgical removal of the entire diseased bladder together with the surrounding structures, including lymph nodes and prostate with the seminal vesicles in men, or the uterus with ovaries in women (Stenzl et al. 2009). Since the functions of the bladder are lost with its removal, an artificial way to store and drain urine is required and this is known as urinary diversion. Conduit and Neobladder are the two main types of urinary diversion performed in the western hemisphere (Hautmann et al. 2012).

1.1.3 A Brief History of Urinary Diversion

Various urinary diversion methods have been trialled since radical cystectomy became feasible in the early 20th century. All methods involve the reconfiguration or reconstruction of the urinary tract anatomy, with the aim to effectively transport urine from the kidneys to outside of the body. The use of bowel segments as conduits to drain urine was first reported in by Simon in 1952 (Simon 1952). Some 60 years later, Coffey introduced ureterosigmoidostomy (Pannek and Senge, 1998), whereby the ureters were connected to the distal portion of the large bowel and urine was expelled along with faeces during bowel opening; both urinary and faecal continence being dependent upon an intact anal sphincter. Ureterosigmoidostomy remained the main type of urinary diversion for some years, but was associated with significant disadvantages, including recurrent kidney infection leading to renal failure, biochemical disturbances, and the risk of developing colon cancer (Müller and Bastian, 2008). After Bricker established the ileal conduit procedure in 1950 (Bricker 1950), ureterosigmoidostomy has become nearly obsolete; however, it is still occasionally considered for patients with good bowel control and a limited life

expectancy, or in areas where stomas are culturally unacceptable or the use of associated appliances are generally not affordable (Yossepowitch et al. 2005).

1.1.3.1 Ileal Conduit

Ileal conduit formation describes a procedure where the ureters, the kidneys' drainage tubes, having been disconnected from the removed bladder, are re-connected to an isolated short (12-18 cm) segment of ileum (small bowel) with an intact blood supply. One end of the segment is connected to the ureters, whilst the other is brought to the surface of the abdomen via an opening known as a urostomy. Variations in connecting the ureters to conduit exist, but generally the ureters can either be connected to the conduit individually or joined at their ends first (Wallace 1970; Le Duc 1987; Sundin 1974; Lee et al. 2004). The urostomy is spouted, and its positioning is usually determined and marked prior to surgery. Urine drains through the urostomy continuously and involuntarily, and is collected into a bag placed over the urostomy itself (Figures 0.2). A urosotomy bag is available in different sizes, colours and textures, and as either a one- or two-piece device. The bag is usually changed on alternate days and is usually connected by plastic tubing to a larger bag overnight to allow uninterrupted sleep (Urostomy Association 2013). Over the past 70 years, the conduit has endured as the standard method of urinary diversion to be coupled with radical cystectomy. However, its incontinent nature and potential body image issues (Somani et al. 2009) have stimulated the development of continent forms of diversion, including the neobladder, which is discussed in details below.

1.1.3.2 Orthotopic Neobladder

'Orthotopic' means 'in the normal place of' and 'neobladder' means a 'new bladder'. Therefore, an orthotopic neobladder can be understood as 'a new bladder placed where the old, native bladder once was' and its formation is viewed as an effort to afford near-normal urine storage and voiding.

Initial attempts at using a long tubular bowel segment as a urinary reservoir were unsuccessful, and it was soon realised that the high pressure generated by peristalsis of the bowel led to significant urinary incontinence and kidney damage (Le Duc et al. 1979). The breakthrough came when it was recognised that peristalsis could be disrupted when a bowel segment was detubularised, thus allowing the creation of a low pressure urinary reservoir (Hinman et al. 1988; Basford et al. 2002). Emptying of the urinary reservoir was at first thought to be best achieved through a continent stoma (opening) with a valve arrangement, on the abdominal wall. This stoma was connected to the urinary reservoir, thus permitting its emptying via intermittent self-catheterisation (ISC, intermittent passage of a fine plastic tube known as a catheter) (Kock et al. 1982; Skinner et al. 1987; Thuroff et al. 1986). This form of urinary diversion is also known as continent cutaneous urinary diversion; unfortunately, many patients who underwent this procedure required multiple surgical revisions of the continence mechanism due to leakages or narrowing of the stoma (Welk et al. 2008). In light of these issues, utilisation of the native, disease-free urethra for maintenance of urinary continence and neobladder emptying was explored and then established as the operation of orthotopic neobladder.

The techniques for creating a neobladder were introduced in the 1990s by Studer et al. (1996) and Hautmann et al. (1997); with both techniques involving the creation of a low pressure urinary reservoir with a reasonable capacity (usually 500 ml), using 40-60 cm of detubularised ileum (Hautmann et al. 2012). When constructing an orthotopic neobladder a long, isolated length of ileum with an intact blood supply is used. The ileum segment is opened along its length and reconfigured into a spherical reservoir, and the ureters isolated from the native bladder are then re-connected to the top of this neobladder. The neobladder is placed where the native bladder was originally located, with its apex being connected to the stump of the native urethra (urine pipe) (Stenzl et al. 2009;

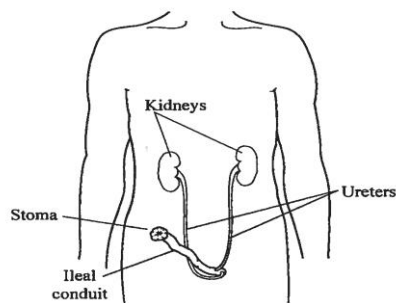
Figures 0.3). The neobladder thus provides internal storage of urine and permits its own emptying by abdominal straining, which aims to mimic natural voiding. There is a possibility that the neobladder cannot be efficiently emptied by abdominal straining alone and additional aid via ISC is required (Urostomy Association 2013). A Studer

neobladder is U-shaped, whereas a Hautmann neobladder is shaped like a 'W'. Subsequently, the neobladder is connected to the stump of the native urethra (Stenzl et al. 2009

Figures 0.4).

Figures 0.2 a and b: ileal conduit (a) anatomical arrangement; (b) external appearance with a urostomy bag

a



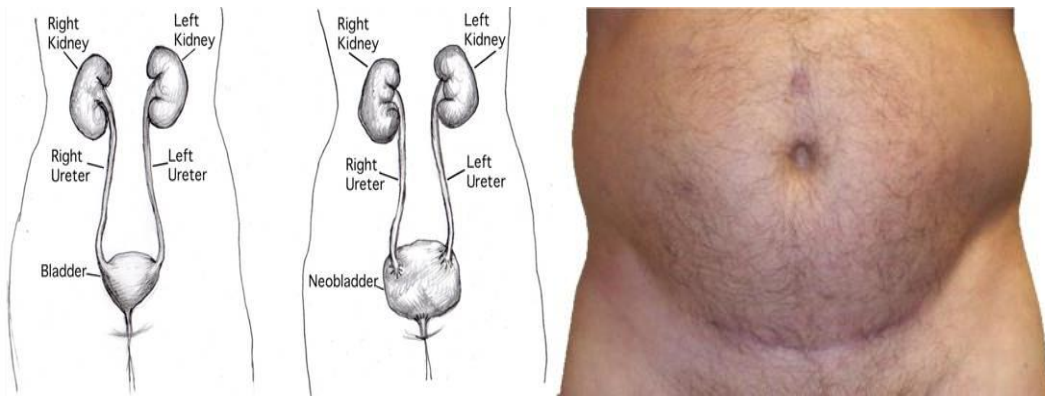
b



(Sources: Images via Google Image Search with term 'urostomy'; both from MacMillan Cancer Support Website 2011

<http://www.macmillan.org.uk/cancerinformation/cancertypes/bladder/livingwithinvasivebladder/cancer/livingwithaurostomy.aspx>)

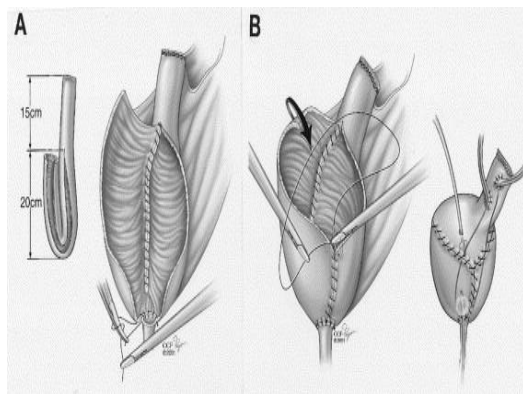
Figures 0.3 a and b: Orthotopic neobladder (a) anatomical arrangement; (b) external appearance



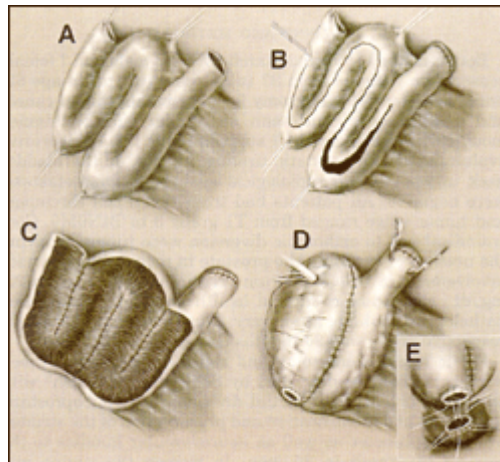
(Sources: Images via Google Image Search with term 'neobladder'; both from <http://www.kegel8.co.uk/blog/2012/12/20/neobladder-surgery-importance-of-kegel-exercise/>)

Figures 0.4 and b: Formation of a neobladder (a) Studer neobladder formation; (b) Hautmann neobladder formation

A



b



(Sources: Stenzl et al 2009)

1.1.4 Patient Selection for Orthotopic Neobladder

Cancer control is primarily achieved through radical cystectomy, whereas urinary drainage is through urinary diversion. As described above, the neobladder is a newer method of urinary diversion which promises to provide near-to-normal urinary

storage and voiding. As experience with the neobladder accumulates, research evidence on the clinical characteristics which impact upon the outcomes of the neobladder procedure become clearer.

The current literature mandates against the neobladder procedure for patients whose urethras have been involved with bladder cancer, due to the significant concern of cancer recurrence and progression (Studer et al. 1998; Skinner et al. 1995).

Creatinine is an indicator of kidney function, and a patient with a creatinine count of 120-150 $\mu\text{mol/L}$ or above is also usually excluded from the neobladder procedure (Hautmann et al. 2007). This has stemmed from the concern regarding the exacerbation of pre-existing kidney function impairment, secondary to inadequate neobladder emptying. Bladder cancer involvement of urethra and pre-existing kidney function impairment are also termed as 'absolute contraindications' by some opinion leaders in urinary diversion (Hautmann et al. 2012; Stenzl et al. 2011). However, there are other considerations which are taken into account by clinicians when determining the appropriateness of the neobladder procedure for patients and these are outlined in brief below.

The time required for the formation of the chosen urinary diversion is additional to the time spent performing the radical cystectomy. Time taken to create a neobladder is on average 30 minutes longer than that for an ileal conduit (Gburek et al. 1998; Parekh et al. 2000), and the advent of minimally invasive surgical approaches using laparoscopic ('key hole') techniques and robotic technologies, has meant that the total operating time may be further lengthened (Murphy et al. 2008). Longer operating times translate into longer periods of general anaesthetic, which in turn pose an increased risk of operative mortality and morbidity, especially for patients who are deemed less fit by the American Society of Anaesthesiologists (ASA) classification system (Bainbridge et al. 2012). The median length of a hospital stay after the neobladder procedure is also longer, with one study reporting a mean stay of approximately 20 days for a neobladder compared to 15 days for a conduit (Afak et al. 2009). A longer stay can pose an increased risk of hospital-acquired infections and also results in a higher economic cost.

After a neobladder has been formed the patient is left with an indwelling urethral catheter for about three weeks, which serves to irrigate and drain the neobladder.

The patient is then required to learn how to void voluntarily to empty the neobladder, which involves the recognition of the sensation of fullness of the neobladder (Peremenis 2004) and learning to void with abdominal straining, as well as regularly exercising the pelvic floor muscles to help maintain urinary continence between voids (Kane 2000; Razor 1993). During this initial period, in order to protect the anastomoses, a patient needs to consciously remember to void once every two hours, although this interval may be increased as time goes on, thereby allowing the neobladder to slowly stretch to an optimal capacity of around 500 ml (Hautmann et al. 2007). A neobladder of this capacity should theoretically empty effectively by voiding through straining (Hautmann et al. 2007). In some cases, particularly for women, effective voiding is not achievable, even after adhering to this regime and this necessitates the use of ISC at appropriate intervals throughout the day.

In contrast, a patient with a conduit needs to learn how to care for their urostomy, to select the most appropriate appliance, and to change the urostomy bag as required.

1.1.5 Complications Common to both Ileal Conduit and Orthotopic Neobladder

There are complications common to both procedures, some of which become more apparent over the course of time, i.e. longer term complications. Given the anatomical alteration to the urinary tract, the use of intestinal segments, and less efficient emptying, it is obvious that a patient living with a urinary diversion will be expected to be at risk of developing a urinary tract infection (UTI) and kidney function impairment. In one study, symptomatic UTIs were observed in 23% patients with a conduit who had been followed up for 5 years and a minority of them had evidence of systemic infection (Minton 1964). In contrast, following the formation of a neobladder, the recorded rate of symptomatic UTIs was as high as 39%, with 12% having evidence of systemic infection (Wood et al. 2003). The current literature does not show any significant difference regarding the loss of kidney function following a neobladder or conduit procedure (Hautmann et al. 2007; Somani et al. 2009).

Another common concern for both conduit and neobladder patients is metabolic disturbances, which include metabolic acidosis, a result of excess acid in the blood

as a consequence of urinary ammonium and chloride absorption by the bowel segments, and a vitamin B12 deficiency due to the reduced length of the terminal ileum for absorption of vitamin B12 (Hautmann et al. 2007). Weakening of bones through bone demineralisation may also occur, and the extent of this appears to be dependent upon the type of bowel segment used, as when the colon is used instead of the ileum, then the risk of reduced intestinal calcium absorption is higher (Mundy et al. 1990).

Mucus production from the bowel segments incorporated into the reconstructed urinary tract also poses a significant issue. Mucus retention can promote the development of a UTI as it can block urine drainage from the diversion (Hautmann et al. 2007). In addition, dysfunction of the remaining bowel system caused by the transposition of bowel segments into the urinary tract has been described, which can manifest as diarrhoea, faecal leakage, faecal urgency and increased flatus. However, an 8-year prospective cohort study showed similar proportions of conduit and neobladder patients reporting troublesome diarrhoea (19% vs. 17%, respectively) (Somani et al. 2007).

1.1.6 Complications Unique to Ileal Conduit and Orthotopic Neobladder

Specific complications are associated with a conduit which may develop over time and are mainly associated with the actual urostomy and the conduit itself, including a parastomal hernia (bulging of the abdomen around the urostomy), urostomy/conduit narrowing, and skin problems around the urostomy. Overall, urostomy-associated complications have been observed in up to 31% of patients two years after formation (Iborra et al. 2001; Nordstrom et al. 1990; Singh et al. 1997). Perhaps the most troublesome is a parastomal hernia, which occurs in up to 15% of patients two years after formation (Iborra et al. 2001; Loisodes et al. 1995). There are also questions surrounding body image, and the perceived significance of this issue after conduit formation is variable (Hawighorst-Knapstein et al. 2004, Jenks et al. 1997, Salter et al. 1992, Somani et al. 2007, Somani et al. 2012).

Some degree of urinary incontinence is suffered by the majority of patients following neobladder surgery. One of the main factors influencing urinary continence is the intactness of the external urethral sphincter (Hautmann et al. 2012). In general, continence with a neobladder improves during the first 6-12 months after surgery, as the compliance of the neobladder increases and sphincter function returns (Hautmann et al. 2012). It is expected that most patients with a neobladder will achieve daytime continence early on after surgery, as reflected by the findings from a number of patient self-reporting questionnaires (Constantinides et al. 2001; Gburek et al. 1998; Studer et al. 1997); however, it takes longer to achieve night time continence (Hautmann et al. 2007). Moreover, there have been a wide range of self-reported complete night time continence rates, ranging from 45-65% (Hautmann et al. 2003; Lee et al. 2003). Female neobladder patients in particular are prone to incomplete neobladder emptying, which necessitates ISC (Ali-El-Dein B et al. 1999; Hautmann et al. 1996; Stenzl et al. 1996). A further serious complication of neobladder formation is rupture, which is precipitated by mucus retention in the neobladder leading to its over-distension (Hautmann et al. 2007). Rupture can occur in an acute or a chronic setting, and the rate of spontaneous neobladder rupture ranges from 1.5 to 4.3% (Desgrandchamps et al. 1997; Hautmann et al. 2007).

1.1.7 Relative Benefits and Risks of Orthotopic Neobladder and Ileal Conduit

Among some specialist urology centres the proportion of patients having a cystectomy who also undergo neobladder formation is as high as 66.2%; however, from more population-based datasets this proportion decreases to 15% (Gore et al. 2006; Hautmann et al. 2007), a rate echoed by population-based data from the UK (Hounscome et al. 2012). The variation in the rate of the neobladder procedure between hospitals within the UK is further explored in the Chapter 4.

In the current literature there is no evidence to support the superiority of a neobladder over a conduit in terms of benefits and risks (Nabi et al. 2005, Sogni et al. 2008, Hautmann et al. 2007); however, the quality of studies comparing the outcomes between the two diversion methods is generally poor (Nabi et al. 2005; Somani et al. 2009). Similarly, there is insufficient quality data to support the

assumption that a neobladder would result in better health-related quality of life (HRQOL) outcomes (Porter et al. 2005; Gerhaz et al. 2005). When Somani and colleagues (2007) examined the constituents of 'quality of life' for patients undergoing radical cystectomy with varying types of urinary diversion, family, relationships, health and finance, were the most important determinants, and surprisingly, body image was not prioritised by patients. In contrast, a more recent postal-questionnaire study demonstrated that patients with a conduit appeared to fare worse in terms of satisfaction with their body image compared to those with a neobladder (Philip et al. 2009).

As illustrated, the current evidence implies that there are some heterogeneous procedural, aftercare and lifestyle characteristics to be traded off between the two urinary diversions procedures of a conduit and a neobladder. Moreover, it would appear that at the population level it is difficult to determine which of the two diversions is more beneficial. Choosing between an ileal conduit and orthotopic neobladder in the context of radical cystectomy can be a daunting task for individual patients and clinicians, and is likely to be preference based. The process through which such a choice is reached for preference-based decisions can be facilitated by SDM, a concept which has attracted much attention over recent decades. In the next section SDM and its application in clinical practice are discussed in detail and the relevance of SDM in the decision-making process associated with urinary diversion with radical cystectomy is discussed.

1.2 Shared Decision Making in Clinical Practice

1.2.1 Effectiveness of Healthcare Modalities and Preference-Sensitive Choices

Many healthcare decisions today are guided by research evidence on the effectiveness of the specific treatment options; 'do nothing' is arguably also an ever-present option. The effectiveness of a given healthcare modality refers to the extent to which it 'works' within real practice settings (Mandelblatt et al. 1997). Currently, half of the known modalities are of unknown effectiveness, just over 10% have been demonstrated to be clearly effective, where benefits far outweighed harms, whilst another 7% call for trade-offs between benefits and harms (Clinical Evidence 2014).

For some health conditions a single clearly effective management modality exists (Wennberg 2002). However, there are many other conditions where there are two or more reasonable management options, and the research evidence fails to demonstrate which option is more effective; therefore the best choice rests on a patient's trade-off between the benefits and risks of each option (Elwyn et al. 2010; Wennberg 2002). The decision regarding which treatment to have for such health conditions can be described as being 'preference-sensitive'. Currently there is no convincing research evidence demonstrating that one urinary diversion method is more effective than the other in the context of radical cystectomy; specific benefits and harms are unique to a particular diversion method, and the best diversion choice depends on a weighing-up of the benefits and harms of the two options by individual patients assisted by their health advisors. The choice of urinary diversion after a cystectomy is therefore a 'preference-sensitive' healthcare decision.

There has been keen interest in regional variation in healthcare practices and studies have shown that such variation is not necessarily explained by the differences in the aggregate population health status (Birkmeyer et al. 2013; Wennberg 2002). The variation which exists in the management of preference-sensitive conditions is of particular relevance to this thesis, and is further discussed below.

1.2.2 Regional Variation in Rates of Surgical Procedures

Since Glover's (1938) classical study on the tonsillectomy rate among UK children in the late 1930s, regional variation in the rates of many surgical procedures within a nation has been persistently documented (Dartmouth Atlas of Healthcare, 2014; NHS Right Care, 2014). Individual surgeons' attitudes and beliefs regarding the indications for procedures, as well as the extent to which patients' preferences are incorporated into the decision making process, are viewed as the main reasons for such variation (Birkmeyer et al. 2013; Mulley et al. 2012). However, there are numerous other factors which may also contribute to regional variation in rates of various surgical procedures, but these are considered as less influential by a number of authors (Birkmeyer et al. 2013; Chassin et al. 1981; Leape et al. 1990; Mulley et

al. 2012). These include differing regional incidences of a given condition (The Dartmouth Atlas of Health Care, 2013), diverse regional diagnostic practices (Lu-Yao et al. 2012), varying collective patient willingness to undergo a surgical procedure (Hawker et al. 2001), and differing regional collective clinician opinions regarding indications for a particular surgical procedure. Surgical technology diffusion, surgical training, the supply of surgical expertise, financial incentives, and clinical governance are considered as additional factors affecting the regional variation in the rates of many surgical procedures (Birkmeyer et al. 2013; Mulley et al. 2012; Wennberg 2002).

When regional variation is secondary to the differing regional incidence of surgically-suitable patient candidates and/or collective patients' willingness to undergo a procedure, then the variation is regarded as 'warranted', whilst under other circumstances the variation is regarded as 'unwarranted' (Mulley et al. 2012; Wennberg 2002). With specific regards to preference-sensitive procedures (such as the two urinary diversion procedures), 'silent misdiagnosis' leads to unwarranted regional variations in their use; a term first employed by Mulley and colleagues (2012) to refer to clinicians' inaccurate perception of patients' preferences. Shared Decision Making (SDM) via decision support (DS) has been advocated as the main solution to silent misdiagnosis (Birkmeyer et al. 2013; Elwyn et al. 2010; Mulley et al. 2012; Wennberg 2002). Multiple studies have shown changed proportions of patients opting for specific treatments where the choice was preference-sensitive after SDM has been included in the decision making process (Collins 2009; Kennedy et al. 2002; Morgan et al. 2000; Deyo et al. 2000; Wagner et al. 1995), and this in itself demonstrates that silent misdiagnosis is widespread issue in the management of preference-sensitive conditions.

The greatest magnitudes of regional variation have been observed for preference-sensitive procedures. As with preference-sensitive conditions and healthcare choices, there is insufficient research evidence to demonstrate the clear-cut merits of these procedures over alternative management options, and the decision of whether or not to proceed with a procedure should rely on patients' informed preferences for procedure-specific features and outcomes. Examples of preference-sensitive procedures include radical prostatectomy (versus radiotherapy) for localised prostate

cancer, transurethral resection of the prostate (versus drug treatment) for benign prostatic enlargement, a mastectomy (versus lumpectomy) for localised breast cancer, total knee replacement (versus conservative management) for osteoarthritis of the knee, and coronary artery bypass (versus stent) for coronary artery disease (Birkmeyer et al. 2013; Appleby et al. 2011). The varying extent of the incorporation of patients' preferences in the decision making process is held particularly accountable for the regional variation in this context by a number of authors (Birkmeyer et al. 2013; Mulley et al. 2012).

Aside from the unwarranted variations in health care delivery outlined above, there are several other issues which have culminated in the endorsement of SDM into clinical practice, one of which is the change in the patient-doctor relationship.

1.2.3 The Changing Patient-Doctor Relationship

The subject of how patients and doctors relate to each other has been much studied over time, and implicated in this relationship is the power dynamics between the two parties. Within the wider societal context of the western hemisphere, this relationship has undergone a number of observed transitions over the past two centuries. It began with the shift from 'bedside medicine' towards 'hospital and laboratory medicine' between the late 18th and mid-19th centuries, where the influence of patients' narrated illness experiences and personal circumstances were diminished. This was mediated mainly through the centralisation of healthcare, e.g. the establishment of hospitals, sources of doctors' income, and the advancement of medical science and technology (Jewson 1976; Morgan 2008). It was not until the 1980s that attention once more focused on patients' influence, through the arrival of 'person-centred medicine or care'. The central ethos of person-centred medicine is mutuality, whereby patients and doctors recognise and respond to each other's knowledge and experience, and jointly participate in making healthcare decisions (Mead and Bower 2000). The popularisation of person-centred medicine was argued as being catalysed by two main factors: firstly, the changing health burden in many societies from acute to chronic, which calls for a longer-term patient-doctor relationship and a heavier reliance on patients to self-manage their conditions (Campbell and McGauley 2005); and secondly, the increasing realisation of the

significance of patients' biographical contexts and behaviour in the causation, natural course and management of disease (Locker 2008).

In parallel with the rise of person-centred medicine was the development of 'evidence-based medicine', which emphasises the use of quality, objective scientific research evidence disseminated via clinical guidelines and protocols for diagnosing and managing health conditions (Morgan 2008). The pioneers of evidence-based medicine explicitly stated that it would be essential to incorporate both individual doctors' expertise and patients' experience (Sackett et al. 1996), thus carrying the spirit of person-centred medicine to an extent. However, to others, evidence-based medicine was counter-intuitive to the practice of person-centred medicine. Armstrong (2002) viewed doctors as being pressured to practise under the constraints of guidelines and protocols endorsed by their employing health organisations, hence losing their individual autonomy in exercising their own judgement when caring for a patient.

At the level of an individual medical encounter, the relationship between a patient and doctor can be described by the level of control held by each party; control is mainly concerned with that deployed in making a healthcare decision. Among the earliest authors who offered such descriptions are Roter and Hall (1992), who classified the relationship as 'default', 'paternalistic', 'mutualistic' or 'consumerist'. At one end of the spectrum is the default relationship, which arises when an encounter lacks focus, where a patient remains passive and a doctor forgoes some of his/her control, whilst at the opposite end is the consumerist relationship, whereby a patient is dominant and a doctor is obliged to accord with a patient's views and rights. In a paternalistic relationship there is a reversal of this dominance, and a doctor will act as a patient's guardian, making decisions in what they perceive to be a patient's best interest. Finally, in a mutualistic relationship a patient and doctor act as equal partners, sharing each other's knowledge, experience and views, embarking on a joint venture in making health care decisions. Some authors have described a mutualistic encounter as a 'meeting between experts', particularly in the context of chronic conditions (Campbell and McGauley 2005; Tuckett et al. 1985).

1.2.4 Shared Decision Making

Building on Roter and Hall's classification, Charles and colleagues (1997; 1999a; 1999b) defined several models for treatment/healthcare decision making within a medical encounter. The qualities of these models largely resonate with the patient-doctor relationships outlined above. The informed and paternalistic models are broadly comparable to the consumerist and paternalistic patient-doctor relationships, respectively, whereas the shared model is largely identifiable with the mutualistic relationship.

Charles et al. analysed treatment decision making in three stages: information exchange, deliberation regarding treatment preferences, and decisions concerning which treatment to implement (Charles et al. 1999b), further specifying that during information exchange the flow, type, direction, and amount of information were to be considered. Both the informed and paternalistic models are characterised by a one-way flow of medical information from the doctor or other sources to the patient; however, in the informed model the minimum amount of information required would include all treatment options and their associated benefits and risks, in whatever amount deemed sufficient by a doctor to enable a patient to make an informed choice, whereas in the paternalistic model, the minimum amount of information is required to meet the medico-legal requirements (Charles et al. 1999a, 1999b). Other contrasts between the two models lie in who takes steps to deliberate over the treatment preferences and makes the ultimate decision on which treatment to proceed with. In the informed model, the responsibilities of treatment deliberation and decision rest with the patient, whereas in the paternalistic model the doctor decides.

Interaction is the central characteristic of the SDM model, where the two way exchange between the patient and doctor is present at each stage of decision making. As defined by Charles et al. (1997), SDM is:

“... the involvement of both the patient and the doctor, a sharing of information by both parties, both parties taking steps to build a consensus about the preferred treatment, and reaching an agreement about which treatment to implement”

(Charles et al. 1997, p.681)

The above definition of SDM is only one of many, with 'patient values/preferences', 'options' and 'partnership' as the elements most commonly associated with SDM (Makoul and Clayman 2006). Nonetheless, the definition by Charles et al. is the most widely accepted (Moumjid et al. 2007). Some authors have later sought to refine this prevailing definition of SDM, for instance Coulter and Collins (2011) added testing and management/support to treatment decisions, specified the use of evidence-based information, and the need to enact patients' preferred healthcare option:

"[SDM] is a process in which clinicians and patients work together to select tests, treatments, management or support packages, based on clinical evidence and the patient's informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients' informed preferences"

(Coulter and Collins 2011, p.2)

Over the past two decades the departure from paternalistic decision making to SDM has become apparent, and the body of literature on SDM has rapidly expanded with many examples of SDM being formally incorporated into clinical practice. Several drivers for advocating SDM as the ideal decision-making/clinical practice model have been proposed, which include the rise of consumerism in healthcare, feminist movements in challenging medical authority, the passage of legislation on patients' healthcare rights, and geographical variation in healthcare practice (Charles et al. 1999a; 1999b).

Paternalistic decision-making can be linked with certain macro sociological perspectives on the relationship between patients and doctors, such as Parsons' Sick Role Model (Morgan 2008). This model was largely constructed in the context of acute illness, and illness was regarded as a form social deviation, disrupting the overall smooth running of society. In this model there is a clear power asymmetry, whereby the dominant doctor who is assumed to 'know best' acts as the patient's

guardian, deciding which treatment the passive patient should proceed with (Charles et al. 1997). The patient assumes a temporary sick role and is obliged to promptly seek and concord with medical advice in order to get well again and resume his/her usual social role as soon as possible, in return, the patient is temporarily granted the right to shed some routine activities, e.g. work (Morgan 2008). The doctor is expected to apply professional expertise to treat the patient and be free from personal values and judgements at all time; the doctor is granted the rights to examine the patient, including intimate body parts and personal life, and hold professional autonomy and a position of authority over the patient (Morgan 2008). Parsons viewed this asymmetrical relationship as complementary, characterised by consensus, and invariably leading to positive consequences (Nettleton 2010).

However, Parsons' sentiments have been challenged by a number of authors. For instance Friedson (1970; cited in Nettleton 2010) argued that the medical profession was not merely the police of the sick role, but also a powerful agent exerting social control. This is achieved by creating a host of deviant sick roles, thus the social opportunities for 'acting sick', and as a result society's demand on the profession's expertise is enhanced. Moreover, the relationship between patients and doctors is often built upon conflicts rather than consensus in reality, as suggested by Friedson (1970; cited in Nettleton 2010). This notion is further supported by a number of studies carried out across a range of healthcare settings (Hussey et al. 2004; Jeffrey 1979; Dingwall and Murray 1979), which demonstrated diverse views on the perceived seriousness of an illness and the appropriate treatment between the two parties. Furthermore, Parsons' model was based on acute illness and there is a trend of increasing cases of chronic illness.

The dictum of 'no decision about me without me' is closely related to the spirit of SDM and was adopted at the 1998 Salzburg Global Seminar convention (<http://www.salzburgglobal.org/calendar/1990-1999/1998.html>). Thereafter, the principles of SDM within healthcare were endorsed by governing bodies elsewhere in the world and closer to home in the UK (Washington State Legislation 2011; General Medical Council 2009; Nursing and Midwifery Council 2008). The use of SDM is regarded by some as an ethical imperative in the everyday practice of a healthcare professional (Coulter and Collins 2011).

1.2.5 Practising Shared Decision Making and Decision Support

There are two well-published Shared Decision Making models which aim to ultimately improve the quality of healthcare decisions, i.e. decisional quality (DQ). The two models are namely the Ottawa Decision Support Framework (ODSF) (Ottawa Patient Decision Aid Group 1995) and the Shared Decision Making for Clinical Practice (SDMCP) (Elwyn et al. 2012), which differ in the theoretical basis on which they are constructed and in the broad approach through which they improve DQ.

The ODSF was developed from a more diverse range of theories, including those rooted in psychology, decision analysis, decisional conflict, social support and expected utility (Durand and Elwyn 2008). It aims to enhance DQ through identifying and addressing the decision making population's needs in making a particular decision, and subsequently build interventions to address such decisional needs. These needs can be classified into decisional conflict, knowledge and expectations, values, support and resources, nature of decision and patient/clinician characteristics. In contrast, the SDMCP was derived mainly from the agency and shared mind theories (Elwyn et al. 2012; Epstein et al. 2012), and it aims to improve DQ by framing the communications within patient-healthcare professional encounters according to the ideals of SDM. For a given decision the related encounters are embedded in the wider process of 'deliberation', which is iterative and recursive (Elwyn et al. 2012). Deliberation is considered as a sequence of three stages, from 'choice talk' through to 'option talk' and then 'decision talk', with each of these stages corresponding to the introduction of choice, a description of the options (including their pros and cons), and the exploration of patients' preferences for outcomes and making decisions, respectively. The SDMCP has essentially provided clinicians with some guidance on how to conduct each stage of the doctor-patient encounter in order to help patients mature their initial preferences into informed preferences about outcomes, and ultimately to make an informed decision (Elwyn and Charles 2008; Elwyn et al. 2012).

Common to both ODSF and SDMCP is the incorporation of Decision Support (DS) to improve DQ. DS is broadly regarded as interventions which help people deliberate about the healthcare choices they face and are categorised according to the setting in which they are used: 1) during a face-to-face, patient-healthcare professional encounter; 2) used independently by patients (and the significant individuals advising them) outside clinical encounters; and 3) over more social/interactive interfaces. The DS interventions within the consultation do not contain sufficient information for patients to make decisions without input from healthcare professionals, rather they serve more as a framework for conversations between patients and their healthcare professionals during clinical encounters, in order to increase patient involvement in the overall decision-making process (Elwyn et al. 2010). In contrast, the DS that patients can use at their leisure outside a consultation include patient decision aids (PDAs), which are evidence-based tools designed to help patients participate in making preference-sensitive healthcare choices (IPDAS 2013) and are intended to be supplementary to, rather than replacing healthcare professionals' counselling regarding options (Stacey et al. 2014). The International Patient Decision Aid Standards (IPDAS) have set out three essential objectives which a PDA should achieve:

- Explicitly state the decision that needs to be considered
- Provide evidence-based information about the health conditions concerned, the management options available, along with their pros and cons with their associated probabilities/scientific uncertainties
- Help patients to recognise the preference-sensitive nature of the decision and to clarify the values they place on pros and cons, their probabilities and scientific uncertainties

(IPDAS 2013)

The distinguishing difference between PDAs and conventional healthcare education material is that the latter only provide information and thus help patients to understand a condition/diagnosis concerned and its management options. In general terms, such materials are not explicitly designed to assist the deliberation process and engagement in the decision-making process nor do they elicit values and preferences (Stacey et al. 2014).

The socially interactive category of DS includes decision coaching (DC) and patient-to-patient decision support (Elwyn 2010). DC is predominantly a nurse-led service, with trained nurses helping patients in the deliberation process, explaining to patients about issues surrounding the decision, and highlighting appropriate information resources (O'Connor et al. 2008; Stacey et al. 2008). PDAs and DC can be used in conjunction with each other (Ottawa Patient Decision Aid Group 2013). Patient-to-patient DS is mainly mediated via social media, such as Twitter and Facebook groups (Elwyn et al. 2010); whilst feasible and effective, there is also a question of the need for moderation from healthcare professionals (Eysenbach et al. 2002).

The use of DS has been increasingly advocated as part of standard clinical practice and has been shown to improve DQ, but there remains some unresolved development issues which may impinge upon their validity and utility. There is little evidence suggesting the use of decision-making theories in the design of DS (Durand and Elwyn 2008), and even when there is, explicit explanations on translating the corresponding theories into design and outcome measure specifications are often lacking (Durand and Elwyn 2008; Elwyn et al. 2010). The appropriateness of using certain theories to develop a specific DS is also a matter of debate (Durand 2009). Another question is whether patient narratives should be included (Elwyn et al. 2010), although a recent systematic review failed to demonstrate that the integration of such material into PDAs increased their effectiveness (Bekker et al. 2013).

1.2.6 Decisional Quality

The ethos of Shared Decision Making has been increasingly recognised as being conducive to quality healthcare. In order to promote the application of SDM in clinical practice, it is necessary to demonstrate its benefits via objective, measurable changes, and one such measure is Decisional Quality (DQ).

Over recent years it has been generally agreed that the quality of a given decision should be evaluated by the decision itself and the decision-making process involved (Elwyn et al. 2006; IPDAS 2003; Sepucha and Fowler 2013; Stacey et al. 2014).

With regards to the decision itself, the extent to which it reflects the preferences of an informed patient and whether it is implemented are the main concerns (Stacey et al. 2014; Coulter and Collins 2011). During the decision-making process there are several considerations: the patient's recognition of the need to make a decision; understanding the benefits and harms associated with all available options; clarity over personal views/values concerning features related to a specific option and discussing these with responsible healthcare professionals; and lastly, involvement in the decision-making process in the individually preferred way (Marteau et al. 2009; Sepucha and Fowler 2013; Stacey et al. 2014). Patient's knowledge about their options, as well as preference over the features related to these options, are therefore of central importance in evaluating DQ (Ratcliff et al. 1999; Sepucha and Fowler 2013). The outcome of a given decision has been deemed non-meaningful as a proxy measure of DQ based on three arguments: firstly, it is impossible to know the ultimate outcome in advance (Baron et al. 1988; Fischhoff 1975); secondly, the outcome may change over time (Elwyn et al. 2008); and finally, the odds around the benefits and harms mean that the desired outcome will not occur 100% of the time (Edwards and Elwyn 2006).

Whilst there is a broad consensus on what conceptual variables need to be measured when evaluating DQ, pragmatic issues concerning the actual measurement of these concepts have been raised by academics in the field of SDM research. With regards to the measurement of knowledge required for making a given decision, it is difficult to determine the specific dimensions to be measured, e.g. nature (medical vs. lifestyle) and attributes (short vs. long term) at the outset, and it is also difficult to determine the optimal level of knowledge needed to be acquired by patients for making that decision (Elwyn et al. 2009). Furthermore, the varying time-decay impact on information retention by individuals means it is hard to determine the best timing of knowledge measurement (Edwards and Elwyn 2006). The measurement of preference is complicated by the interchangeability between the terms 'preference' and 'values'. According to expected utility theory and its variants, values can be scaled between 0 and 1 in order to reflect a patient's overall assessment of different options with their attached likely outcomes (Thomson 2008); however, as evident from the literature, value is also understood as a patient's broader attitude towards healthcare decision-making in general, such as risk

aversion in the case of avoiding taking a medication due to its side-effects (Elwyn et al. 2009).

Another recently developed concept which is closely related to DQ is the decision readiness of a patient, which refers to 'the extent to which the patient understands the options available to them and feels ready to choose' (Shared Decision Making Programme 2012 p. 19). The degree of this readiness is indicated by the level of patients' perceived support from the responsible healthcare team and in deliberating between the options and making a choice. It is also indicated by the time available to patients to comprehend the options, and the appropriateness in the timing of the introduction of DS intervention (Coulter and Collins 2011).

1.2.7 Measurement Tools for Decisional Quality

Whilst there are recognised challenges in measuring decisional quality as outlined above, there has been an explosion in the development decisional quality measurement tools, although many are still awaiting wider, rigorous validation and cover only a limited number of the dimensions that define DQ (Scholl et al. 2012; Simon et al. 2007). Among these tools, the decisional conflict scale (DCS) is regarded as the most widely validated and multi-faceted (Stacey et al. 2014). This measures how informed, value-based and satisfactory a choice is, and its likelihood to be implemented from a patient's perspective (O'Connor 1997). The DCS is also aimed at eliciting patient's self-reported level of decision-specific knowledge, records degree of clarity concerning benefits and risks, together with the uncertainty around the decision and the support received. In clinical practice it can be difficult to fit the 16-item long DCS into routine clinical work. A shorter adaption of the DCS, the SURE scale (4-items long), has been created and has undergone limited validation (Legare et al. 2010). However, as with the DCS, the SURE scale does not measure the concordance between patients' values and their chosen choice (O'Connor 1997; Legare et al. 2010).

Whilst the DCS offers an attractive prospect for evaluating the DQ in a range of clinical contexts via a single standard, generic measure, some authors, such as Sepucha and Fowler (2013) have advocated a decision-specific approach for DQ evaluation. The main criticisms regarding DCS and SURE are concerned with the

ability of these measurement tools to capture a patient's actual level of decision-specific knowledge (Sepucha et al. 2010). In response, a small number of 'decisional quality instruments' (DQIs) have been developed and validated for a limited range of healthcare decisions. In the UK, the Making Good Decisions in Collaboration (MAGIC) Programme and the independent charity which funded MAGIC, The Health Foundation, have been driving the implementation of SDM in clinical practice. The MAGIC Team has adapted a number of DQIs into 'decisional quality measures' (DQMs), which have been piloted but their wider validation is still awaited (Shared Decision Making Programme 2012). DQIs are generally longer in length compared to the DCS, which may render them even less practical for use in the daily clinical context.

With considering patients' preference for involvement in the decision-making process, it has been demonstrated that younger people, patients from a higher socio-economic class, and females tend to prefer a more active role in decision making (Say et al. 2006). Another factor which needs to be recognised when considering the use of DS is that when patients face a more serious diagnosis, e.g. cancer, when they are in the more advanced stages of a disease, and where evidence on the most effective management option is inconclusive, the reported control over decision-making by patients tends to be reduced (Keating et al. 2010; Say et al. 2006). However, counterarguments to cancer patients' involvement in decision-making have been offered by other studies, where many cancer patients reported not being involved enough in the decision-making process (Tariman et al. 2010; Singh et al. 2010). From the perspective of a small group of Australian oncology clinicians, most felt that it was important to invest time in explaining a condition and the treatment options to patients, irrespective of their education or comprehension ability; furthermore, uncertainty over the relative effectiveness of treatment options, their far-reaching impact on quality of life, and the higher level of public awareness regarding the condition, together with a more advanced disease stage were reportedly motivators for these clinicians to involve their patients more (Shepherd et al. 2010).

1.2.8 Benefits of Patient Decision Aids

Leaving the developmental issues surrounding DS and the measurement of decisional quality aside, there is compelling evidence to demonstrate the effectiveness of PDAs in improving decisional quality. With the third update of the Cochrane Review 'Decision aids for people facing health treatment or screening decisions', the positive impact of PDAs on DQ across a wide range of healthcare contexts have persisted and been further strengthened by newly assessed evidence (Stacey et al. 2014). This impact was found to be particularly pronounced in the context of preference-sensitive decision-making. PDAs were shown to significantly improve decision-specific knowledge, accuracy of knowledge of the odds of particular outcomes, and congruence between the chosen option and the patients' preferences/values for option-features and outcomes. There was also a significant increase in the proportion of value-/preference-congruent choices being made with the use of PDAs. Furthermore, the introduction of PDAs into practice has led to significant reductions in the degree of decisional conflict and an increase in the number of patients who were feeling more informed and involved in the decision-making process.

However, the use of PDAs exerted little effect on overall satisfaction about the decision-making process. This may be explained by the pre-existing high level of satisfaction with usual care, i.e. without the use of PDAs, and the psychological comfort which patients derive from declaring being satisfied with their choices (Gruppen 1994; Stacey et al. 2014). Another area in which PDA use achieved only a modest improvement were generic health outcomes, although this can be attributed to the fact that most of the conditions studied were those with no one clearly advantageous management option, and patients might experience the outcomes which they prefer (Stacey et al. 2014). Any effect of SDM and DS on adherence to treatment choice and any health economic benefits remain unknown. Patients who were exposed to PDAs were less inclined to choose invasive treatments/surgery (Stacey et al. 2014), which has also been reported as the conclusion from individual studies (Mulley et al. 2012). Common to all systematic reviews, the interpretation of the results and the strength of the conclusions drawn should be treated with caution due to three main factors: firstly, the variability in the quality of the studies included

(measured by risk of bias score); secondly, the heterogeneity in the clinical contexts covered; and lastly, the diverse measurement tools and outcomes adopted by individual studies. In addition to the Cochrane Review, the positive effects of increased knowledge and reduced decisional conflict are also apparent from the findings of another systematic review where controlled studies of PDAs for a range of preference sensitive surgical decisions were evaluated (Knops 2013 et al.).

Like many other healthcare systems worldwide with a finite budget, the National Health Service (NHS) is constantly under financial pressure as health costs and population needs rise. A £20 billion shortfall by 2014 has been projected (Mulley et al. 2012), although a potential solution to this was proposed over a decade ago in the Wanless report (Wanless et al. 2002). This report suggested that by maximising patient engagement and improving adherence to evidence-based clinical guidelines, the two elements of SDM, it would be possible to make an estimated annual saving of £30 billion.

1.2.9 Decision Support for Making Decisions Related to Urological Conditions

The Cochrane review discussed above offers a partial insight into the effectiveness of PDAs concerning urological conditions, as a small number of relevant studies from this specific area of medicine were included. PDAs related to urology mainly focused on the availability of preference-sensitive treatment options for two conditions, benign prostatic enlargement (BPE) and prostate cancer. For BPE, the main management options are watchful waiting, medication and surgery (Reynard et al. 2013), while for prostate cancer the options available to a patient depend on the stage of disease and co-morbidities (EAU Guidelines 2013). Management modalities for early, localised prostate cancer include watchful waiting, radiotherapy, brachytherapy and radical surgery to remove the prostate in its entirety (Reynard et al. 2013).

The effectiveness of a number PDAs designed to help patients in the choice of treatment for BPE and prostate cancer have been evaluated in both randomised controlled trials (RCTs) and observational studies. In the Cochrane Review two

RCTs on two different PDAs for BPE were included, and both trials reported improvements in DQ after the use of PDAs, particularly in the dimensions concerning knowledge and patient-reported satisfaction with the decision-making process (Barry et al. 1997; Murray et al. 2001). The trial conducted by Barry and colleagues (1997) also demonstrated a significant decrease in decisional conflict scores, although the follow-up measurement time frame was relatively short at nine months. The influences on general health perceptions, physical functioning, anxiety, general health status, utility and costs were deemed negligible with the use of PDAs. In addition to these RCTs, the results of a number of non-randomised observational studies have added to the evidence that PDAs for BPE enhance DQ. The amount and quality of knowledge were generally rated highly by patients, and those who attained lower educational levels in particular found that the information provided was clear, but also too much in amount for them (Barry et al. 1997). The use of a PDA resulted in a near 40% decrease in the number of men choosing surgery (Wagner et al. 1995). Knowledge scores and satisfaction with the decision-making process were also higher (Piercy et al. 1999, Rovner et al. 2004), and over two thirds of those who were originally undecided about which treatment to choose were able to decide after using the PDA (Piercy et al. 1999).

For localised prostate cancer the trend that PDAs are helpful in promoting DQ continues to hold true. A systematic review demonstrated that PDAs significantly improved self-reported knowledge was demonstrated across eight out of the ten non-randomised trials included (Lin et al. 2009). In terms of patient involvement in decision-making, there was an overall trend that patients assumed a more active role after exposure to PDAs. In addition, in a few of the selected studies there was also a modest decrease in decisional conflict, as well as in anxiety and distress. The effect on treatment choice remained unclear, but there was a worrying finding in a study by Kim (1999) that patients who had used PDAs prior to consultation in the end received a treatment which differed from their prior stated preference. Lin et al. (2009) postulated that this could be due to either the clinicians' influence during the consultation which changed the patients mind, or the patients' preferences were not being taken into account by the clinicians. As with the Cochrane Review (Stacey et al. 2014), the inherent problems concerning the interpretation of the results and the conclusions in Lin's review stemmed from the general lack of quality among the

studies' methodologies, as well as the heterogeneity of the outcome measures which made a meta-analysis impossible.

The ways in which DS is delivered also seems to have an impact on patient's decision-making. An interdisciplinary approach using two specialists who can provide expert opinions regarding certain options (e.g. a urologist and a radiotherapist for localised prostate cancer) jointly holding a consultation with a patient has been demonstrated to improve a patient's subjective knowledge and to achieve high level of patient satisfaction with the consultation process; however, this approach is time consuming and this would have implications on the daily clinical workflow and costs (Schostak et al. 2004). Another way to deliver DS is to provide decision-specific knowledge via video, and whilst this would not necessarily save consultation time, the discussion regarding treatment options could be taken to a more sophisticated level, where trade-offs of risks and benefits become the focus of discussions, rather than descriptions of treatment alternatives by the clinicians to the patients (Flynn et al. 2004; Onel et al. 1998).

A pilot of the implementation of decision aids for localised prostate cancer and benign prostatic enlargement, developed in the US, was carried out in England in 2003. The overall feedback from both staff and patients was very positive, particularly with regards to knowledge acquisition (Archer et al. 2011). However, confusion regarding which options were applicable to the UK raised some concerns, which were addressed through the publication of a revised set of PDAs in 2009 (Coulter and Collins 2011). Subsequently, concerted efforts in developing PDAs for urological conditions have been made by the NHS Shared Decision-making Right Care Programme, with the commercial company Totally Health commissioned in 2012 to develop PDAs for UK NHS patients (NHS SDM Right Care 2014). To date, 36 PDAs have been created, three of which are for urological conditions (lower urinary tract symptoms, localised prostate cancer and bladder cancer) (NHS SDM Right Care 2014), but wider evaluation of the use and benefit of these internet-based PDAs are awaited.

In today's healthcare setting the need for healthcare professionals to work together with patients and others towards the goals of SDM cannot be ignored, particularly in view of the ever-growing number and complexity of healthcare options available,

albeit constrained by the persistent problem of scarce healthcare resources (Légaré et al 2010). Positive outcomes resulting from an inter-professional approach to SDM have been evident although from a limited range of clinical settings (emergency department, diabetes care and mental health care), ranging from increased patient satisfaction with the care received to a reduction in the rate of errors (Reeves et al. 2008). The fundamentals of instigating an inter-professional approach to SDM are broadly concerned with a team's collective will to strive for 'quality' healthcare decisions and team members' willingness to learn from one another whilst being supported by the leadership of the overarching organisation (Légaré et al 2010). However, similar to many other health innovations, the effective implementation of an inter-professional approach to SDM is subject to many barriers, such as the efficiency of team working (e.g. team premises) and an organisation's motivation to drive SDM (Xyrichis and Lowton 2008; Gravel et al 2006).

1.3 Summary

Against the backdrop of political initiatives, changing patient-doctor dynamics, documented geographical variation in healthcare delivery, increasing diversity and complexity of healthcare options, and the understanding that engaging a patient in healthcare decision-making is an ethical imperative, Shared Decision Making is here to stay as a guiding ethos for providing quality healthcare.

The ultimate goal of SDM is enhanced decisional quality, which is a combined function of the quality of the decision-making process and the decision itself. Decision-specific knowledge, as well as congruence between a patient's preferences/values and the chosen option which is also implemented, are the two main dimensions which the quality of a healthcare decision is evaluated upon. PDAs or DS in general have been persistently shown to improve DQ, particularly with regards to these two dimensions. The most pronounced effects have been observed in preference-sensitive healthcare decisions.

The choice central to this thesis, urinary drainage by either an ileal conduit or an orthotopic neobladder in the context of a radical cystectomy is a preference-sensitive healthcare decision. A healthcare choice is deemed preference-sensitive when there are scientific uncertainties over which one is clearly beneficial; the best choice

depends on patients' trade-offs between known benefits and harms. DS facilitates this trade-off process by informing patients with the relevant knowledge, eliciting their preferences and thus encouraging their participation in the preference-sensitive decision-making processes in particular, and ultimately promoting DQ. Given the positive influences of SDM observed in multiple healthcare contexts, an assumption that SDM enhances the DQ concerning urinary diversion in the context of a radical cystectomy can be made, and the quality may be enhanced by exposing patients to relevant DS. However, prior to beginning the construction of DS for this specific decision, it is important to explore if there is any relevant existing DS and their impact on the quality of this decision. A narrative review on existing DS for the decision between conduit and neobladder formation in the context of a radical cystectomy is the focus of the next chapter.

Chapter 2 Patient Decision Support for choosing a Urinary Diversion after Radical Cystectomy: A Narrative Review

2.1 Introduction

Decision support interventions have been the main vehicle for driving Shared Decision Making (SDM) into clinical practice, with Patient Decision Aids (PDAs) as the predominant form of such interventions. The multiple benefits on decisional quality yielded from the use of PDAs are particularly evident for preference-sensitive healthcare decisions (Stacey et al. 2014) – those decisions where there is more than one reasonable healthcare options and trade-offs between the benefits and harms associated with the options are required. Also noteworthy in the context of preference-sensitive decision is that certain features/outcomes are unique to a certain option, thus making the direct comparison among the options difficult, if not inappropriate. The best choice in this instance is the one that best aligns with the preferences and values of a patient, who is informed and making the choice in partnership with the responsible healthcare professionals (The Dartmouth Health Care Atlas 2014). Various parameters have been used in judging decisional quality, some of which are related to the choice made while the others to the decision-making process itself (Stacey et al. 2014; Volk et al. 2013).

As discussed in Chapter 1, certain bladder cancers can be cured with radical cystectomy but this needs to be coupled with a urinary diversion for subsequent alternative urine drainage. Urinary diversion is considered to be an irreversible

procedure and its impact on a patient's life is far-reaching. The two commonly performed urinary diversion procedures are ileal conduit (conduit) and orthotopic neobladder (neobladder) (Hautmann et al. 2013). The main feature that distinguishes conduit from neobladder is the requirement for a urinary stoma (urostomy) – an opening on the abdominal wall through which urine drains. Moreover, currently there is no convincing evidence demonstrating which of these two diversions is superior, in terms of both clinical and quality of life outcomes (Nabi et al. 2009; Somani et al. 2010; Somani et al. 2014). Hence, the decision between conduit and neobladder in the context of radical cystectomy is preference-sensitive. Management of certain bowel conditions, such as rectal cancers and inflammatory bowel disease treatable with surgical bowel removal (bowel resection) and low grade colonic dysplasia, can also involve preference-sensitive decisions. These decisions again lie between options involving permanent bowel stoma (ileostomy and colostomy) formation and those which do not (Siegel 2013; Wu et al 2014). The bearer of a stoma, may that be for drainage of urine or bowel contents, wears a device placed over it and the device is required to be changed regularly (Urostomy Association 2014; Colostomy Association 2014; The Ileostomy and Internal Pouch Support Group 2014).

It could therefore be hypothesised that the use of decision support interventions (including PDAs) improved the quality of a decision between stoma and non-stoma forming management options, for bladder cancer treated with radical cystectomy, and for rectal cancer, low grade colonic dysplasia and inflammatory bowel disease treated by bowel resection. However, before embarking on building decision support interventions for the stated choices, it is prudent to explore the current availability of relevant decision support and evaluate their influences on the choices and corresponding choice-making processes; this would in turn inform on whether construction of an entirely new support intervention or modification of existing support interventions would be required. This notion leads to the objective of this review, which is to identify decision support available and evaluate their impact on the decisional quality for the choice between stoma and non-stoma forming management options, in the following conditions:

- Bladder cancer treated with radical cystectomy
- Rectal cancer treatable with bowel resection

- Low grade colonic dysplasia treatable with bowel resection
- Inflammatory bowel disease treatable with bowel resection

2.2 Methods

All primary research studies (quantitative, qualitative or mixed method) which described and/or compared the use of a decision support intervention (including PDA) to no intervention, usual care, alternative support interventions or a combination, in deciding between stoma and non-stoma forming management options in the conditions stated above, were considered. At least one of the following parameters must be compared:

Attributes of choice made:

- Knowledge
- Accuracy of risk perception
- Congruence between choice made and personal preferences and/or values

Attributes of decision making process:

- Recognition for the need to make a decision
- Knowing the options and their features
- Understanding that personal preferences/values can influence the decision
- Clarity over the option features that personally matter most
- Discussion of preferences/values with the responsible healthcare professionals
- Being involved in the decision making process in the preferred ways

Other Attributes:

- Decisional conflict
- Patient-Healthcare professional communication

- Level of participation in decision making process
- Proportion of undecided
- Patient satisfaction with decision made and/or decision making process
- Behaviour
- Chosen option being implemented
- Health status and quality of life (generic and condition-specific)
- Anxiety, depression, emotional distress, regret, confidence
- Costs, cost effectiveness
- Consultation length
- Litigation rates

2.2.1 Information sources

The search strategy included searching in:

- Electronic databases of OVID MEDLINE (R) and Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Years 1946 - December 2010; EMBASE, Years 1974 – December 2010; all EBM Reviews including Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED, Years 1991 – December 2010; CAB Abstracts, Years 1910 – December 2010; HMIC Health Management Information Consortium, Years 1979 - June 2014; PsycINFO, Years 1806 – December 2010; EBSCO 1982 – December 2010.
- Internet websites of Bandolier; the A to Z inventory of Patient Decision Aids hosted by Ottawa Hospital Research Institute; Patient Decision Aid Library hosted by Dartmouth-Hitchcock Medical Centre; NHS Shared Decision Making
- Personal e-mail enquiries to the academic communities at Dartmouth-Hitchcock Medical Centre, US and School of Medicine, Cardiff University, UK

The detailed search strategy including search terms is presented in Appendix 1.

Studies were limited to English language only.

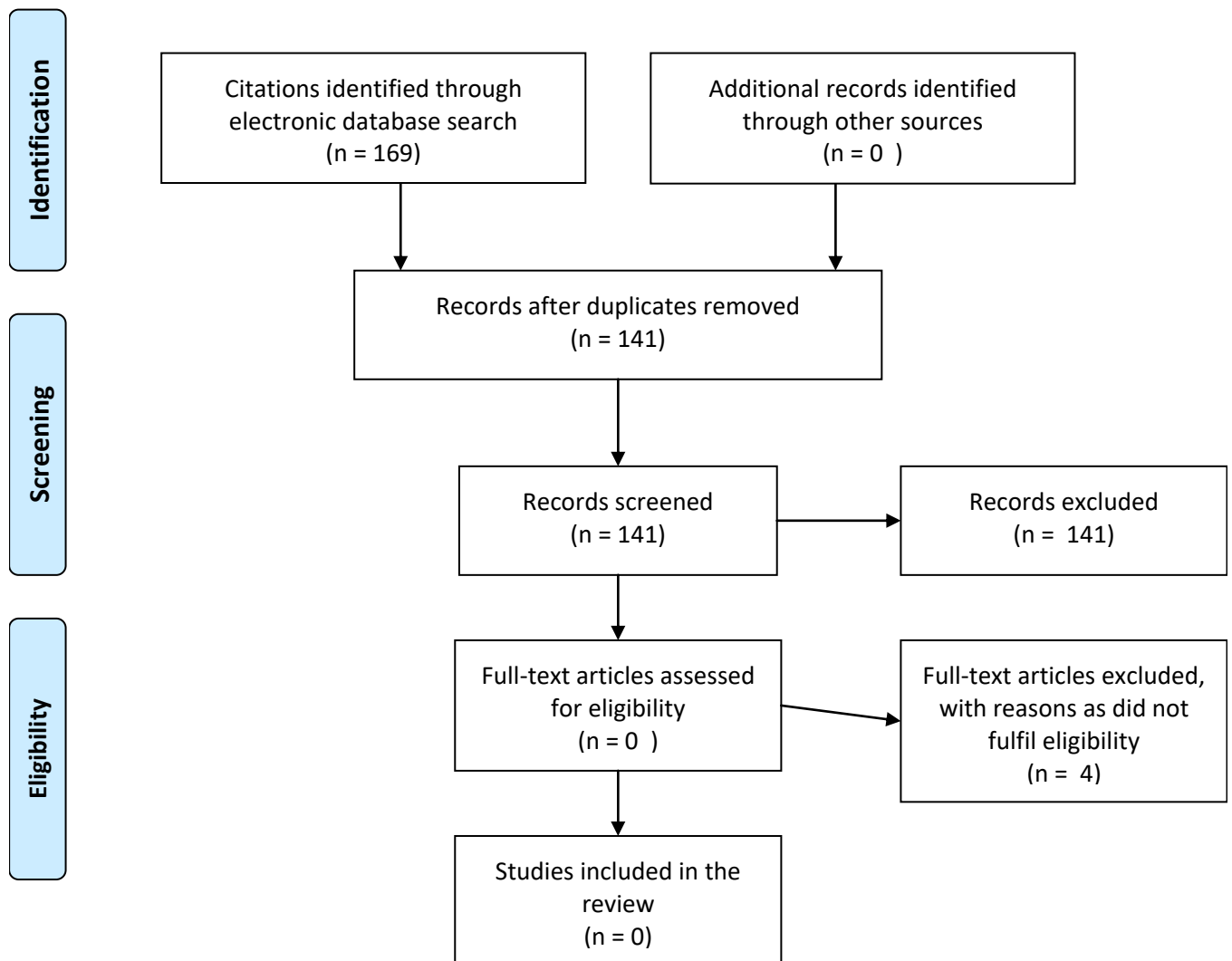
2.2.2 Data collection, appraisal and presentation

The author of this thesis was solely responsible for screening the identified abstracts for their eligibility and quality assessment of included studies. The full texts of included studies were then retrieved by the author. The author was also solely responsible for extracting and critique of the relevant data from individual included studies. The relevant data was that related to any of the parameters of comparison stated above, and was presented under the three headings of 'attributes of choice made', 'attributes of decision making process' and 'other attributes'.

2.3 Results

The searches returned 169 abstracts from electronic databases, and 141 remained for screening after removal of duplicates. However, after screening none were deemed eligible for inclusion. Personal e-mail enquiries yielded no positive responses and scanning of internet websites including their integrated search functions also did not yield any eligible studies. The reason for exclusion was focus on colorectal cancer screening and other decisions which were not relevant to stoma formation, in the management of the target conditions mentioned.

Figure 2.1 Study inclusion and exclusion for review



2.4 Discussion

At the time of the search there was a clear lack of decision support available for making the decision between stoma and non-stoma forming treatment options after cystectomy or bowel resection. An updated search had been performed between December 2010 and June 2014 including browsing of internet websites mentioned, two PDAs relevant to the stated decision for rectal cancer (Patient Decision Aids, NHS Right Care 2014; Wu et al. 2014) and a further PDA relevant to bladder cancer management were identified (Patient Decision Aids, NHS Right Care 2014). Both NHS PDAs were developed in the UK healthcare context, by the British Medical Journal group in conjunction with UK based advisory groups consisting of:

healthcare professionals, patients, the relevant charities and patient support groups, and health policy makers. The exact methodology and methods used for developing these two PDAs were unclear. Moreover, the main decision concerned with the NHS Bladder Cancer PDA was between radical cystectomy and other bladder preserving treatment strategies, rather than between conduit and neobladder in the context of urinary diversion after radical cystectomy; the two diversion options were described, but decision-specific information such as probabilities of the benefits and harms associated with these diversions were not covered, nor was there any mechanisms eliciting patient's preferences and values for this decision. On the other hand, the NHS Rectal Cancer PDA did provide some decision-specific information with risk and benefit probabilities, related to choosing between surgery which would result in permanent bowel stoma and other treatment strategies which would preserve bowel continuity, both medical and surgical. There remains the debate on how best to deliver PDAs and uptake of web-based PDAs varies across different decision settings and decision-making populations (Hoffman et al. 2013). Using computer/web-based PDAs with the healthcare professionals during consultations had been trialled, with varying responses from the healthcare professionals. Some viewed the use of such material hindered their daily work flow (Jimbo et al. 2013).

The rectal cancer PDA mentioned in the article by Wu et al. (2014) was developed in the Canadian healthcare context and in contrast to the UK (NHS) prototype, the guiding, validated framework for its development was explicit (Ottawa Decision Support Framework); also, the decision which it was concerned with was narrowed to between permanent bowel stoma formation (abdominal perineal resection procedure) and surgery which preserved bowel continuity (low anterior resection). This PDA was available in both paper and web-based formats.

The three PDAs described pose as a promising step forward in introducing SDM principles for decisions between stoma and non-stoma treatment options, but their impact on the corresponding decisional quality is yet to be evaluated.

2.4.1 Critique of papers that were deemed ineligible but did contain some relevant information

During screening for eligible articles, there were a small number of primary research studies (n = 4) which had raised a number of issues pertinent to quality of the decisions to be studied in the review, even though there was no use of decision support reported. Summarised findings of these studies are set out in Table 2.1.

2.4.1.2 Knowledge gaps

Overall, there were definite knowledge gaps between patients and their healthcare professionals, as reported the patients themselves. In Fitch's in-depth interview study (Fitch et al. 2010), a group of 22 patients treated with radical cystectomy for bladder cancer reported their desire for more information on bladder cancer, together with clearer and more consistent treatment plans both given in a timely manner. They also regarded additional information related to their condition and treatment other than that directly provided by their responsible clinical team as important, but many felt the task of searching for such information was 'left up to them' and expressed their need for more assistance. A semi-structured interview study involving colorectal cancer patients treated with surgery with/without resultant stoma and their spouses, found that 50% only half of the couples interviewed were satisfied with the amount of information provided by their health providers before their surgery (Northouse et al. 1999); the reported shortfalls in knowledge delivery were in the areas of treatment process, possible side effects, discharge arrangements and colostomy care, information on pain relief and support groups. Similarly, in Persson's questionnaire study (Persson et al. 2005), nearly half of each of the studied patient groups living with ileostomy or colostomy wanted more information before surgery concerning the surgical procedure itself and its outcomes, as well as medical examination and test results and dietary-requirements following surgery.

Cultural issues implicated in treatment information delivery were highlighted in Bakhta's questionnaire study involving people from the UK and India (Bakhta et al. 1992). They found only half of the specialist stoma nurses in the UK had experience in working with Asian patients, with around a quarter of them with no access to a translator. Also only half of the UK Asian patients discussed their management with a clinician in the same language. In India, despite limitations of literacy and the diversity of local dialects, 58% of the surgeons reported providing their patients with

written information leaflets, as an adjunct to their joint counselling of patients with nurses or stoma care therapists.

2.4.1.2 Participation decision making process and other issues

In Persson's study (2005), there was patient-reported involvement in decision making relating to stoma formation, the patients felt they were not sufficiently involved in the decision making process and 52% of them felt they were not provided the opportunities to discuss their sexual issues, home circumstances and overall happiness (Persson et al. 2005); however, from the reporting of the study, it was unclear whether the patients were referring to discussion opportunities before or after surgery, or both.

In terms of methodological issues related to the two studies with mixed/quantitative design neither studies (Persson et al. 2005; Bakhta et al. 1992) detailed a sample size calculation and therefore the degree of power could not be assessed. With regards to the use of research tool, only Persson's study used a validated questionnaire, whilst the development and validation of the questionnaire employed in Bakhta's study were unclear and therefore, its validity was questionable.

Nonetheless, these studies did serve to highlight the gaps in knowledge provision to patients in the process of treatment decision making. These gaps lie in the amount and depth of information about patients' own conditions and their treatment options.

Even though Persson's study did not specifically set out to measure patient involvement in decision making, and indeed, from the reporting it was difficult to decipher what the decision was about, it points out that there was some degree of dissatisfaction among patients regarding their level of involvement in their care.

Bakhta's study (Bakhta et al. 1992) on the other hand, reminded healthcare professionals the importance of not discounting the ethnic and cultural diversity in patient pool and the cultural and language barriers implicated in counselling. As pointed out by Rapley et al (Rapley 2008), decision making is a process which is distributed in time, space and people, and patient's significant others could play a central role in the process. Additionally the significance of spouse in the process of receiving cancer diagnosis and deliberation over treatment options was reflected by Northouse's study (Northouse et al. 1999).

2.5 Conclusions

The decision making process of choosing stoma versus non-stoma forming treatment options in bladder cancer treated with cystectomy, and rectal cancer, low grade colonic dysplasia and inflammatory bowel disease treated by bowel resection is not well understood. The impact of the differing surgical options for these conditions is far reaching and given the scientific uncertainties surrounding their relative outcomes, it is difficult for patients and their health advisors to come to a decision well-aligned to preferences and values. A basic requirement for the patient to make a quality choice is to be sufficiently informed and involved in the decision making process. Decision support, particularly in the form of PDAs, has been demonstrated to improve the quality of decision, particularly when the decision is preference-sensitive, as is the case for stoma/non-stoma urinary and faecal diversion options. To date, decision support/PDA for the decision central to this thesis, which is to select between conduit and neobladder for patients requiring urinary diversion after radical cystectomy is not yet available. This indicates the urgent need to build such a support; however, construction of the support needs to be guided by an understanding of the current decision making process, including what patients and clinicians consider when facing the choice; in this way, the contents of the support are much more likely to be relevant; moreover, likely barriers as well as facilitators to the decision making process may also be identified and in turn, this may inform effective delivery of the subsequent constructed support.

This chapter and the previous one have established that little is known about the process involved in making the preference-sensitive decision of urinary diversion in the context of radical cystectomy. The thesis' author was a UK based clinician in Urology and considered understanding of this decision making process based on the Ottawa Decision Support Framework and potential subsequent construction of formal decision support would benefit much for her patients, hence conducted the research work embodied in this thesis. As in the previous chapter, there are a number of decisional needs under the framework and the author intended to focus on knowledge and expectations, values and support and resources for the decision of urinary diversion after radical cystectomy. The author was also aware that the

findings of her research query into the decision making process would not be necessarily be transferrable to another healthcare system for various reasons such as different funding arrangements, governance structure and legislations, work cultures as well as clinicians' and patients' characteristics. The aim and objectives of the body of research in this thesis are as stated in the next section.

2.6 Aim and Objectives

2.6.1 Aim of Research

'To understand the decision making process concerning urinary diversion after radical cystectomy in the UK, in order to improve the process in the future'

2.6.2 Objectives of Research

The author employed mixed methodology and methods (detailed discussions on which are in the next chapter) in order to achieve the specific objectives below. The research query itself encompassed three components: **1) Analysis of the joint Southwest Public Health Observatory-British Association of Urological Surgeons (SWPHO-BAUS) 2) Needs Assessment Questionnaire Surveys of patients and clinicians and 3) Qualitative Semi-structured Interviews with patients and clinicians.**

- ***To describe the variation of neobladder use in the UK***
 - **with analysis of the joint Southwest Public Health Observatory-British Association of Urological Surgeons (SWPHO-BAUS) Cystectomy Dataset Analysis**

- ***To gain insights into the decisional needs for choosing urinary diversion after radical cystectomy in the UK***
 - **with Needs Assessment Questionnaire Survey of Patients and Clinicians AND Semi-structured Qualitative Interviews with Patients and Clinicians**

- **To understand the aspects taken into account by patients in the UK when they were choosing a method of urinary diversion after radical cystectomy**
 - **With Semi-structured Qualitative Interviews with Patients and Clinicians**

Table 2.1 Detailed descriptions of relevant but ineligible studies retrieved from the literature search

Study	Study Population	Study Design & Method(s)	Outcomes	Results
<p>Fitch M I et al. 2010 (Canada)</p>	<p>Patients (n=22) who underwent radical cystectomy for bladder cancer, with ileal conduit (n=9) or orthotopic neobladder (n=13)</p> <p>Focus group: interviewees involved (n=6)</p>	<p>Qualitative semi-structured, face-to-face interviews and focus group discussion</p>	<p>Post-surgery experiences of radical cystectomy patients</p>	<p>Themes</p> <ol style="list-style-type: none"> 1. Emotional shock at diagnosis of bladder cancer, with a sense of losing control and death being a close reality 2. Desire for open communication, and clear information on bladder cancer and treatment plans given in a consistent and timely manner. 3. Search for additional information was important, but many felt the task was 'left up to them'. 4. Support from family and friends was important 5. Location of home and the availability of local healthcare support together with unexpected emotional stress led to dissatisfaction with level of home care support. 6. Dealing with incontinence or leakage was problematic for some patients. Some

<p>Fitch M I et al. 2010 (Canada) (cont'd)</p>				<p>patients had not acquired any knowledge regarding incontinence prior to surgery and how to deal with it after surgery.</p> <ol style="list-style-type: none"> 7. All experienced change in body image and function, but more pronounced among younger patients and conduit patients. 8. Older age increased acceptance about changed sexual functions and relationships. The value of intimacy was reportedly to be improved through the cancer experience. 9. Changes in life perspectives and shifts in priorities were reported by all 10. Patients would like healthcare professionals to focus more on understanding the experiences the patient undergo.
<p>Northouse et al. 1999 (US)</p>	<p>Convenience sample of patients with colon cancer treated surgically (with/without colostomy) and their spouses (n=30).</p>	<p>Mixed quantitative and qualitative. Structured interviews. Patients and their spouses were interviewed separately, face-to-face.</p>	<ol style="list-style-type: none"> 1. Impact of cancer diagnosis 2. Changes in lifestyle after cancer diagnosis 3. The greatest concerns after the diagnosis of 	<ol style="list-style-type: none"> 1. Patients: Almost half (47%) described negative feelings when told of the diagnosis with 37% reporting more positive feelings. Spouses: A greater proportion were more negative about the diagnosis. 2. Patients: More than half of the patients (57%) changed their functional ability especially regarding their own daily care and

<p>Northouse et al. 1999 (US) (cont'd)</p>			<p>cancer</p> <p>4. Reactions to living with a colostomy</p> <p>Information need at the time of the diagnosis</p>	<p>symptoms. Around a third (30%) of the patients reported an increase in health-related activities such as travelling to medical appointments and taking more medications. Twenty percent of patients experienced reduced level of social activities such as time with friends, partly due to symptoms they were experiencing. Another 20% of patients reported a change in their roles and relationships, such as compromised ability to work and to perform certain tasks within the homes. Spouses: Reported being in a caregiver role more often and to take on more household responsibilities. Also experienced increased health related activities including travelling to medical appointments, and alteration of diet plans. Fewer spouses reported changes in their own functional ability and social activities (17% and 13% respectively).</p> <p>3. Patients: Greatest concerns were cancer recurrence, ability to deal with adverse effects of illness and treatment. More likely to have concerns regarding quality of life issues. Spouses: Greatest concerns also</p>
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<p>Northouse et al. 1999 (US) (cont'd)</p>				<p>around cancer recurrence and unwanted effects. Less concern regarding changes in quality of life. Some expressed concern to maintain their own health so that they would be able to assist the patient.</p> <p>4. Patients: Half reported negative feelings towards their colostomy, whilst the other half described their colostomy in positive terms. The great majority (92%) felt that they were able to care for colostomy independently. Spouses: The majority of (75%) were positive about colostomy; 42% reported direct caring for patients' colostomy.</p> <p>5. Patients: About half were satisfied with the amount of information provided with the gaps being information on treatment process and possible side effects. A greater proportion wanted specific information on discharge arrangements and colostomy care. Spouses: Again half were happy overall but particularly felt the need for more information on the</p> <p>6. Overall, patients and spouses felt that clinicians could help with their illness by providing them more information in general,</p>
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				<p>and in preparation for colostomy. Promotion of rest, relaxation and pain relief, increase in co-ordination among clinicians and offer of support groups were also mentioned by both patients and spouses.</p>
<p>Persson et al. 2005 (Sweden)</p>	<p>Patients who had undergone ileostomy for ulcerative colitis and those who underwent colostomy formation for colorectal cancer (N=91).</p>	<p>Cross-sectional survey. Self-completed postal questionnaire survey</p>	<p>The quality of care for ostomy patients from a patient perspective, assessed in the following dimensions:</p> <ol style="list-style-type: none"> 1. Information 2. Participation in decision making process 3. Attitudes and treatment 4. Complications 	<ol style="list-style-type: none"> 1. More than 90% of both ileostomy and colostomy patients viewed the information on the surgical procedure, medical examination and test results, the results of the surgical procedure, the responsible doctors and specialist nurses, as well as on special dietary requirement important. However, between 15-45% of colostomy patients and 10-52% of ileostomy patients were not fully satisfied with the information given in these areas. Significantly more ileostomy patients than colostomy patients were dissatisfied with the information on the medical examination and test results related to their illness. 2. Although nearly all the ileostomy and colostomy patients felt that their participation in the decision-making process was important, more than 50% were

<p>Persson et al. 2005 (Sweden) (cont'd)</p>				<p>dissatisfied with the opportunities offered to participate in the decision-making process about their medical and personal care; particularly about the effect on sexual life. Significantly more ileostomy patients viewed that speaking to specialist nurse about sexual matters as important.</p> <p>3. Generally, patients were happy with the attitudes and care given by specialist nurses although they felt that more interest could have been taken in their home situations and their overall happiness.</p> <p>4. The participants were treated for a spectrum of stoma-related complications. Patients without complications tended to be dissatisfied with information on surgical procedure and opportunities to speak with specialist nurses regarding life and health situation whilst those with complications were more dissatisfied with the nurses' understandings of their general situation.</p>
<p>Bhakta et al. 1992 (UK)</p>	<p>Specialist Stoma Care Nurses (N=84 responded); patients</p>	<p>Cross-sectional survey. Self-completed postal questionnaire survey.</p>	<p>1. Experiences of specialist nurses in working with</p>	<p>1. Half of the specialist nurses had experience in working with patients of Asian origin. White British stoma patients appeared to</p>

<p>Bhakta et al. 1992 (UK) (cont'd)</p>	<p>with ileostomy (N=60 responded), and members of the UK general public (N=56 responded) and surgeons who performed ileostomies/colostomies (N=12 responded) in India.</p>		<p>British Asian patients</p> <ol style="list-style-type: none"> 2. Anxieties of White British and British Asian patients with ileostomy before and after surgery, counselling received and subsequent availability of social support 3. Attitudes of White British and Asian employees at seven local companies in Leicester, UK towards gastrointestinal investigations and stoma surgery. 4. Information provision and problems encountered by 	<p>attend review clinic three times more frequently than those of Asian racial origin. Three quarters of the specialist nurses had access to a translator with 28% having the view that Asian patients needed an Asian specialist nurse and 31% considered that Asians preferred a specialist nurse of the same gender. Half of the specialist nurses believed that Asian stoma patients wished to see a fellow patient before/after surgery and all would aim to discuss stoma siting with regard to preferred clothing prior to surgery.</p> <ol style="list-style-type: none"> 2. Only half of the patients who wished to see a specialist nurse or fellow patients pre-surgery did so and two thirds recalled discussing their stoma site before surgery. Half of the Asian patients reported to have discussed their management with a doctor or nurse in the same language. A similar proportion of both White British and Asian patients felt Asian nurses were needed. Few patients recalled counselling on employment, education matters and marital problems, and both White British and Asian patients reported similar anxieties before and after surgery. Forty-six percent were
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			<p>stoma patients in India as perceived by surgeons working in India.</p>	<p>concerned about the appearance of the mechanics of changing appliances, with the sight of faeces and odour being of lesser concern. Concerns over sexual matters were equally expressed by both groups. A majority (90%) of patients told their family and friends about their stomas.</p> <p>3. From the general public's perspective, Asian respondents were significantly more anxious about radiological procedures and the prospect of stoma surgery such that they would refuse the operation. Many aspects of a stoma (appearance, presence of faeces, possible odour, bag emptying and partner's views) bothered half of the surveyed general public. Asians also raised religion as a concern and many Asians (64%) would like medical advice written in languages other than English.</p> <p>4. Of the surgeons in India surveyed, 58% provided their patients with written information, despite limitations of literacy and local dialects. Counselling was carried out by the surgeons, along with a nurse or stoma therapist. They all covered the nature of the underlying disease, the purpose of the</p>
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				stoma, techniques of changing the appliances, and most covered diet (83%), marital relationships (75%), stoma site (57%) and odour (50%).
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Chapter 3 Methodology and Methods

This chapter is divided into two parts: 'Methodology' and 'Methods'. Methodology discusses some of the philosophical underpinnings of the use of 'Mixed Methods Research' (MMR); following from this is Methods, which describes the procedures employed in the conduct of this research.

3.1 Methodology

Methodology refers to the logic of an overall research approach (Hay 2006; Grix 2002); the methodological approach adopted by a researcher reflects his or her philosophical assumptions about reality and knowledge, and considerations over the potentialities as well as limitations of research methods (Grix 2002). On the other hand, methods, refers to the techniques or procedures used to collate and analyse data (Blaikie 2000).

According to Hay (2002), research consisted of five inter-related 'building blocks', which included ontology, epistemology, methodology, methods and sources; he also asserted that there was a directional flow through these blocks, starting with ontology which 'logically precedes epistemology which logically precedes methodology'. In line with Hay's view, ontology and epistemology are considered in the next section, before proceeding to discussions on other methodological issues pertinent to this research.

3.1.1 *Ontology and Epistemology*

Philosophical assumptions about reality and knowledge have traditionally been discussed under 'Ontology' and 'Epistemology', respectively. Ontology is concerned with the nature of reality and what can be known about it, whereas epistemology is concerned with how to know about reality and the basis of knowledge about reality (Snape and Spencer 2010).

There are two opposing fundamental ontological positions, namely 'Realism' and 'Idealism'. Realism acknowledges an external, stable world reality which exists

independent of human beliefs and understandings; thus there can be a distinction between what the reality is and the meanings or interpretations held by humans. Conversely, idealism contends that there is no external reality which exists separately from human beliefs and understandings; rather reality is constituted through the human mind and socially constructed meanings, and therefore multiple realities can present (Snape and Spencer 2010). In between realism and idealism, there are also a number of less extreme ontological positions such as 'Subtle Realism', which accepts that the external reality does exist but it is only accessible via the human mind and socially constructed meanings (Hammersley 1992); in the context of research, subtle realism encourages researchers to represent that reality rather than obtaining 'the absolute truth' (Mays and Pope 2000).

Within epistemology there are also two polarised fundamental positions, known as 'Positivism' and 'Interpretivism'. Positivism has traditionally been associated with natural sciences and it links with realist assumptions (Green and Thorogood 2005). A positivist regards that even human behaviour and the social world are governed by law-like regularities as seen in the natural world, thus observable and predictable (Snape and Spencer 2010); furthermore, the knowledge gained from a research enquiry is regarded as 'value-free', untainted by emotional, political or other personal viewpoints (Green and Thorogood 2005). In contrast, interpretivism follows from idealism and regards that all research is value bound, as well as time and context specific (Johnson and Onwuegbuzie 2004).

Whilst ontological and epistemological assumptions shape the research questions asked about a particular phenomenon (or reality) studied, the ultimate choice research method(s) should be guided by the questions themselves (Mays and Pope 2000); as Grix (2002) asserted, research methods should be regarded as free from ontological and epistemological assumptions'.

There is another branch of philosophy frequently encountered in debate around reality and knowledge, known as 'Pragmatism'. It is concerned with practical solutions to problems (Patton 1990), and it regards the most important aspect of research being the phenomenon studied and the questions asked about this phenomenon (Rossman and Wilson 1985). There have been many attempts among the pragmatist community in refining the idea of pragmatism; generally speaking,

pragmatism is not committed to any one single system of ontology nor epistemology; it recognises the existence of both the external and the subjective world, and the truth is what works at the time; it also agrees that research always occurs in social, historical, political and other contexts (Cherryholmes 1992; Murphy 1990). When pragmatism is applied in research, it encourages researchers to view different methods as part of their 'research toolkit' choose the most appropriate methods to address specific research questions without being embroiled in the underlying philosophical debates around ontology and epistemology (Seale 1999). The author of this thesis had taken into account the multi-faceted and context-specific nature of the decision making process to be studied and adopted pragmatism in her research query.

3.1.2 Paradigms

In close relationship with ontology and epistemology is 'Paradigm'. As illustrated by Morgan (2007), 'paradigm' can be considered in a number of ways; for instance, it can be considered as a philosophical stance taken by a researcher which provides a basic set of beliefs that guides action, 'a net that contains the researcher's epistemological, ontological and methodological premises' (Denzin and Lincoln 1994); alternatively, it can be treated more broadly as a worldview which encompasses certain beliefs about morals, values and aesthetics. For this thesis the former definition is used, and, and stemming from this there are three research paradigms, namely quantitative, qualitative and mixed methods research (MMR). Of these three paradigms, MMR is the most newly established. Before the more detailed discussion on MMR (the paradigm of choice for this research), it is perhaps useful to consider the other two paradigms.

The quantitative paradigm is rooted in realism and positivism. Quantitative research employs deductive reasoning, is useful in establishing causal relationships and predictors for outcomes; often through hypothesis testing under controlled conditions, prior established theories are challenged; often through statistical sampling a large population can be studied at a time; precise, numerical data is yielded and analysis of which involves the use of statistics; moreover, findings from quantitative research are believed to be objective, generalisable to a wider target

population and are replicable at different times and in different contexts (Johnson and Onwuegbuzie 2004).

In contrast, the qualitative paradigm is founded upon idealism and interpretivism; research with a qualitative orientation is useful when in-depth description and/or understanding of a complex phenomenon are sought; data are collected from usually a smaller, purposive sample of the target population in naturalistic settings; the researcher can empathically understand (i.e. putting oneself into other people's shoes) the phenomenon studied; The data yielded tends to be textual or images and data analysis is an iterative process the pursuit of neutral, time and context-free generalisations is not possible or desirable (Cresswell 2007, Johnson and Onwuegbuzie 2004).

Over the recent years, the MMR paradigm has been gaining popularity in health services research and in the specific field of urological research (Wentzell and Salmerón 2009; Ream et al 2009; Woods et al 2004). MMR is built upon the philosophical foundation of pragmatism and its development can be traced back to the conception and subsequent rejection of 'incompatibility thesis' - a product of the 'paradigm war' that sparked off between the advocates for the quantitative paradigm and those for the qualitative paradigm during the 1980s (Johnson and Christensen 2010). Incompatibility thesis posited that qualitative and quantitative paradigms could not and should not be mixed (Howe 1988). As time moved on, many researchers started to consider the merits of combining the two paradigms which led to the development of the MMR paradigm (Pope and Mays 2009, Lingard et al 2008). One of the broad definitions for the MMR paradigm has been stated as:

'...research in which the investigator collects and analyses data, integrates the findings, draws inferences using both qualitative and quantitative approaches or methods in a single study or program of inquiry' (Tashakkori and Cresswell 2007)

Further to the above definition, integration may also take place at design and sampling (Pope and Mays 2009); as for integration of findings, it can occur at analysis or interpretation (O'Cathain 2010).

A key merit of the MMR paradigm is that researchers can select from the full range of research methods, the most appropriate ones to answer their research questions.

There is room for a wider range of research questions to be answered, and hence a broader perspective of a phenomenon can be gained. (Ligard et al 2008; Cresswell and Plano Clark 2007). Nonetheless, the MMR paradigm does not equate to 'anything would go together'; instead, it requires the researcher to thoughtfully combine various research methods, so that the complementary strengths and non-overlapping weakness of such can present in the resultant combination (Johnson and Turner 2003). The need for improvement in the design and findings integration in mixed methods research studies has been raised as a concern (O'Cathain et al 2008).

3.1.3 Considerations in designing mixed methods research

The design of a mixed methods research starts with a consideration to the numerous purposes of conducting MMR, and the ones which are commonly cited include: triangulation, complementarity, initiation, development and expansion (Greene et al 1989; Azorín and Cameron 2010).

Triangulation is usually used to describe the process of studying a phenomenon from different 'angles' using different methods to gain a more complete picture, or less commonly used to describe the corroboration between or convergence of findings from two datasets (O'Cathain 2010); complementarity means seeking elaboration and clarification of the results from one method with that from the other; in a developmental MMR study, the researcher uses the results from one method to inform the development of the use of the other); initiation means discovering paradoxes and contradictions that which helps reframing the original research questions; and a MMR study with a purpose of expansion seeks to extend the breadth and range of research by using different methods for different inquiry components (Greene et al. 1989).

The timing of and priority given to quantitative and qualitative studies within a MMR are largely dependent on the purpose of conducting MMR and research objectives, but are also influenced by both the anticipated and actually encountered practical constraints during the conduct of research (Morse 1991, Cresswell et al 2011). Integrating data from the different components at some point within a MMR is required, and this often happens at the interpretation stage, when analyses of

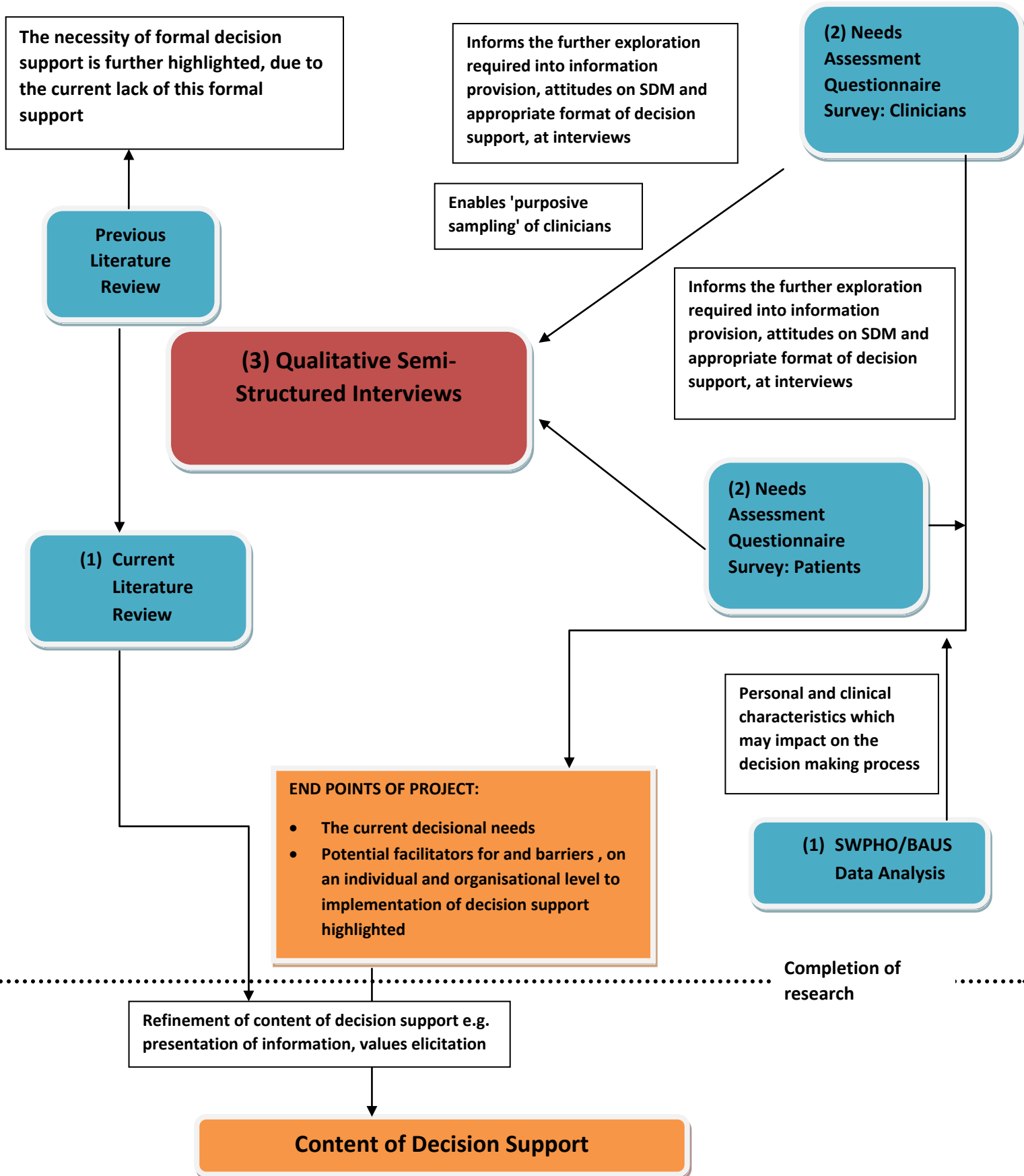
different datasets are completed (O'Cathain 2010). Some mixed methodologists emphasised the need to consider whether findings agree or disagree with one another, or offer complimentary information on a common issue (Farmer et al 2006; Foster 1997; Erzergerger and Prein 1997).

3.1.4 Use of mixed methods research approach for this research

Before considering the support required and how to deliver such to future British patients when deciding between the two main urinary diversion options after radical cystectomy, for the author it was of prime importance to understand how this decision was made within the contemporary UK. The decision making process for urinary diversion after radical cystectomy embedded in the nation's current healthcare, social and cultural settings thus became the phenomenon central to this research. This process was complex and little was known about it. The author aimed to obtain a broad understanding of this process and raised a range of questions of varying intentions, which were translated into the stated objectives for this research.

As a pragmatist, the author focussed on the research objectives and how best to address them. Some of these objectives were better addressed by quantitative research methods whilst the others by the methods from the qualitative paradigm. By adopting the MMR approach, the author would be able to use the methods deemed most appropriate for the research needs and gain a more comprehensive picture of the phenomenon of interest; quantitative methods could not offer detailed accounts of patients and clinicians experiences in the decision making process and therefore when used alone, an in-depth understanding how the decision was made would be lacking; on the other hand, if only qualitative methods were used, the author would be unlikely to yield population-based experiences of and opinions on the decision making process. Triangulation and expansion were the main reasons for the use of MMR approach in this research, and therefore the timing of its quantitative and qualitative components was of less relevance. However, there was some degree inter-dependency among these components; **the planned timing (order denoted by**

numbers) and interactions of the various components encompassed in this research was as below:



As illustrated in the 'Methods' section, sampling of a group of clinicians relied on the needs assessment questionnaire survey with clinicians, moreover, the quantitative and qualitative components were also intended to cross-inform one another on certain issues relevant to the phenomenon studied. Integration of findings took place at interpretation, after the quantitative and qualitative components were analysed. However, in reality the pragmatics of the conduct for various research components i.e. ethics and organisation approvals were not obtained according to plan and therefore, the planned interactions as illustrated above did not necessarily take place and the implications of such are further discussed in the Chapter 9 (Limitations and Conclusions).

At the outset the thesis' author adopted a pragmatist's stance and acknowledged that to better answer her research questions, a combined use of quantitative and qualitative methods was called for and was less concerned about the reconciliation issues between the two sets of methods. Whilst being an ontological and/or epistemological purist in this thesis' research context would not necessarily be 'hindering the advance of science', as strongly put by some proponents of MR (Östlund et al 2011), certainly the picture of the decision making process concerning this thesis would be less complete.

Various systems exist to typify a piece of mixed methods research based on its design, but these all appear to focus on three main considerations: timing of quantitative and qualitative components, weighting of quantitative and qualitative results and the level of mixing (Cresswell and Plano Clark 2007; Leech and Onwuegbuzie 2007). These considerations, particularly that related to weighting, are inextricably related to the purpose and research questions of the research. The research presented in this thesis was intended to gain a more complete overview on the decision making process concerning urinary diversion after radical cystectomy and in the author's mind, both quantitative and qualitative findings helped understanding of the process and therefore should be given equal weighting.

Considerations which led to the choices of quantitative and qualitative research methods employed in this research are discussed.

3.1.5 Quantitative Inquiry

Quantitative research possesses characteristics which are rather different to that of qualitative research. Some aspects of the decision making process would be better understood at a population level and these would reflect the overall requirements for improving the current decision making process. A quantitative inquiry would suit the purpose of acquiring a population-based understanding of the process, as statistical inferences for the wider target population could be drawn with the (mainly) numerical findings generated from the larger samples studied. In the next subsection, sampling in quantitative inquiry is discussed.

3.1.5.1 Sampling in quantitative inquiry

In contrast to qualitative research which often employs purposive sampling, quantitative research frequently relies on 'probability sampling'. Its pursuit is to draw a statistically representative sample from the wider, target population, i.e. to produce a representative model of the population of interest (Green and Thorogood 2004; Ritchie et al 2010). Each potential study participant may have or not an equal chance of being selected. The former case usually occurs in 'random sampling' whereas the latter in strategies such as 'stratified sampling'. The aim of probability sampling in a particular quantitative study is to produce findings which are generalisable to the wider target population. With regards to sample size determination, the researcher considers the confidence intervals and significance level desired for the study then calculates the appropriate sample size accordingly ('power calculation').

3.1.5.2 Secondary data analysis

The use of secondary data is common in epidemiological and outcomes research (Sørensen et al 1996; Best 1999). The distinction between secondary and primary data is that the former is collected by someone else for other research purposes

(Boslaugh 2007). There are a number of recognised advantages of using secondary data sources; the key one is economy - since data has already been collected, extra time and efforts for data collection are not required; furthermore, the breadth of variables collected, the size and representativeness of sample would not be normally available in studies led by individual researchers, due to limited resources (Best 1999; Smith et al 2007). With regards to the choice of secondary data source, this relates back to identifying the most appropriate source for the particular research questions or needs.

However, as a number of writers have pointed out some obvious disadvantages inherent to use of secondary data source; the data collected are not tailored specifically to the questions which the researcher would like to address and the researcher also has little control over the quality of the data, such as the accuracy and degree of completeness of data registered (Boslaugh 2007; Sørensen et al 1996). In order to circumvent these common issues with secondary data analysis, the author heeded some advice found in the literature (Smith et al 2007) which included asking plausible research questions; paying attention in selecting an appropriate dataset; familiarising with the dataset and structure an analytical strategy which would generate outcomes relevant to this research (Smith et al 2007).

Among the many aspects related the decision making process studied, the variation in the rates of performance of each diversion type in UK, and whether this variation was due to factors other than the clinical ones were of particular interest to the author. In order to address these aspects, the author looked to the joint Southwest Public Health Observatory and British Association of Urological Surgeons (SWPHO-BAUS) Radical Cystectomy Dataset, primarily because it houses a large amount of data across a range of variables of relevance from demographical to clinical e.g. postcodes, age and type of diversion performed. Also, it offered the author the key advantages highlighted above with using a secondary data and it was relatively accessible, through an overall straightforward approval process with SWPHO and BAUS. However, the author was aware that this dataset would be subjected to the anticipated issues with data quality; an additional concern for this dataset was the fact that all data were submitted by the operating urological surgeons and/or local hospital data management, on a voluntary basis. Early on in the process of examining data completeness, it became apparent that case capture (of radical

cystectomy with diversion) was an issue with a number of hospitals. In light of this, the total number of radical cystectomies performed at each hospital in the joint dataset was compared with that registered in the Hospital Episode Statistics (HES) dataset.

3.1.5.3 Questionnaire surveys

As well as understanding the decision making process on a more detailed, individual basis, the author considered it crucial to gain a population-based picture of what the current decision making process would be. To reiterate, the decision making process involved interactions among a network of individuals and them with their environment. The two key groups of individuals in this decision making process would be the clinicians and the patients; it would therefore be vital to learn from each group of their experiences with the current decision making process then determine on how to improve it. This process of assessing the requirements for improving a decision making process in health is also known as a 'needs assessment', and one of the recommended data collection method was questionnaire survey (Jacobsen and O'Connor 2006). Questionnaire survey is generally useful in obtaining objective information about a group of individuals' reported actions, knowledge, attitudes, opinions and specific needs (Boynton and Greenalgh 2004; Crombie and Davies 1996). After being informed by my reading of the 'population needs assessment' development workbook by the Patient Decision Aid Research Group based at the Ottawa Hospital Research Institute (OHRI), the author refined the areas about the current decision making process which the author would like to explore further with the populations of patients and clinicians:

- Satisfaction with information provided on each diversion option (for the patient group only)
- Comprehensiveness of information provided on each diversion option (for the clinician group only)
- Opinion on who else apart from the clinicians would be helpful in the decision making process

- Opinion on the helpfulness of supplementary information materials/resources over and above the verbal counselling provided by the clinicians
- Feelings encountered when faced with two options of urinary diversion (for the patient group only)
- Satisfaction with the perceived level of involvement in the decision making process (for the patient group only)
- Preferred level of involvement of patients in the decision making process (for the clinician only)

It is advisable to use validated questionnaire as it should provide a degree of internal validity, saves time in development and validation and allow comparison with other studies using the same questionnaire (Boynton and Greenalgh 2004); however, at the time of this research there was no pre-existing questionnaire to study the decision making process and therefore two new questionnaires (one for the patients and the other for the clinicians) were constructed; the questions and response items of which were largely based on the OHRI needs assessment workbook (Jacobsen and O'Connor 2006).

When building a new questionnaire, possible biases related to its design should be taken into account. There are many types of bias associated with questionnaire surveys documented in the literature; 'response', 'non-response' and 'selection' biases were of particular concerns to the questionnaire surveys embedded in this research. Response bias concerns whether respondents answer the question in the manner intended, whereas non-response bias occurs when the characteristics of those who do not respond differ significantly to those who responded; selection bias occurs when those invited to participate are not representative of the population of all possible participants (Crombie and Davies 1996; Sedgewick 2011). In order to minimise these biases, the author attended to the sampling for, the design as well as delivery of the questionnaires.

For the patient questionnaire, the author sampled from the original population of the nationwide, prospective Outcomes of Transposed Intestinal Segments (OTIS) study, which evaluated outcomes who underwent cystectomy and urinary diversion for all urological conditions including cancer. The author focussed on the specific cancer

sub-group as it would include those who faced the choice between the two diversion options with radical cystectomy. The author sampled the clinicians for the clinician questionnaire via the relevant professional organisations (BAUS; British Association of Urological Nurses - BAUN; World Council of Enterostomal Therapists UK - WCETUK). The author decided to recruit through these organisations as they would be most likely to provide me with access to the pools of representative clinicians (urological surgeons who performed radical cystectomy and specialist nurses who counselled patients about radical cystectomy and urinary diversions).

Survey participants should ideally be randomly selected (Sedgewick 2011), but feasibility of this sampling strategy needs to be considered in line with the size of target population, time and other resource constraints. An alternative to random sampling is convenience sampling, but as mentioned before results should be interpreted with caution, due to the higher risk of non-response and selection biases. For this research, it could be argued that more statistically powerful and less biased samples could be drawn by randomly sampling patients and clinicians from NHS hospitals which carry out radical cystectomy and urinary diversion, but in doing so the time required would have been prohibitively lengthy and the negotiation process through the different individual local research governance bodies would have been extremely cumbersome.

For both the patient and clinician questionnaires, the author was unable to isolate the patients who had a choice between the two diversion methods and clinicians who were involved in the decision making process at the outset, due to lack of a decision making administrative support. In order to obtain responses from the representative patients and clinicians, the author incorporated an introduction to the questionnaires and some questions which served to identify them (Appendix 2 and 3)

It is generally recognised that question wording and sequencing would impact on response rate and the quality of responses, and that general questions should precede the specific ones (McColl et al 2001). Questions regarding respondents' demographic/professional details were placed near the start in both the patient and clinician questionnaires. Closed questions with pre-set responses can be advantageous as it is less problematic to analyse (Bowling, 2002), and they can be less of a burden to respondents and hence increase response rates (Bowling, 2002).

However, the additional use of free-text boxes gives some degree of freedom for respondents to expand on any uncertainty or ambiguity in responses to closed questions (De Bellefeuille 1992; O'Cathain 2004). In light of these respective advantages of closed and open questions, the questionnaires in this research were largely composed of closed questions with fixed responses, but also supplemented with a few open questions allowing free-text responses

In order to maximise the response rates, the author adopted some of the practices commonly quoted for this purpose: personalisation (inclusion of covering letter/invitation e-mail), use of first class post with stamped return envelopes and reminders.

Mode of administration and delivery also warrant consideration in relation to response rate. There is no current evidence to support the superiority of the self-completion mode over the interview-administered mode, and vice versa. Completion of web-based questionnaire is positively associated with "professional connectedness", familiarity with using e-mails and internet for social and task purposes (Yun 2000), ownership of computer and secure computer access (Belling et al, 2011), as well as ease of navigation through the web-interface of the questionnaire (Thomas 2003). Surveying healthcare professionals with web-based questionnaire is supported by the empirical literature (Braithwaite et al 2003). With older people postal questionnaires still tend to yield higher response rates (Smeeth et al. 2001). After taking these considerations into account, the author decided to administer both the patient and clinician questionnaires for respondents to complete in their own time; however, the patient questionnaire was delivered in a postal format rather than through the web after the author had considered the overall group characteristics of patients - they tend to be older (mean age of bladder cancer in the UK was 70 in 2008) and I had concerns for their access to internet.

3.1.5.4 Quantitative Statistical Analysis

With regards to analysis, the starting point for is data entry and coding. These procedures should be checked for accuracy, and it is not until data is 'cleaned' the statistical analysis should commence (Coggon et al 2013). Before the author commenced the analyses, I removed the duplicate cases, identified and coded

the missing cases, and checked for accuracy of entered data. Microsoft Excel 2007 ® and SPSS ® v.19.0 were used for carrying out the statistical analyses. The author's analyses started with an analytical plan with outcomes relevant to the current decision making process. Descriptions of respondent groups' characteristics with display of tables and bar charts, preceded further more sophisticated statistical tests in my analyses.

3.1.6 Qualitative Inquiry

The main characteristics of qualitative research have already been mentioned in section 3.1.3. Similar to many other social phenomena, the decision making process central to this research was complex and it involved a network of interactions between different individuals, as well as them and their environment. Certain complexities associated with the decision making process would be better described and understood in greater depth when explored in the 'natural' context i.e. contemporary healthcare, social and cultural settings of UK. Some of such complexities included how patients weighed up between the two diversion options, individual attitudes of patients and clinicians towards personal involvement in the decision making process, individual opinions of patients and clinicians on the additional information materials provided in the pre-surgery counselling process, as well as other individual and institutional factors which would facilitate or hinder the decision making process. Over the next few sub-sections, further considerations to some specific aspects of qualitative inquiry relevant to this thesis are presented.

3.1.6.1 Sampling in qualitative inquiry

After deciding on which group(s) of individuals should be studied, a researcher considers from where and how these individuals/research subjects could be selected regardless of whether the study is qualitative or quantitative in nature.

With regards to the 'where', the researcher deliberates further on the choices of sampling frames. Sampling frames are categorised into 'existing' and 'generated'; examples of existing sampling frames include government-managed administrative

records (e.g. Census), published registers of professional organisations, hospital-held patient databases and survey samples (Ritchie et al 2010; Crombie and Davies 1996). On the other hand, generated sampling frames can be created through techniques such as household screen and snowballing (Ritchie et al 2010). An ideal sampling frame encompasses individuals with a range of characteristics relevant to a particular study and is relatively accessible.

With regards to the 'how', qualitative research overall follows a very different sampling strategy to that of quantitative research - known as 'purposive sampling'. The aim of drawing a sample purposively is to select research participants who possess certain characteristics, which then enable detailed exploration of the central issues related to the phenomenon studied (Patton 1990); hence, purposive sampling is also known as criterion-based sampling. 'Theoretical sampling' is an approach to purposive sampling. It is an iterative process, where the researcher would simultaneously collect, code and analyse data so that he or she can decide who and where to sample next, according to emerging codes and categories; and data collection stops when 'data saturation' has been achieved (Lewis et al 2010; Coyne 1997). However, this notion of data saturation has stimulated many debates around how to judge whether the data saturation has been attained. Some authors argued that saturation was a matter of degree, and suggested that the time a researcher spent on examining the data as well as the researcher's experience in qualitative data analysis, would influence when data saturation is deemed to be reached (Strauss and Corbin 1998; Charmaz 2006; Dey 1999). The sampling process in the qualitative inquiry of this research was guided by the overall aim of purposive sampling, with the practical concerns associated with sample size determination taken into account.

Furthermore, as mentioned before the sample size for a qualitative study is usually smaller as compared to that for a quantitative study. Qualitative researchers would usually justify for the smaller study samples by contending about the difference in research focus between qualitative and quantitative research, the necessity of further sampling after rigorous analysis of the existing dataset, as well as the time and relative labour-intensiveness required in analysing qualitative data (Lewis, Ritchie and Elam 2003). However, there remains the question of just how small (or large) a

qualitative sample should be. Some authors provided recommendations on the minimum number of participants required for qualitative research have been made, which ranges from 10-15 (Bertaux 1981; Guest 2006; Francis 2009). However, these recommendations should be treated as guidance only since there is a host of other issues should be considered, such as nature of the phenomenon and the context in which it is studied; study design; complexity and quality of data; use of shadowed data; researcher's experience and fatigue; and the number of researchers reviewing the data (Charmaz 2006; Dey 1999; Morse 2002; Ryan and Bernard 2004)

There are other sampling methods which are frequently encountered in both qualitative and quantitative research, such as convenience sampling. As its name suggests, in convenience sampling the researcher selects the study participants according to the ease of access. However, a researcher who adopts this sampling strategy should be cautious about the issue of bias and hence the generalisability of findings, a particular concern in quantitative studies, is questionable. Nonetheless, this form of sampling is usually accepted in pilot or exploratory work (Crombie and Davies 1996; Ritchie et al 2010).

There is a wide range of data collection methods applicable in qualitative research. This research employed the method of semi-structured interviews and this is discussed in further details in the next section.

3.1.6.2 Semi-structured interviews

Interview is one of commonest data collection methods employed in qualitative health research (Britten 1995, DiCicco Bloom and Crabtree 2006). There are three broad types of qualitative interviews, namely structured, semi-structured and unstructured interviews (Britten 1995). These represent a continuum where structured and in-depth interviews locate at the opposing ends, with semi-structured interview occupying a mid-way position (Britten 1995).

Semi-structured interviewing involves the researcher asking their research participants/respondents pre-determined, open-ended questions, in order to gather answers to address certain issues related to a defined research area (Green and

Thorogood 2005). These questions are usually presented as interview schedule (also known as 'topic guide'), which has a number of functions; it can act as an aide-memoir to the researcher of the main topics to be covered (Burgess 1984); as a preliminary scheme for analysis (Gaskell 2000) and helps to maintain a degree of uniformity and consistency in the topics explored when there is more than one researcher involved in the study (Cohen and Crabtree 2006). The last point was of particular relevance to this research, as apart from myself there was a research associate (RA) colleague, an experienced qualitative health researcher who conducted some of the interviews as well. The length of and the details included in a guide usually depends on the topics to be explored, as well as the amount of the details which the researcher who creates the guide is comfortable with (Arthur and Nazroo 2003).

As the interview evolves, the researcher may ask additional questions as per guided by the respondent's answers; this allows the researcher to explore these issues in more depth, as well as to negotiate through new emergent issues additional which are pertinent to the research area (Britten 1995; Green and Thorogood 2005). In this way the researcher and the respondent have the flexibility to probe issues in more detail and clarify over certain answers (Bowling 2009). This flexibility was the main reason why the author adopted the semi-structure interviewing techniques.

Moreover, I could explore more than just one or two issues only in great details (as with unstructured interviewing) and the author would not be constrained by a set of standardised questions which would be asked in specific order and with fixed responses (as with structured interviewing). Over the past decade, there has been growing popularity with semi-structured interviewing in the clinical discipline of urology, as reflected by an increase in the number of published urological studies that quoted the use of the research technique. (Rivers et al 2011; Oliffe et al 2009; Eng et al 2005; Sinfield et al 2008; Cohen and Britten 2003; Chapple et al 2002); many of these studies are orientated around the impact and management of prostate cancer.

Two keys to a good qualitative interview are 'active listening' and 'language' (Green and Thorogood 2005). When the researcher is actively listening to the respondent's answers, he or she can presently distil out the issues to be explored further and

formulate promptly further relevant questions to ask (Hammersley and Atkinson 1995). As for language, it has been generally recognised that good interview questions posed by the researcher should be open-ended, neutral, sensitive as well as clear to the respondent, and should not be leading (Patton 1987; Legard et al 2010; Britten 1995); the breadth and depth of the respondent's answers can be maximised with the use of prompting and probing questions (Green and Thorogood 2005; Legard et al 2010). The researcher should also check if the respondent has understood the questions asked, and clarify the meanings behind certain words and phrases used by the interviewer as necessary (Green and Thorogood 2005, Britten 1995). Furthermore, the researcher should also be conscious of his or her own and the respondent's body language, in order to develop and maintain a good rapport which would in turn facilitate the interviewing process (DiCicco Bloom and Crabtree 2006; Thompson 2000). During the conduct of the interviews for this research the author strived to apply the 'good practices' described.

As in many other qualitative interview-based studies, the interviews in this research were audio-recorded and transcribed verbatim, to maintain data accuracy and hence validity and reliability of analysis (Gill et al 2008); moreover, audio-recording allowed RA and I to concentrate on the interview process itself and not to be distracted by note-taking (Green and Thorogood 2005). With regards to the mode of interviewing for qualitative studies, 'face-to-face' has been the traditional one in use, but there has been an increased uptake of the 'telephone' interviewing mode over the recent years; the main criticism levelled at telephone interviewing is concerned with the lack of feedback of non-visual cues from the respondent (Miller 1995). There is a divided opinion on the effectiveness of telephone interviews (Sturges and Hanrahan 2004; Minnick and Young 1999; Einarson et al 1999,). In this research, the telephone mode was adopted for interviews with some of the clinicians due to the geographical distribution of these clinicians and travelling distances involved in meeting with them for interviews (Carr and Thomas 1997; Sturges and Hanrahan 2004).

Another consideration for researchers carrying out qualitative research, including myself, is 'Reflexivity'; it refers to the recognition demonstrated by a researcher, of his or her own role in the process of producing data and their meanings, as well as the conscious reflection of this process. The goal of reflexivity is to improve the

overall quality of qualitative research (Barry et al 1999). This research called for individual as well as team (RA and the author) reflexivity, both of which are discussed in greater details in Chapter 10.

In the next subsection, the analytical strategy employed in this research is discussed in further details.

3.1.6.3 Qualitative interview data analysis

A number of authors have pointed out that satisfactory qualitative analysis 'can never be adequately summed up by a neat tag' (a named analytical approach), and in reality many qualitative researchers have adopted a pragmatic mix of approaches which reflect the aims and needs of their work (Rapley 2011; Green and Thorgood 2005). The four most commonly encountered qualitative analytical approaches are 'Thematic Analysis', 'Grounded Theory', 'Framework Analysis' and 'Interpretive Phenomenological Analysis'. However, as Rapley (2011) asserted, these approaches are in fact rather similar to one another and there are certain procedures which cut across all of them:

- Starting data analysis by engaging in close, detailed reading of the dataset
- Systematically dataset labelling
- Reflecting upon the reasons for assigning a label a particular name
- Reviewing and refining label practices
- Interrogating key labels and the relationships between them

In addition to the above, Rapley (2011) also advocated researchers to engage in cycles of data collection and analysis, which may inform further purposive or theoretical sampling; he also emphasised the need for researchers to continually check for coherency and exceptions under a label and between labels, and to note of emergent ideas about the dataset and phenomenon studied regularly.

The author's analytical strategy for this research was largely based on thematic analysis and incorporated with the principles described above. In this way the author sought to develop a 'qualitative analytical attitude' which would be conducive to a

satisfactory qualitative analysis (Rapley 2011). The author focussed on the application of the principles behind this analytical attitude, rather than committing to then declaring a fixed analytic approach for this research.

Thematic analysis was considered as well as the most common of qualitative analytic approaches (Green and Thorogood 2005; Pope et al 2006); it involves the researchers reading through interview transcripts and drawing out categories ('themes') from participants' accounts. The gathered accounts are then compared with each other to classify common themes in the dataset (Green and Thorgood 2005). However, some authors have cautioned about the risk of producing superficial work with thematic analysis, by simply presenting a list of emergent themes, without much attempt to explore the relationships between the themes and explain the data (Pope and Mays 2009).

There are a number of operational steps to thematic analysis; once data collection has been completed, the researcher first engages in close reading of transcripts ('familiarisation'); from this an initial list of codes ('coding scheme') is generated and the entire dataset is then systematically coded; codes that are similar in characteristics are then grouped together as themes. In this way data from codes which are similar to each other can also be gathered under common themes; the applicability of each theme is then checked in relation to the dataset and research aims and items which appear to be misfits under a certain theme are noted. Next the more 'sophisticated' level of analysis is performed, where the specifications of a theme is refined, and associations between themes are sought which may lead to further propositions or theories about the phenomenon studied (Braun and Clarke 2006; Grbich 1999). In this research, myself and RA very much followed these steps, with the exception that data collection and coding would occur concurrently which an iterative development and refinement of the coding scheme.

The development of my analytical attitude and interview skill set were facilitated by working alongside the RA colleague, the author's wider reading on qualitative data analysis as well as attendance at training courses on conducting qualitative interviews and data analysis.

The next part is 'Methods', where the actual procedures used during the conduct of this research are detailed.

3.2 Methods

This second part of the chapter describes in detail the procedures used in this research. The research itself encompassed three components: qualitative semi-structured interviews with patients and clinicians, secondary data analysis of the SWPHO-BAUS dataset and questionnaire surveys of patients and clinicians.

3.2.1 Analysis of the joint SWPHO-BAUS Cystectomy Dataset

The use of secondary data is widespread in epidemiological and outcome research (Sørensen et al 1996; Best 1999). Secondary data is information that has already been collected for a purpose other than the current research project but is considered a useful and relevant resource for the research (Boslaugh 2007). There is a number of recognised advantages of using secondary data sources, the key one being economy - since the data has already been collected, the time and effort for data collection are not required; furthermore, usually if the dataset is large and has a wide breadth of variables collected, the size and representativeness of that sample would not be normally available in studies led by individual researchers, due to limited resources (Best 1999; Smith et al 2007). With regards to the choice of secondary data source, there is a need to identify the most appropriate source for the particular research questions or needs.

However, as a number of writers have pointed out, there are some clear disadvantages inherent to the use of a secondary data source; the data collected are not tailored specifically to the questions which the researcher would like to address; also, the researcher has little control over the quality of the data, such as the accuracy and degree of completeness of data registered (Boslaugh 2007; Sørensen et al 1996). In order to circumvent these issues, the author heeded guidance found in the literature which advised asking plausible research questions; selecting an appropriate dataset; familiarising oneself with the dataset and structuring an analytical strategy which would generate outcomes relevant to the research query concerning this thesis (Smith et al 2007).

One of the indicators that a decision making for choice of urinary diversion was needed was the variation in the rate of neobladder use within the UK. As mentioned

in Aims and Objectives, I sought to estimate the level of this variation at three different healthcare organisational levels (cancer networks, hospitals and consultants) and compare them, with and without controlling for various patient characteristics. Having read through the relevant literature on pre-operative patient characteristics associated with neobladder use (Hautmann et al. 2012; Lee et al 2014; Hounsome et al 2013; Gore et al 2006), the pre-operative patient characteristics which were considered in the analysis conducted for this thesis were demographic (age, gender and deprivation) and clinical (physical fitness pre-cystectomy: ASA, stage of the cancer, renal function, pre-cystectomy chemotherapy, radiotherapy and continence status). ASA and stage were previously studied (Hounsome et al 2013) but the other four clinical characteristics were also selected as they have been listed as required for consideration for selection of patients who were most likely to benefit from neobladder (Babjuk et al 2013; Hautmann et al 2013; Sugihara et al 2013; Witjes et al 2014).

It had previously shown that hospitals with higher cystectomy caseload also had higher proportion of patients undergoing neobladder formation (Hautmann et al 2013; Sugihara et al 2013; Gore et al 2006). Due to the issue with case capture of cystectomy with the SWPHO-BAUS dataset (see explanation below), the author did not feel it would be particularly meaningful to examine the association between cystectomy caseload and neobladder use in this instance and therefore did not include caseload as an analytical parameter.

3.2.1.1 Deprivation index

To investigate whether social factors influenced use of neobladder, the author calculated the Index of Multiple Deprivation (IMD) Rank for use in the analysis. An IMD score in itself is a more comprehensive marker of deprivation than individual indicators e.g. income and employment, and is calculated for at a locality level within the UK defined by postcode. It reflects the general level of affluence of people living in that locality area, but not that of any one particular individual or household (Noble et al 2006). Each of the four nations of the UK has its own system for IMD score calculation; for England, the score is generated from indicators contained under seven domains which include income, employment health education and training,

access/barriers to services, living environment/housing and crime (Payne and Abel 2012). However, IMD scores are rarely used and often they are converted to ranks, with the area with the lowest (most deprived) score ranked 1 (Adams 2011). IMD ranks reflect the relative deprivation of one area to another and thus facilitates comparison of deprivation status between areas only, but not individually.

3.2.1.2 Clinical characteristics

Physical fitness pre-cystectomy was indicated by the American Society of Anaesthesiologists (ASA) score, from one to five (one being the fittest and 5 representing close to death) (American Society of Anaesthesiologists 2014). Clinical stage of the cancer, as explained in Introduction, reflects the estimated extent of cancer invasion into the bladder wall from the combined evidence of examination, cystoscopy and pathology; generally speaking the higher the number, the more advanced the cancer is. Creatinine value was used as the measure of renal function with the upper limit of normal in the literature ranged from 90-120 $\mu\text{mol/L}$ (Hautmann et al 2012; Lee et al 2014; Edinburgh Renal Unit 2010). Continence level prior to cystectomy was defined in the dataset as a scale from no urinary leakage to reliance on appliance to manage incontinence, but it remained uncertain whether this scale used was a validated one in the literature.

During the process of the analysis in the thesis, by chance a formal publication on independent predictors of neobladder use in England by the SWPHO team, based on their analysis on the same dataset (Hounscome et al 2013) was discovered. There were two objectives to their analysis – first was to determine if and how age, gender, deprivation, stage of cancer as well as cystectomy caseload of a given cancer network predicted neobladder use and if so, how would they do so, after taking into account the random effects exerted by organisational variables including cancer networks and consultants; second was to estimate the level of variation in neobladder use among cancer networks, after accounting for the patient and consultant-level variations. In contrast, as mentioned earlier, the author's analysis focused on comparing the residual degree of variation in neobladder use, after all the patient characteristics of the author's interest and the random effects exerted by cancer networks, hospitals and consultants.

3.2.1.3 Secondary datasets used

The author accessed the joint Southwest Public Health Observatory and British Association of Urological Surgeons (SWPHO-BAUS) Radical Cystectomy Dataset, primarily because it was the only known dataset which housed a large amount of data related to the characteristics of interest as mentioned above. Apart from its relevance and size, it was also relatively uneventful to gain approval for use of the data from SWPHO and BAUS. However, there were some significant disadvantages with the use of the dataset; firstly, the data were submitted by the operating urological surgeons and/or local hospital data management, on a voluntary basis leading to missing values and quality issues; the dataset was linked to the Hospital Episode Statistics (HES) records i.e. another secondary dataset to identify as many missing patient residence postcodes in the SWPHO-BAUS dataset as possible, as to aid analysis. This linkage was approved and assisted by the responsible statistician at SWPHO headquarters. Using the HES dataset was not possible as it did not contain procedure specific codes (OPCS) for neobladders associated with the radical cystectomy cases i.e. the only specified diversion was conduit (Hounsome et al 2012).

Written permission was sought and granted from the guardian of the BAUS database, the Chair and Executive Committee of the Oncology Section of BAUS, to all access to the dataset. The principal investigator was granted permission towards the End of January, 2011 and she retrieved the dataset from SWPHO based in Bristol, UK in March, 2011. The dataset was subsequently encrypted and saved onto the university's password protected network. The information related to cystectomy caseload for English hospitals during the study period was obtained from the Northern and Yorkshire Cancer Registry and Information Service (NYCRIS) and they also granted the permission for use of the information.

Microsoft Excel 2007 ® and SPSS ® v.19 was used to carry out appropriate statistical analyses – from descriptive, frequency counts, chi-square tests, t-tests as well as logistic regression with funnel plotting. Non-disclosure form was signed to protect the confidentiality of the HES dataset (Appendix 4)

3.2.1.4 Data Quality

Only cases registered from England NHS between 2004 and 2009 were considered as these formed the main bulk of the dataset at the time of the analysis and could be linked to postcode data from HES. Furthermore, early on in the process of examining data completeness, it became apparent that case capture of radical cystectomy cases was a significant issue, particularly with a number of hospitals.

The total number of radical cystectomies performed at each hospital site in England in the dataset was compared with that recorded in the HES dataset. The SWPHO-BAUS dataset was found to have captured 2503/4546 (55.1%) of the radical cystectomies cases registered to have been undertaken in England on HES, during the study period (Appendix 5). The options of either using the whole dataset in the analysis or limiting it to a subset of hospital sites with higher rates of concordance with HES data, for example using an arbitrary cut-off of more than 50% capture, were considered. The author in the end decided that the benefits of including a larger a sample of cases as possible outweighed considerations of risks of selection bias and used the whole dataset for my analysis (Appendix 5). With regards to the other characteristic fields of interest, the data completion rate within the dataset itself ranged from 70-98% (Appendix 5).

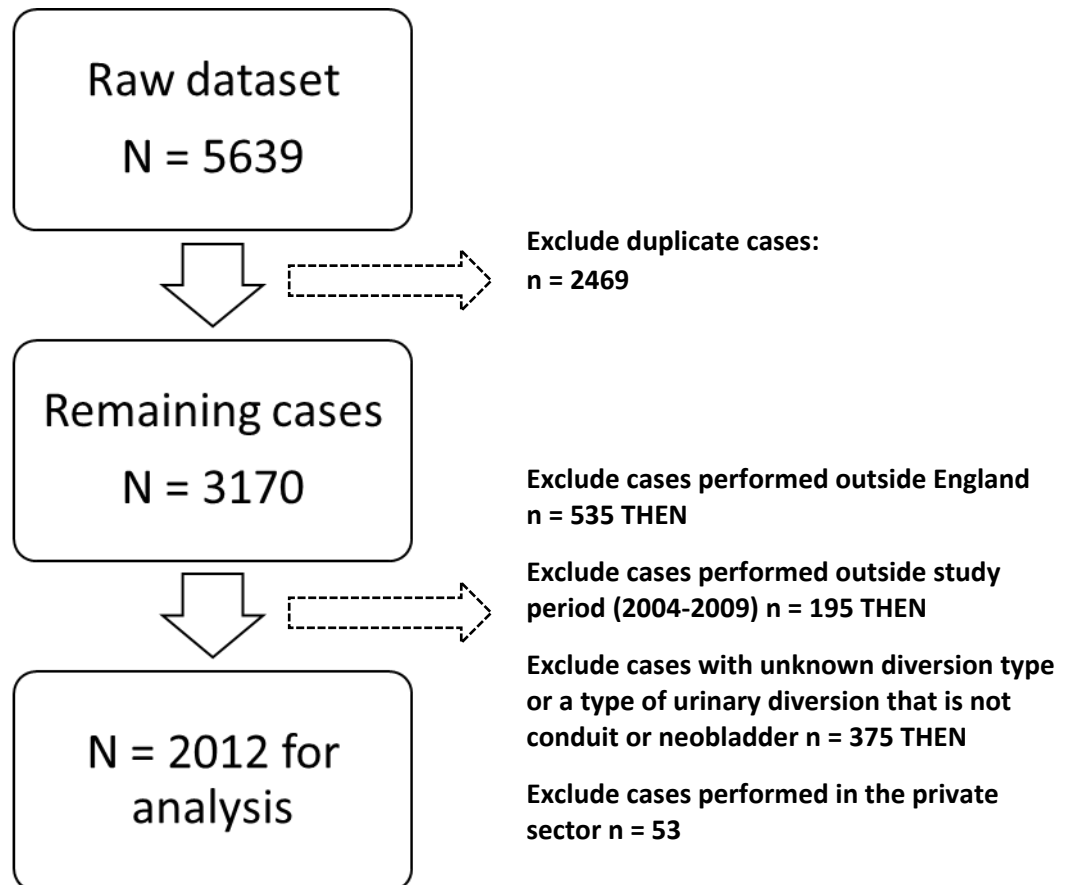
3.2.1.5 Dataset cleaning

Cases were identified for exclusion by examining patient identifiers including NHS numbers, hospital numbers and postcodes as well as the names of associated centres and/or consultants, dates of operation and urinary diversion type. Inclusion criteria for cases were radical cystectomy with known associated diversion performed of either conduit or neobladder, in 2004-2009 in England NHS.

Screening of the five thousand six hundred and thirty-nine radical cystectomy cases, performed in UK between December 2003 and July 2010 contained in the raw SWPHO dataset showed 2469 duplicate cases detected by comparing the NHS numbers and Postcodes of residence for individual cases. A further 1,097 cases were excluded because of the reasons detailed in figure 3.1. This left a total of 2065 cases for inclusion in my analysis (Figure 3.1).

Personal enquiries to the SWPHO team responsible for the management of the dataset did not yield any answers as to why there were such a high number of duplicates and what quality checks had been conducted on the dataset.

Figure 3.1 Identification of cases for analysis



Microsoft Excel 2007 ® and SPSS ® v.19 were used to carry out appropriate statistical analyses – from descriptive, frequency counts, chi-square tests, t-tests to logistic regression and generalised linear mixed modelling (GLMM).

3.2.1.6 Analytical plan

The analysis was divided into two parts – the first part being the univariate analysis, which sought to examine the overall trend association between each of the characteristics aforementioned and neobladder use, rather than determining which of

these would be independent predictors of neobladder use in the UK. This part of the analysis was therefore involved with a number of descriptive statistical tests, from the more simplistic frequency counts to univariate logistic regression. In the second part of the analysis, the author aimed to determine the presence and degree of variation in neobladder use at each of the three organisational levels (consultant/centre/cancer network) which could not be explained by patient characteristics and random variation in neobladder use which pre-existed at each organisational level (residual variation); the outcome of interest was binary i.e. use of neobladder: yes or no and the patient characteristics to be taken into account would not all necessarily follow Gaussian distributions. GLMM is an extension to linear mixed models which allows response variables from different distributions, such as binary response (neobladder use in this case) and considered both fixed and random effects (patient characteristics – fixed effects and random variation in neobladder use which pre-existed at each organisational level – random effects). Therefore, the author employed GLMM (UCLA Institute for Digital and Education Research; http://www.ats.ucla.edu/stat/mult_pkg/glmm.htm#summary).

3.2.2 Needs Assessment Questionnaire Survey

As mentioned before, the development of these questionnaire surveys were largely informed by the population needs assessment workbook by OHRI (Jacobsen and O'Connor 2006).

The draft questionnaire was first reviewed by members of the supervisory team (a professor of urology, a professor of epidemiology and public health and a senior lecturer in medical sociology), and the academic and administrative staffs within the local research group who volunteered for the reviewing task. Each was asked to complete the questionnaire and provide individual feedback on the relevance and readability of the questions and response items, as well as the formatting and ease of completion. A revised draft of the patient questionnaire was then piloted with a sample of patients who had previously undergone cancer cystectomy and urinary diversion at a local urology unit. The patients were approached by the research nurse at the unit at the end of their outpatient follow-up visits and asked to complete

the questionnaire and comment on its relevance, readability of questions and response items, and formatting and ease of completion. Those who agreed to help were given the draft questionnaire to complete and invited to provide feedback face-to-face with the author in a private consultation room within the out-patient clinic after completion of the draft questionnaire. The draft was then revised further based on the patients' comments. This resulted in a final version of the questionnaire (Appendix 2).

3.2.2.1 Patient questionnaire survey

As described before, the sample for this survey was drawn from the OTIS study. As part of this study the patient participants had already given consent to be sent additional questionnaires concerning their experiences. A substantial amendment to the main OTIS study was submitted and approved by the Grampian Research Ethics Committee (REC) Panel 2 in June 2011.

Eligible patients for this questionnaire were those who domiciled in the UK and had undergone radical at least 12 months previously. The identification of eligible participants was conducted by the research nurse on the OTIS team based in Aberdeen; the living status of potential participants was confirmed with their GPs before they were approached. They were then sent the invitation letter and questionnaire.

The questionnaire, accompanied by the study information sheet and invitation letter (Appendix 2, 6 and 7) and a pre-paid envelope addressed to the OTIS Trial Office in Aberdeen were sent to each eligible OTIS participant during the last week of October 2011. Participants were asked to complete the questionnaire and return by post. A single postal reminder letter together with a second copy of the questionnaire and the study information sheet, and another pre-paid envelope were sent to all the participants two weeks after the initial posting with an apology to cover those that had already replied. No further communication with the participants was made thereafter. The survey closed three weeks after the forwarding of the last reminder.

Responses from the returned questionnaire were entered by the OTIS research nurse or data co-ordinator onto the password protected database set up for the OTIS

study. An accuracy check for data entry was carried out by the Principal Investigator and OTIS research nurse by randomly sampling 20% of all returned questionnaires to check against the respective data base entries. Subsequently, an encrypted spreadsheet in Microsoft Excel 2007 ® was created for the data gathered.

Analysis of the collated data was then carried out with the aid of the SPSS ® v. 19 software. Descriptive statistics such as frequency counts and percentages, Pearson's Chi-Square test, Student's T-test as well as Wilcoxon Signed Rank test were carried out as appropriate.

3.2.2.2 Clinician questionnaire survey

This questionnaire survey was carried out with the help and collaboration of three UK-based professional bodies, namely the British Association of Urological Surgeons (BAUS), the British Association of Urological Nurses (BAUN) and the UK Section of the World Council of Enterostomal Therapists (WCET UK) using their membership databases with e mail contact details. Since any contacted member could choose to opt-in as an independent healthcare professional rather than an NHS employee, NHS Research Ethics approval was not required. The executive committees of these professional bodies were approached for access to the registers of their memberships and assistance in disseminating the questionnaire. In line with member permissions held by the organisations and the principles of the data-protection act each organisation sent out the web-link to the questionnaire to their members on behalf of the researchers.

The eligibility criterion for this questionnaire was UK-based consultant urological surgeons who performed radical cystectomy and/or urinary diversion, and specialist nurses who were involved in pre-operative discussions with patients about urinary diversion and radical cystectomy.

An invitation e-mail containing a direct web-link to the questionnaire was forwarded to all members of the professional organisations who had previously agreed to receive third party e-mails (BAUS: 25th May, 2011; WCET UK 20th June, 2011;

BAUN: 29th June, 2011 via Fitwise, the communication management company acted on behalf of BAUN). A fortnight after the invitation was sent, a reminder e-mail, which also contained the web-link to the questionnaire was sent to all the agreeable registered members. There was no further communication with the members of BAUS and WCET UK after the reminder was sent.

Shortly after BAUN members were e-mailed with the invitation, I was advised that some BAUN members only agreed to receive third party information by post; and therefore, a paper copy of the questionnaire was forwarded to all BAUN members who agreed to either third-party e-mailing or post, or both, along with an issue of the BAUN newsletter. Subsequently, the paper version of the invitation letter and the questionnaire, along with a pre-paid addressed envelope for return were posted to each of these BAUN members on 10th August, with the August 2011 issue of the BAUN Newsletter. There was no further communication with the BAUN members thereafter.

The web-based questionnaire survey was closed for data collection three weeks after the reminder was sent. Data collection for the paper-based questionnaire survey of the BAUN members was closed on 2nd November, 2011.

Access to the data collected via SurveyMonkeyTM (i.e. for the web-based questionnaire survey) was password protected. An encrypted spreadsheet in Microsoft Excel 2007® was created for data gathered via the web-based questionnaire survey and that from the paper-based BAUN questionnaire survey. The principal investigator was responsible for entry and accuracy check of data from the latter. Analysis of the collated data was then carried out with the aid of the SPSS® v. 19. Descriptive statistics such as frequency counts and percentages, Pearson's Chi-Square test, Student's T-test as well as Wilcoxon Signed Rank test were carried out as appropriate.

3.2.3 Qualitative semi-structured interviews with patients and clinicians

The interviews were conducted between November 2010 and February 2012. Before the start of the interviewing process, a favourable ethical opinion was

obtained from the Newcastle and North Tyneside Research Ethics Committee Panel 2, in July 2010. In addition, local research and development (R &D) approvals were obtained to perform the study within the relevant NHS organisations. In July 2011, an ethical amendment was approved for change in recruitment procedures and addition of a study site.

3.2.3.1 Recruitment of patients

The participating local clinicians were also responsible for approaching potential patient respondents. An identified post-surgery patient was posted a 'study pack' which contained an invitation letter, a study information sheet, consent-for-further-contact form (Appendix 8) and a pre-paid self-addressed envelope (SAE). At the end of the pre-surgery consultation where discussion on urinary diversion methods took place, a potential patient participant would also be handed the study pack described. There would be no direct contact with the approached patients by the research team (the RA and myself), unless they had expressed interest in participating by returning the completed 'consent for further contact' form. Once the patient had made his/her interest known, either the RA or the author would arrange with the patient a convenient time and location for a face-to-face interview. Patients could choose a private setting within the hospital, university or their own homes. Written, informed consent following was obtained just prior to the start of the actual interview.

Early on in the respondent identification and recruitment process, the author realised that the hospital managed databases were not as up-to-date as anticipated. Moreover, due to competing clinical commitments and time constraints there had been occasions where some potential pre-surgery patients not being approached by the participating clinicians. At one of the three original study sites a participating clinician took unanticipated long term sick leave. Recruitment was unpredictable, and within the first few months since the start of the interview process, the author realised that female, neobladder and pre-operative patients were especially difficult to recruit from the three urology units. Ethnic diversity was also particularly lacking in the available patient sample pools.

Better ways to identify and approach patients were suggested by some of the participating local clinicians; the use of radical cystectomy outpatient clinic attendance lists and theatre lists in identifying suitable patients were encouraged. The author was also advised by these clinicians that potential post-surgery patient participants could be approached directly on the wards after surgery when they are well enough, or after their out-patient follow-up appointments. Furthermore, the local clinicians suggested me to involve Comprehensive Local Research Network (CLRN)-funded research nurses based at the three units to further facilitate the recruitment of potential patient participants.

The author discussed my concerns regarding recruitment and the local clinicians' suggestions with my supervisory team; they suggested the inclusion of an additional unit which was based further south; it had a relatively high caseload for radical cystectomies and neobladders and also served a socio-economically and ethnically diverse population. The team agreed that the local clinicians' suggestions were helpful.

The author subsequently submitted a substantial amendment to the ethics committee for the changes to patient identification and recruitment, as well as for the inclusion of the Yorkshire based unit as an additional study site. On approval of the amendment, local research governance clearance for this additional unit applied for and subsequently granted.

3.2.3.2 Sampling of patients

Three urology units in the northeast of England which routinely performed radical cystectomy and both methods of diversion were approached and included. Each of these units served both urban and rural populations with a diverse socio-economic make-up and offered radical cystectomy and the two urinary diversion methods as part of patient treatment for bladder cancer. Eligible patients were those who were 18 years or above, proficient in both written and spoken English and both diversion methods as options prior to surgery. In order to encompass all likely different views and maximise depth of data collected a purposive sample was drawn based on additional criterion and these included age, gender, operative status (pre-surgery or anytime up to two years post-surgery), type of chosen/preferred diversion

The clinicians who were based at the three aforementioned urology units ('local clinicians') and agreeable to participate assisted in the identification of potential patient participants. Hospital managed databases which contained details of patients who had undergone radical cystectomy were used to identify potential post-surgery patient respondents. On the other hand, potential pre-surgery patients were identified through outpatient attendance lists or directly through the local clinicians. The author aimed to recruit a minimum of 15 and up to 30 patients in total and in the end 27 were recruited. Their detailed characteristics are presented in Appendix 9.

3.2.3.3 Recruitment of clinicians

All the local, eligible clinicians were contacted by the author via an invitation e-mail about this interview study, with attachments of the invitation letter and study information sheet (Appendix 3, 10 and 11). A clinician could express their interest to participate by e-mailing me directly, or by returning a completed 'consent for further contact' form attached at the bottom of the letter via e-mail or post. A single e-mail reminder was forwarded to the clinicians who had not replied by two weeks after the initial e-mail. After the reminder there would be no further contact with these clinicians unless they replied to indicate wish to participate. Once interest to participate had been confirmed by the clinician, the RA or the author would arrange with the clinician a suitable time and place for a face-to-face interview. Written, informed consent would be obtained just prior to the actual interview (Appendix 12).

The selected non-local clinicians were also each approached by the author with the invitation e-mail, with attachments of the invitation letter and study information sheet. Again, if there was no response from the clinician after two weeks of the initial e-mail, the clinician would then be e-mailed a reminder. There would be no contact with the clinician thereafter unless they subsequently replied to express willingness to take part. A non-local clinician could opt in by e-mailing the author directly or returning a completed 'consent for further contact' form attached at the bottom of the letter via e-mail or post. A participating non-local clinician would then be e-mailed the consent form (Appendix 13) and requested to return the signed form via e-mail or

post, and a suitable slot for a telephone interview would be arranged between the clinician and the author or the RA. If a signed consent form had already been returned prior to the interview, the author or the RA would still go through the consent form with the clinician then counter-sign it at the time of the interview; in the case that the completed consent form was not available prior to the interview, the author or the RA would go through the actual consent form with the participating clinician and sign it before starting the interview; after the interview the consent form would then be forwarded to the clinician for their signature and subsequently returned to the research team.

As previously mentioned the non-local clinicians were to be recruited following expression of interest on the web-based questionnaire. The response rates among the specialist nurses from BAUN were low and the author was informed by BAUN that some of their membership only agreed to receive third party posts but not e-mails; in order to boost the response rates and hence increase the size of the pool of suitable nurse respondents, the questionnaire was therefore posted in paper form to all the BAUN membership to increase response rate and hence the number and diversity of specialist nurses to be sampled for this interview study.

Between mid-April 2011 to the end of August 2011, patient recruitment was restricted to pre-operative patients. This recruitment 'down time' allowed the author to obtain research governance approval for the additional study site and the other changes requiring further ethical approval, and to complete coding of the interviews completed at the time. The additional study site started recruitment in October 2011.

In all, 43 patients and 42 clinicians (24 consultant surgeons and 18 specialist nurses) were approached; 27 patients and 30 clinicians (total = 57; Appendices 11 and 12) were recruited and completed interviews with the research team. One patient declined and the other 15 patients never responded. With regards to the clinicians approached, the remaining 12 did not respond further to invitation to participate. Due to difficulties in identification and recruitment purposive sampling was performed only to a limited degree and convenient sampling was relied upon in some instances.

3.2.3.4 Sampling of clinicians

Two groups of clinicians were eligible - consultant urological surgeons who performed radical cystectomy and urinary diversion, and specialist nurses who advised patients about urinary diversions before surgery. The sample of eligible clinicians was drawn from the three aforementioned urology units, as well as from the other units in the rest of the UK and Ireland.

All the eligible clinicians from the three urology units of the northeast of England (16 in total) were to be approached, and they varied in age, gender as well as professional experience in terms of time spent in their designation, as well as the proportion of neobladders performed. These were known to either myself (who was also a trainee on the urology specialist training programme of Northern Deanery and rotated through these three units for training) or the clinician supervisor of the supervisory teams, or to both. On agreeing to participate, these clinicians would become 'local clinicians' and they helped with identifying and recruiting patient respondents as outlined above. However, in order to further enhance the diversity of the clinician sample, eligible clinicians from outside the northeast of England ('non-local clinicians') were also to be recruited. They were identified through the membership registers of three UK-based professional bodies: British Association of Urological Surgeons (BAUS), British Association of Urological Nurses (BAUN) and World Council of Enterostomal Therapists UK (WCET UK). A web-based questionnaire survey (see later) was circulated by these professional bodies to their members, and those who responded positively to the invitation to be interviewed, placed at end of the questionnaire would be noted. These clinicians were then purposively selected based on designation (surgeon or specialist nurse), gender, age, years of experience in terms of time spent in the designation, proportion of neobladders performed and the location of affiliated urology units. Again, I aimed to recruit up to 30 clinicians. In the end, 30 clinicians were recruited and their details are presented in Appendix 14.

3.2.3.5 Data Collection

The author developed the interview guides (Appendix 15) for this study with the guidance of the RA and supervisory team. Guides were piloted in the 'mock' interviews with the RA and a number of academic and administrative staff based in the research group which the principal investigator was part of. As data were collected and analysed these guides were modified. It was decided that any participating clinician who had worked directly with the author would be interviewed by the RA.

Interviews with all patients and the local clinicians were conducted on a one-to-one, face-to-face basis. When interviewing a patient, if a family member/carer present had expressed an interest to be interviewed, or had contributed significantly to the interview, written, informed consent would be obtained from the family member/carer. Individual interviews with the non-local clinicians took place by telephone. Most of the conducted interviews lasted for an hour each, with the range being 25 minutes (clinician interview) to 2 hours 45 minutes (patient interview). All interviews were audio-recorded. The author conducted 38 interviews in total and the remaining 19 were conducted by the research associate.

3.2.3.6 Data management and analysis

Each recorded interview was transcribed verbatim and these were checked afterwards against the recordings of the interviews to check for any inaccuracies within the transcripts; all transcripts were anonymised.

The RA and the author then independently coded the transcripts of the interviews which they conducted, but these coded transcripts were then also reviewed by each other; annotations were made on each transcript. At the beginning of the analytical process, two transcripts from the same interviewee group i.e. clinicians or surgeon were coded then cross-reviewed at a time; after this we met at a 'data session' where the application and the understanding of codes were discussed. Earlier transcripts were coded by one paragraph at a time and these earlier codes were more descriptive. Subsequent transcripts were fed into the cyclical process of coding and annotating, cross-reviewing and discussion, thus allowing an iterative

development of a coding frame for each of the patient and clinician interviewee groups.

Development of the coding frame was also informed by the input from the supervisory team and other researchers within the author's base Institute. As time progressed the meanings of codes were refined, with some codes merging to form conceptual categories and from categories themes were created; and relationships between categories and themes were sought. Conceptual maps regarding how codes and categories were related were outlined at about halfway into the data collection process. The last iteration of coding frames was completed in February 2012 and these were applied to the remaining uncoded transcripts. After coding had been completed, the author adopted the method of manual highlighting and annotating along margin on the printout of coded data, in order to familiarise herself with the data further leading to further merging, refinement and reduction of codes and categories.

3.3 Research findings integration and interpretation

With specific regards to mixing research methods and interpreting data, many approaches have been described and again, the approach to be adopted depends on the overall purpose of and questions to be answered by the research (Doyle et al 2009; Östlund et al 2011; Zhang and Cresswell 2013). One of the main pitfalls of mixing and interpreting data was simply reporting quantitative and qualitative data independently without deeper consideration to the joint meanings of such data. Some specific procedures in cross-interpreting quantitative and qualitative data have been described (Curry et al 2013; O' Cathain 2010; Zhang and Cresswell 2013). One of the more suitable procedures was the triangulation protocol (O' Cathain 2010) but was highly labour-intensive, time-consuming and required a degree of training. Due to the constraints of time and lack of appropriate formal training resources, the thesis' author endorsed the central ethos of the triangulation protocol instead, and summarised the main findings from each of the three research components, re-familiarized such and placed them side by side on paper, and deliberated their joint meanings against the prior stated research objectives and the overall context of this research.

3.4 Rigour in research

Before closing this chapter, a final consideration should be given to the issue of rigour. Validity has been considered in two dimensions, internal validity (credibility in the context of qualitative research) and external validity/generalisability (transferability in the context of qualitative research) (Lincoln and Guba 1985). Internal validity refers to whether the research 'investigating what you claim to be investigating?' (Arksey and Knight 1999). External validity relates to the extent of which research findings and conclusions are applicable to other groups within the population from which the research sample has been drawn (LeCompte and Goetz 1982). By explicitly describing the research methods adopted for this research the author hoped to have achieved a degree of transparency (Green and Thorgood 2005), but I was aware that transparency alone would not confer rigour - more considerations on validity would be required.

Through careful selection of secondary data source, questionnaire samples and thoughtful design of questionnaires a degree of internal validity should have been achieved for the quantitative part of this research. As for the qualitative inquiry, the author sought to achieve rigour through a number of procedures; one of them was constantly comparing the nature of codes and the data they house; with regards to external validity of the questionnaire survey, this could have been compromised by the nature and sizes of the samples; in order to compensate for this the author adopted practices to maximise response rates; on the other hand, the external validity of the qualitative inquiry was increased by having both the author and the RA as interviewers, coders and the fact that they cross-checked and discussed each other's coding practices regularly. The external validity of this whole research was enhanced by the fact that more than one research method was used in studying the decision making (Barbour 2001).

According to Green and Thorgood (2005), sensitising concepts are especially relevant to under-researched topics, where the aim of the research was to stimulate new ways of thinking and potential views of respondents could confer further external validity of a piece of qualitative research. For instance, the decision making process is under-studied and so the research findings generated can demonstrate new ways to both patients and clinicians of considering the choosing of urinary

diversion option. Conceptual generalisability relates to the notion that wider concepts, rather than specific, narrow research findings, should be considered in determining generalisability (Green and Thorogood 2005). With reference again to the phenomenon studied in this research, perhaps understanding that there is variation among patients in the way they consider the issue of diversion choice is more important than how exactly the decision is made by individual patient participants.

In summary, this chapter has explored the philosophical underpinnings behind research and that applied to this specific research. It also gives a detailed description of the research methods used in studying the phenomenon central to this thesis.

Chapter 4 SWPHO-BAUS Radical Cystectomy Dataset Analysis Results

4.1 Summary Statistics

Two thousand and twelve cases of radical cystectomy (cystectomy) associated with either ileal conduit (conduit) or orthotopic neobladder (neobladder) performed in NHS England during 2004-2009 were analysed (Figure 3.1, Chapter 3). These cases were performed by 141 named consultants, across 81 centres within 27 cancer networks (Appendix 16). Conduit was the predominant type of urinary diversion performed, with approximately 15 times as many conduits as neobladders registered in the dataset (1883/129). About two thirds of the consultants (92/141 = 65%), over half of the centres (44/81 = 54%) and over a third of the cancer networks (10/27 = 37%) performed only conduits; on the other hand, few consultants (n = 5) from five different centres within three cancer networks performed only neobladders (Appendix 16). The clinical activity (radical cystectomy with urinary diversion) recorded for each organisational level is summarised in Table 4.1 below.

Table 4.1 Clinical activity by organisational level

Organisational level	Cystectomy N = 2012	Urinary diversion	
		Conduit n = 1883	Neobladder n = 129
Consultant*			
Mean (range; SD)	13 (1-113; 20)	13 (0-106; 19)	1 (0-13; 2)
Median (IQR)	5 (2-16)	5 (1-16)	0 (0-1)
Centre			
Mean (range; SD)	25 (1-267; 40)	23 (0-244; 38)	2 (0-23; 3)
Median (IQR)	9 (3-29)	9 (3-27)	0 (0-2)
Cancer Network			
Mean (range; SD)	75 (1-395; 97)	70 (1-370; 91)	5 (0-26; 7)
Median (IQR)	42 (11-96)	36 (11-89)	3 (0-7)

* 127 cases with unknown consultant excluded from this analysis

IQR: inter-quartile range

4.2 Univariate Analysis

4.2.1 Demographic characteristics

As detailed in Table 4.2, neobladder use would be significantly increased with younger age and the male gender ($p < 0.001$ and 0.003 respectively), but not associated with deprivation (as measured by IMDR, $p = 0.516$). A patient aged forty-nine years or less would be approximately 23 times more likely to receive a neobladder relative to a patient aged 70 years or more, and a male patient would be about twice more likely than a female patient to receive a neobladder.

Table 4.2 Association between demographic characteristics and urinary diversion performed

Demographic characteristic	Urinary diversion		OR (95% CI)*	p†
	Conduit (N = 1728) n (%)	Neobladder (N = 124) n (%)		
Age groups (Total = 1852; u/k = 160)				<0.001
≤ 49 years	62 (4)	19 (15)	23.12 (10.54 – 50.75)	<0.001
50–69 years	836 (48)	94 (76)	8.48 (4.51 -15.96)	<0.001
≥ 70 years	830 (48)	11 (9)	Ref	
	Conduit (N = 1860) n (%)	Neobladder (N = 126) n (%)		
Gender (Total = 1986; u/k = 26)				
Male	1364 (73)	108 (86)	2.18 (1.31 – 3.63)	0.003
Female	496 (27)	18 (14)	Ref	
	Conduit (N = 1693) n (%)	Neobladder (N = 121) n (%)		
IMDR quintiles (Total = 1814; u/k = 198)				0.516
1 st (most deprived)	349 (21)	21 (17)	0.89 (0.49 – 1.64)	0.714
2 nd	342 (20)	20 (17)	0.88 (0.47 – 1.61)	0.651
3 rd	323 (19)	28 (23)	1.29 (0.73 – 2.28)	0.390
4 th	338 (20)	29 (24)	1.27 (0.72 – 2.24)	0.406
5 th (least deprived)	341 (20)	23 (19)	Ref	

u/k = case with unknown information and excluded from analysis; * OR (95% CI) = odds ratio (95% confidence interval), calculated from univariate logistic regression. An OR less than 1 indicated a lower odds of neobladder use relative to conduit use; †p = p value from univariate logistic regression, with the top p value corresponding to the test for heterogeneity in OR between the categories specific to the demographic characteristic concerned

4.2.2 Pre-operative clinical characteristics

Better renal function and physical fitness (as indicated by Creatinine level and ASA class respectively) were associated with a significantly increased likelihood of neobladder use ($p = 0.004$ and <0.001 respectively); in particular, the patients with a Creatinine level of $99 \mu\text{mol/L}$ or less were 2.6 times more likely to be treated with neobladder than those with higher Creatinine levels (Table 4.3a). Most of the neobladder patients ($114/118 = 96.6\%$) were classified to be either ASA 1 or 2; and relative to the patients of ASA class 1, the odds of those patients of ASA class 2 and 3 being treated with neobladder were lowered by a factor of 2.7 and 11.7 (Table 4.3a)

With regards to clinical stage, a majority of neobladder patients ($89/102 = 81.4\%$) were at Stage 2 or below. There was a suggestion, albeit being statistically insignificant ($p = 0.064$), that the odds of neobladder use decreased with advancing clinical stage (Table 4.3b).

Lastly, radiotherapy status was significantly associated with neobladder use ($p = 0.02$). Those patients who did not receive radiotherapy before their surgery were nearly 4 times more likely than those who did, to be treated with neobladder; on the other hand, there were no statistically significant associations between neobladder use and chemotherapy or urinary continence status ($p = 0.10$ and 0.223 respectively; Table 4.3c).

Table 4.3a Association between pre-operative clinical characteristics and urinary diversion performed: creatinine level and ASA class

Clinical characteristic	Urinary diversion		OR (95% CI)*	p†
	Conduit (N = 1616) n (%)	Neobladder (N = 108) n (%)		
Creatinine groups (Total = 1724; u/k = 288)				
≤99 micromol/L (better renal function)	1251 (77)	97 (90)	2.57 (1.36 – 2.85)	0.004
≥100 micromol/L	365 (23)	11 (10)	Ref	
	Conduit (N = 1795) n (%)	Neobladder (N = 118) n (%)		
ASA (Total = 1913; u/k = 99)				<0.001
1 (Fittest)	363 (20)	54 (46)	Ref	
2	1114 (62)	60 (51)	0.36 (0.25 - 0.53)	
3	302 (17)	4 (3)	0.09 (0.03 - 0.25)	
4 (Most unfit)	16 (1)	0 (0)	0 (N/A)	

u/k = case with unknown information and excluded from analysis; * OR (95% CI) = odds ratio (95% confidence interval), calculated from univariate logistic regression. An OR less than 1 indicated a lower odds of neobladder use relative to conduit use; †p = p value from univariate logistic regression, with the top p value corresponding to the test for heterogeneity in OR between the categories specific to the clinical characteristic concerned

Table 4.3b Association between clinical characteristics and urinary diversion performed: pre-operative clinical stage

Clinical characteristic	Urinary diversion		OR (95% CI)*	p†
	Conduit (N = 1588) n (%)	Neobladder (N = 102) n (%)		
Clinical stage (Total = 1690; u/k = 322)				0.064
0 (Least advanced)	126 (8)	7 (7)	1.72 (0.53 – 5.56)	
1	265 (17)	25 (25)	2.93 (1.10 – 7.80)	
2	704 (44)	51 (50)	2.25 (0.88 – 5.72)	
3	338 (21)	14 (14)	1.28 (0.45 – 3.63)	
4 (Most advanced)	155 (10)	5 (5)	Ref	

u/k = case with unknown information and excluded from analysis; * OR (95% CI) = odds ratio (95% confidence interval), calculated from univariate logistic regression. An OR less than 1 indicated a lower odds of neobladder use relative to conduit use; †p = p value from univariate logistic regression, with the top p value corresponding to the test for heterogeneity in OR between the categories specific to clinical stage

Table 4.3c Association between clinical characteristics and urinary diversion performed: pre-operative chemotherapy, radiotherapy and continence status

Clinical characteristic	Urinary diversion		OR (95% CI)*	p†
	Conduit (N = 1684) n (%)	Neobladder (N = 111) n (%)		
Chemotherapy (Total = 1795; u/k = 217)				0.10
Yes	358 (21)	31 (28)	Ref 0.70 (0.45 – 1.07)	
No	1326 (79)	80 (72)		
	Conduit (N = 1640) n (%)	Neobladder (N = 111) n (%)		
Radiotherapy (Total = 1751; u/k = 261)				0.02
Yes	162 (10)	3 (3)	Ref 3.95 (1.24 – 12.57)	
No	1478 (90)	108 (97)		
	Conduit (N = 1680) n (%)	Neobladder (N = 113) n (%)		
Urinary continence (Total = 1793; u/k = 219)				0.223
Complete	1484 (88)	108 (96)	4.44 (0.61 – 32.33)	
Minor stress leak	94 (6)	2 (2)	1.30 (0.12 – 14.63)	
1 pad/day	10 (1)	1 (1)	6.10 (0.35 – 105.60)	
>1 pad/day	31 (2)	1 (1)	1.97 (0.12 – 32.53)	
Appliance	61 (4)	1 (1)	Ref	

u/k = case with unknown information and excluded from analysis; * OR (95% CI) = odds ratio (95% confidence interval), calculated from univariate logistic regression. An OR less than 1 indicated a lower odds of neobladder use relative to conduit use; †p = p value from univariate logistic regression, with the top p value corresponding to the test for heterogeneity in OR between the categories specific to the clinical characteristic concerned

4.3 Variation in neobladder use by organisational level (Generalised Linear Mixed Modelling: GLMM)

At each of the three organisational levels (Cancer Network, Centre and Consultant), a notable variation in neobladder persisted, even after holding all the aforementioned patient characteristics (fixed effects) constant and treating the organisational level as a random variable (random effect). For instance, at the consultant level, even when each consultant's patient cohort was identical to the other in terms of characteristics and the random variation in neobladder was considered, there remained a large variation in neobladder use among the consultants. This could be accounted for by the observed variation in patient cohort characteristics and the existing random variation in the neobladder use among the consultants (residual variation in neobladder use among consultants). The evidence for the presence of residual variation in neobladder use was strongest at the consultant level ($p = 0.039$), but there was also some, albeit weaker, evidence that this variation was also present at the cancer network level ($p = 0.069$) (Table 4.4).

Table 4.4 Variation in neobladder use at each organisational level, after holding all patient characteristics (fixed effects) constant AND allowing for the random variation in neobladder use existed for each organisational level (random effect)

Organisational Level	Var log OR*	p†	95% OR range#	Ratio of upper to lower limit of the 95% OR range
Cancer Network	1.30	0.069	0.11-9.30	86.6
Centre	0.61	0.141	0.22-4.65	21.6
Consultant	0.88	0.039	0.16-6.27	39.3

* Var log OR = variance of the logit of the odds ratio, an estimate of dispersion of the set of logits of ORs i.e. an indirect reflection of the degree of variation in OR; † p = p value for var log OR, within 95% confidence interval (CI). # 95% OR range = 95% mid-range of ORs around the mean OR value, a more direct reflection of the degree of variation in OR; the wider the range the greater level of variation. For example, focusing at the consultant level again – the 95% OR range was 0.16 – 6.27, which implied that the ORs of neobladder use of 95% of the consultants fell within this range; in other words, the ORs of neobladder use of 95% of the consultants lied within a factor of 6.27 either way of the average OR, after holding all fixed effects constant and taking into account the random variation in neobladder use existed among the consultants

4.4 Discussions

This section draws together and discusses the main findings from the analysis of the SWPHO-BAUS Radical Cystectomy Dataset, with considerations applied to the strengths and limitations of the analysis itself. The overall significance of its findings in the context of the whole thesis, with correlations to the findings from the other works embedded in this thesis, will be discussed in Chapters 9 and 10.

4.4.1 Univariate Analysis

An increased neobladder use was associated with certain pre-operative patient characteristics including younger age, male gender, better renal function, higher level of physical fitness gender and being radiotherapy naive. This might infer that UK-based surgeons had generally adopted the selection criteria for neobladder, based on empirical research evidence and published in the wider clinical literature/guidelines (Chapter 1). Moreover, the findings related to age and gender echoed with those in other studies (Hounsome et al 2013; Gore et al 2006).

On the other hand, deprivation, chemotherapy and urinary continence status were seemingly not associated with neobladder use, and there was only a trend of inverse association between clinical stage and neobladder use (less advanced disease made neobladder use more likely). The finding regarding deprivation appeared to disagree with some studies, which showed that more affluent patients were more likely to be treated with neobladder (Hounsome et al 2013; Gore et al 2006). There are two plausible explanations for this disagreement: 1) the fundamental difference in the establishment ethos of various healthcare systems; with the UK's NHS being one of the most equitable systems in the world, its patients are more likely to be selected for neobladder on the basis of their clinical characteristics, rather than their ability to afford 2) the deprivation scale (IMDR) used in this analysis was not comparable to that used in other studies. Clinical stage of the disease poses a concern related to cancer control after neobladder among some clinicians, reflected by the fact that locally advanced disease (Clinical stages 3 or above, with or without cancer involvement in the neighbouring lymph nodes to the bladder) was considered a relative contraindication to performing neobladder (Lee et al 2015; Hautmann et al 2012). As demonstrated by the study conducted by Hounsome and colleagues

(Hounscome et al 2013), less advanced disease (lower clinical stage) was associated with more frequent neobladder use; the comparatively smaller sample size of the analysis concerning this thesis might partially account for the subtle association it demonstrated. Indeed, sample size effects would always be implicated in any discrepant findings identified when comparing different studies with the same or similar research intents.

4.4.2 Generalised Linear Mixed Modelling (GLMM)

The Generalised Linear Mixed Modelling (GLMM) highlighted that, at every organisational level, there was a notable degree of variation in neobladder use which could not be explained by the variables studied (organisational levels and patient characteristics). This can be interpreted against the suggestion in the wider literature that, the often very pronounced geographical variations in the uptake of different healthcare options were driven by other factors, rather than aggregate patient health states/patient cohort characteristics and preferences for the healthcare options concerned (Birkmeyer et al 2013; Mulley et al 2012; Green et al 1996). Such other factors included clinicians' beliefs about risks and benefits associated with certain healthcare options, patients' preferences for healthcare options, the variations in disease incidence, access to specialist care, diagnostic testing, referral to specialist care and a host of local clinical environmental factors, including technology diffusion (introduction and uptake new technology), training and experience of clinicians, regulatory framework and financial incentives/constraints (Birkmeyer et al 2013). Some authors further asserted that patients in general were suboptimally informed about their healthcare choices and therefore, the large geographical variations in the uptake of these choices would unlikely to be explained by genuine variations in patient preferences about these choices.

With reference to Chapter 1, the selection criteria for neobladder encountered in the clinical literature offer guidance only when clinicians decide if their patients are suitable for the choice of neobladder or conduit; moreover, some criteria, such as patient's motivation and capability for the future care of neobladder (Lee et al 2014), are difficult to quantify. Clinicians often exercise their experience and discretion when deciding which patients would be suitable for neobladder or conduit; such bias

can be implicated in the decision making process concerning urinary diversion after radical cystectomy. This may in turn influence the patient-clinician dynamics during those clinical encounters where discussions of choice of urinary diversion take place; patients' genuine preferences for the treatment outcomes associated with each may not have been accurately determined and/or adequately incorporated in the decision making process, by their responsible clinicians. No study to date has examined the decision making process related to urinary diversion after radical cystectomy, and this is reflected by a current lack of understanding of this process; certainly, no study has yet explored how patients form their preferences and how these were taken into account in the decision making process. Therefore, genuine differences in patient preferences would unlikely to be a main contributor to the large discrepancies in neobladder use in this study's context. Indeed, when Mulley and colleagues (Mulley et al 2012) investigated differences in patients' preferences for healthcare options, delivery of effective healthcare options and patient collective health states, they concluded that these would contribute only a small degree to the large geographical variation in the uptake of various healthcare interventions. In other words, the variation in patient preference for either diversion method would unlikely to be the main cause for the large variation in neobladder use across the three organisational levels.

Given the availability of national guidelines for treating bladder cancer, the existence of quality assurance organisations for cancer services, such as the cancer networks, and the fact that NHS is 'free at the point of use', it seems unlikely that the large variations in neobladder use highlighted by the GLMM would be mainly accountable for by the variations in patient access to specialist care and diagnostic testing. This leaves the variations in disease incidence, clinicians' beliefs regarding risks and benefits associated with each diversion method, local clinical environmental factors including technology diffusion (introduction and uptake new technology), training and experience of clinicians, regulatory framework and financial incentives/constraints to be the more likely factors, perhaps all contributing to the large variations in neobladder use observed. As commented before, the evidence for variation in neobladder use was strongest at the consultant level, followed by the cancer network level, and weakest at the centre level. This might signify the large variation in individual consultant's beliefs in which patient would be suitable for neobladder and

therefore, how they selected and counselled patients for neobladder. Within a centre, there could be more than one consultant who would perform radical cystectomy and/or urinary diversion and some were proponents for neobladder, and patients might be referred to these consultants from the others who did not/were less keen to perform neobladder – almost akin to homogenisation of professional opinion on neobladder use within the centre. This might have led to the subtle evidence of variation in neobladder use between centres. However, the distribution of higher volume centres for neobladder among the various cancer networks might not be even, with some cancer networks with higher concentration higher volume centres and hence the evidence for variation in neobladder use among cancer networks had become more obvious. The concentration of specialist surgeons in performing neobladder, peri-operative nursing support, surgeon training frameworks in single centres and networks may account for the variation at these higher organisational levels (Birkenmyer et al 2013; Goodman et al 2006; Morden et al 2012).

4.4.3 Strengths and limitations

There were other studies which also examined the relationship between neobladder use and certain patient characteristics which were mainly demographically related (Hounsome et al 2013; Gore et al 2006). The analysis concerning this thesis considered not only patient demographic characteristics (age, gender and deprivation) but also wider range patient clinical characteristics, some of which were not covered by these other studies e.g. renal function and pre-operative radiotherapy status. Having said that, the analysis concerning this thesis examined the relationship and all the patient characteristics described by univariate analysis, on a more descriptive level. This was fit for the purpose of this thesis since the author only intended to delineate the trend association between these individual characteristics and neobladder use, whereas other studies such as that by Hounsome and colleagues (Hounsome et al 2013), set out to identify the independent predictors for neobladder use, and they had to organise the data in a hierarchy (nested – patients within cancer networks) prior to analysis. The author of this thesis recognised the hierachial nature of the data (patient within centre within cancer network), but the aim here was to only describe trend association between

neobladder use and each of the patient characteristics described. Moreover, Hounsome et al focused on determining if age, gender, deprivation and cystectomy caseload – all of which were independent predictors for neobladder use in North America, continued to be independent predictors in the UK (Gore et al 2006; Hounsome et al 2013), rather than looking for other new independent predictors for neobladder use.

Furthermore, this thesis represents the only study to date which examined and demonstrated the notable variation in neobladder use at each organisational level, which could not be explained by the organisational and a wide range of patient variables (residual variation). It also afforded the organisational level at which the residual variation was most evident. On the other hand, Hounsome et al examined the variation in neobladder use at cancer network level after taking into account the nested nature of data (consultant nested within cancer network) after taking into account age, gender, deprivation by income, clinical stage and overall cystectomy case load per cancer network.

The main limitation of this study, which is common to other studies, is the degree of case capture for radical cystectomy and the corresponding diversion. This was highlighted in the Methods chapter (about which was inherent to the SWPHO-BAUS Cystectomy dataset (Section ____: many hospitals with 50% or less case capture of cystectomy when compared to the figures in the Hospital Episode Statistics – HES Database). In addition, due to poor case capture, the thesis' author placed less emphasis on cystectomy caseload per cancer network as a factor associated with neobladder use and did not include it in the univariate analysis. Hounsome et al (Hounsome et al 2013) concluded that there was no difference between high and low volume cancer networks for radical cystectomy in terms of neobladder use. However, this might change if the case capture for radical cystectomy was more satisfactory. Another data accuracy issue, which was beyond the author's control, was that there was no formal ICD-10 code for orthotopic neobladder in the HES database; should the information on neobladder and conduit be more sufficient, the HES database might have been the database of choice for analysis, rather than the SWPHO-BAUS Dataset.

Given a patient who has no clear clinical contraindication to neobladder, the patient is arguably suitable for either diversion method. Neobladder and conduit share some common risks and the rates of such are comparable; on the other hand, each carries risks and benefits which are unique. Individual patients have different values and preferences for outcomes and whichever diversion they select, should be down to personal choice but before making such a choice, patients would need to be informed and involved in the decision making process. How informed and involved UK patients are in the decision over which diversion to proceed with radical cystectomy remain unknown. This analysis demonstrated that the degree of variation in neobladder use at each organisational level could not be accounted for by the random and fixed effects studied. Other aforementioned factors could be accountable, and these have provided the ground to further explore the current decision making process related to urinary diversion after radical cystectomy in the UK context – by means of questionnaire surveys and semi-structured qualitative interviews, with both patients and clinicians involved – which form the rest of the body of research for this thesis.

CHAPTER 5 NEEDS ASSESSMENT QUESTIONNAIRE SURVEY RESULTS

5.1 Patient survey

5.1.1 Demographic characteristics

The overall response rate was 75% (141/188). The surgery (radical cystectomy and urinary diversion) occurred on average 41 months prior to the questionnaire (12-191 months). A majority of the respondents were 60 years of age or older at the time of surgery; four times as many of the respondents were male. The main diversion procedure was ileal conduit, with three times as many conduits performed as neobladders (Table 5.1.1)

Table 5.1.1 Demographic characteristics of all respondents

Months between surgery and survey – Mean (range) N = 141		No response
41 (12 – 191)		0
Age group N = 138	n (%)	No response
70 years or over	52 (38)	3
60-69 years	59 (43)	
50-59 years	23 (17)	
40-49 years	4 (3)	
39 years or below	0 (0)	
Gender N = 141	n (%)	No response
Male	111 (79)	0
Female	30 (21)	
Diversion N = 140	n (%)	No response
Conduit	102 (73)	1
Neobladder	38 (27)	

As a reminder, the research of this thesis concerned the choice of diversion in the context of radical cystectomy, and hence the remaining analysis of this patient survey focused on the respondents who reported this choice being available. Just under half of all respondents reported that the choice was available to them (66/139 = 48%; no response = 2). A significantly higher proportion of the respondents who were younger at the time of surgery (69 years or below) reported having the choice;

moreover, there was a preponderance of respondents who received neobladder reported the choice was available; however, there was no significant association between gender and choice availability (Table 5.1.2).

For clarity, from this point onwards in this section the term 'respondents' refers to the sub-set respondents who reported having the choice of diversion (N = 66). Among them, a significantly higher proportion of the younger group at the time of surgery (69 years or below) received neobladder. Gender was not significantly associated with diversion type received by the respondents.

Table 5.1.2 Basic characteristics of respondents by availability of choice

Basic characteristic Availability of choice	Age group			Gender			Diversion		
	≥70 years n/N (%)	≤69 years n/N (%)	p	Male n/N (%)	Female n/N (%)	p	Conduit n/N (%)	Neo-bladder n/N (%)	p
Yes	11 (22)	54 (64)	< 0.01	54 (49)	12 (41)	0.60	31 (31)	35 (92)	<0.01
No	40 (78)	31 (37)		56 (51)	17 (59)		69 (69)	3 (8)	
Total N	51	85		110	29		100	38	
No response	5			2			3		

p = from Chi-Squared Test, 95% CI, 1 df

Table 5.1.3 Basic characteristics of respondents with choice by diversion

Basic characteristic Diversion	Age group			Gender		
	≥70 years n/N (%)	≤69 years n/N (%)	p	Male n/N (%)	Female n/N (%)	p
Conduit	10 (91)	20 (37)	< 0.01	23 (43)	8 (67)	0.23
Neobladder	1 (9)	34 (63)		31 (57)	4 (33)	
Total N	11	54		54	12	
No response	1			0		

p from Chi-Squared Test, 95% CI, 1 df

5.1.2 Satisfaction with clinician information provision

Across the various information areas related to conduit, the percentage of respondents who were reportedly satisfied to very satisfied ranged from 54 – 96%; as for neobladder, the range was similar at 57 – 95%. Benefits, complications /risks and course of recovery were the three information areas associated with the highest percentages of satisfied to very satisfied respondents, for both types of diversion concerned. The lowest percentages of satisfied to very satisfied respondents were associated with the information areas employment/retirement, leisure/sports and sexual matters for conduit. On the other hand, again leisure/sports and sexual matters, as well as peer support were associated with the lowest percentages of satisfied to very satisfied respondents (Tables 5.1.4 and 5.1.5; Figures 5.1.1 and 5.1.2). Seventeen respondents reported having received no information in at least one information area related to conduit and/or neobladder (Appendix 17).

With Wilcoxon signed ranks test, there was no significant difference in satisfaction level with the information provided between conduit and neobladder, across all information areas (Table 5.1.6). However, the respondents who underwent conduit reported a significantly higher level of satisfaction with the information provided on daily care for conduit; those who underwent neobladder reported a significantly higher level of satisfaction with the information provided on benefits, employment/retirement and leisure activities/sports (Tables 5.1.7 and 5.1.8)

Sixteen of the 66 respondents reported that they would like additional information on areas which could be mapped onto one of the information areas mentioned above (e.g. herniation, pad supply from NHS, speaking with former patients etc. – see Appendix 17). They also wished for more in-depth information on sexual matters and the alternative diversion to the one they chose.

Table 5.1.4 Satisfaction level concerning clinician information provision for conduit

Information area	Level of satisfaction	Very satisfied n (%)	Satisfied n (%)	Neutral n (%)	Unsatisfied n (%)	Very unsatisfied n (%)	Total N	No information provided n	No response n
Benefits		31 (53)	23 (39)	5 (9)	0 (0)	0 (0)	59	0	7
Complications/risks		24 (41)	30 (52)	4 (7)	0 (0)	0 (0)	58	0	8
Course of recovery		28 (50)	26 (46)	2 (4)	0 (0)	0 (0)	56	1	9
Peer support (groups/individual)		21 (41)	20 (39)	8 (16)	1 (2)	1 (2)	51	4	11
Daily care after surgery		32 (54)	20 (34)	6 (10)	1 (2)	0 (0)	59	1	6
Appliances (e.g. bags, catheters)		24 (41)	28 (48)	4 (7)	2 (3)	1 (2)	59	1	6
Employment /retirement		12 (26)	20 (44)	13 (28)	1 (2)	0 (0)	46	3	17
Leisure activities /sports		13 (24)	28 (51)	14 (26)	0 (0)	0 (0)	55	3	8
Bodily appearance after surgery		19 (33)	27 (47)	8 (14)	4 (7)	0 (0)	58	2	6
Sexual matters		4 (8)	22 (46)	14 (29)	5 (10)	3 (6)	48	8	10

Table 5.1.5 Satisfaction level concerning clinician information provision on neobladder

Information area	Level of satisfaction	Very Satisfied n (%)	Satisfied n (%)	Neutral n (%)	Unsatisfied n (%)	Very Unsatisfied n (%)	Total N	No information provided n	No response n
Benefits		30 (53)	23 (40)	4 (7)	0 (0)	0 (0)	57	2	7
Complications/risks		25 (45)	28 (50)	3 (5)	0 (0)	0 (0)	56	0	10
Course of recovery		24 (44)	24 (44)	6 (10)	1 (2)	0 (0)	55	3	8
Peer support (groups/individual)		19 (41)	14 (30)	12 (26)	0 (0)	1 (2)	46	6	14
Daily care after surgery		23 (46)	16 (32)	9 (18)	2 (4)	0 (0)	50	4	12
Appliances (e.g. bags, catheters)		19 (40)	17 (35)	10 (21)	0 (0)	2 (4)	48	5	13
Employment/retirement		13 (28)	23 (49)	11 (23)	0 (0)	0 (0)	47	5	14
Leisure activities/sports		15 (29)	23 (45)	13 (26)	0 (0)	0 (0)	51	4	11
Bodily appearance after surgery		20 (37)	22 (41)	9 (17)	3 (6)	0 (0)	54	3	9
Sexual matters		5 (11)	21 (46)	14 (30)	3 (7)	3 (7)	46	9	11

Figure 5.1.1

Satisfaction level concerning clinician information provision for conduit

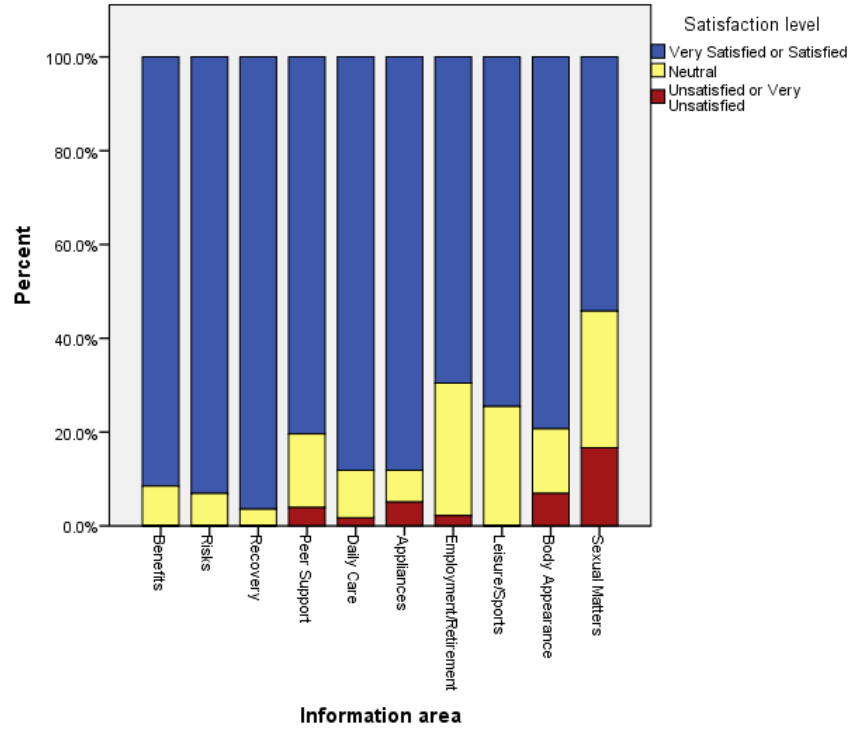


Figure 5.1.2

Satisfaction level concerning clinician information provision for neobladder

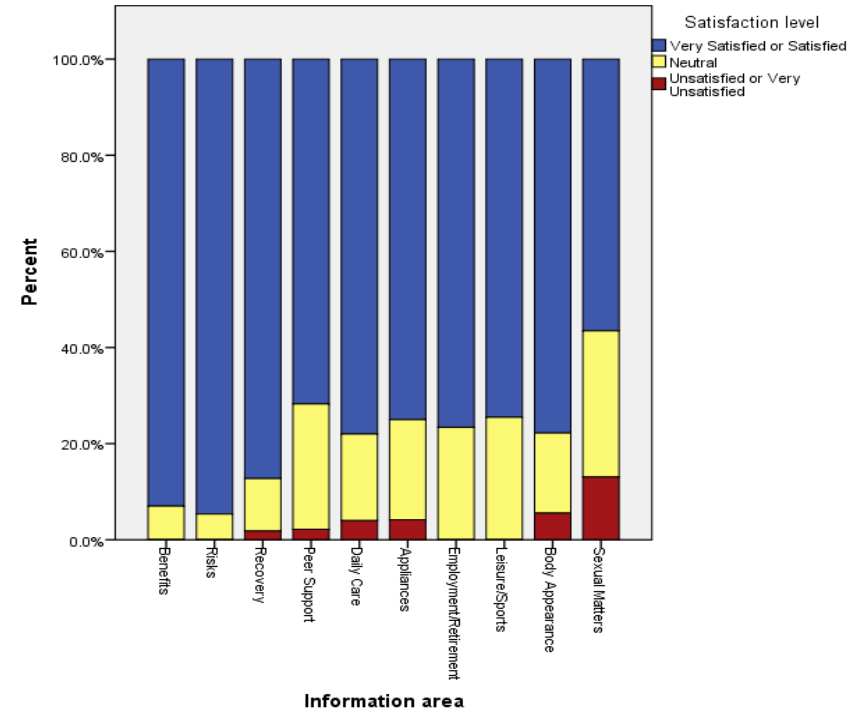


Table 5.1.6 Satisfaction level concerning clinician information provision, conduit vs neobladder

Information area	Mean satisfaction score		Median satisfaction score		Z	p
	Conduit	Neobladder	Conduit	Neobladder		
Benefits	4.4	4.5	5	5	-0.92	0.36
Complications/risks	4.3	4.4	4	4	-0.89	0.37
Course of recovery	4.5	4.3	4	4	-1.70	0.09
Peer support (groups/individual)	4.2	4.1	4	4	-0.17	0.86
Daily care after surgery	4.4	4.2	4	4	-1.54	0.12
Appliances (e.g. bags, catheters)	4.2	4.1	4	4	-1.54	0.12
Employment/retirement	3.9	4.0	4	4	-1.58	0.12
Leisure activities/sports	4.0	4.0	4	4	-1.58	0.12
Bodily appearance after surgery	4.1	4.1	4	4	-1.70	0.09
Sexual matters	3.4	3.5	4	4	0	1.00

Z statistic and p from Wilcoxon signed ranks test, 95% CI; each level of satisfaction level was assigned a score (1-5): 1 = very unsatisfied, 5 = very satisfied

Table 5.1.7 Satisfaction level concerning clinician information provision, conduit vs neobladder, within the conduit respondent group

Information area	Mean satisfaction score		Median satisfaction score		Z	p
	Conduit	Neobladder	Conduit	Neobladder		
Benefits	4.5	4.2	5	4	-1.60	0.06
Complications/risks	4.5	4.3	4	4	-0.71	0.50
Course of recovery	4.5	4.2	4.5	4	-1.51	0.13
Peer support (groups/individual)	4.2	3.7	4	4	-1.16	0.25
Daily care after surgery	4.2	3.9	5	4	-2.46	0.01
Appliances (e.g. bags, catheters)	4.4	3.8	5	4	-1.93	0.05
Employment/retirement	4.1	3.8	4	4	-0.71	0.48
Leisure activities/sports	4.1	3.8	4	4	-0.33	0.74
Bodily appearance after surgery	4.0	3.8	4	4	-0.38	0.71
Sexual matters	3.2	3.3	3	3	-0.33	0.74

Z statistic and p from Wilcoxon signed ranks test, 95% CI; each level of satisfaction level was assigned a score (1-5): 1 = very unsatisfied, 5 = very satisfied

Table 5.1.8 Satisfaction level concerning clinician information provision, conduit vs neobladder, within the neobladder respondent group

Information area	Mean satisfaction score		Median satisfaction score		Z	p
	Conduit	Neobladder	Conduit	Neobladder		
Benefits	4.4	4.7	5	5	-2.71	0.01
Complications/risks	4.2	4.5	4	4	-1.73	0.08
Course of recovery	4.4	4.4	4.5	4	-0.82	0.41
Peer support (groups/individual)	4.1	4.3	4	5	-1.12	0.27
Daily care after surgery	4.3	4.4	4	5	-0.71	0.50
Appliances (e.g. bags, catheters)	4.0	4.2	4	4	0	1.00
Employment/retirement	3.9	4.2	4	4	-2.71	0.01
Leisure activities/sports	3.9	4.2	4	4	-2.53	0.01
Bodily appearance after surgery	4.1	4.3	4	4	-1.90	0.06
Sexual matters	3.5	3.6	4	4	-0.45	0.70

Z statistic and p from Wilcoxon signed ranks test, 95% CI; each level of satisfaction level was assigned a score (1-5): 1 = very unsatisfied, 5 = very satisfied

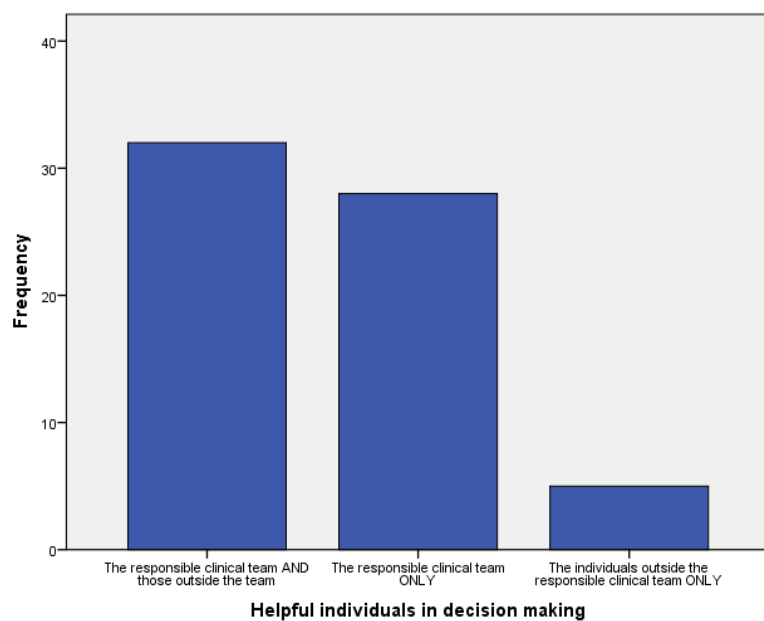
5.1.3 Helpful individuals in decision making

A majority of the respondents (N = 65, no response = 1) selected their responsible surgeons as the group of individuals who were helpful in the decision making process (57/65 = 88%); apart from the surgeons, the responsible specialist/stoma nurses (33/65 = 51%), spouses (24/65 = 37%), former patients (11/65 = 17%) and other family members/friends (9/65 = 14%) were also selected by the respondents. The only group of individuals who were not selected was patient support groups. Seven respondents stated (7/65 = 11%) 'Others' as helpful individuals, with the general practitioners (GP) as the new group of individuals being considered as helpful in the decision making process (n = 1).

Most of the respondents selected their responsible clinical team (surgeons and specialist/stoma nurses) as helpful individuals in the decision making process (60/65 = 92%). Also of note is that nearly half of the respondents (32/65 = 49%) selected both their responsible clinical team and those outside the team (and not necessarily from a clinical background, including spouse, other family members/friends, former patients, patient support groups, others); another 43% of the respondents (28/65) exclusively selected their responsible clinical team as the helpful individuals. Few respondents (5/65 = 8%) selected only those who were outside the responsible clinical team as helpful individuals in the decision making process (Figure 5.1.3).

Half of the respondents who selected their responsible clinicians as helpful individuals (n = 60) included both their surgeons and specialist/stoma nurses (30/60 = 50%), with another 41% included their surgeons only (27/60 = 41%); a few selected their nurses as the only helpful clinicians (3/60 = 5%).

Figure 5.1.3 Helpful individuals in decision making – within and outside the responsible clinical team



The responsible clinical team: surgeons and specialist/stoma nurses; outside the responsible clinical team: spouse, other family members/friends, former patients, patient support groups, others

5.1.4 Helpful information materials in decision making

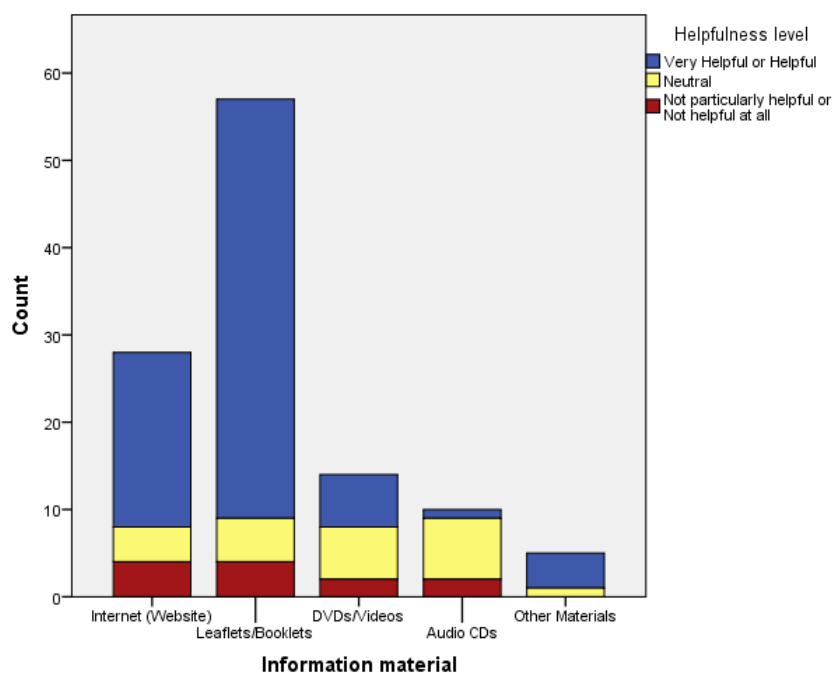
Leaflets/booklets were regarded as helpful or very helpful by a majority of the respondents (48/57 = 84%), but the format of Internet (Websites) was also regarded as so by many (20/28 = 71%). Relatively few respondents reported DVDs/Videos, Audio CDs and Other materials as helpful or very helpful; furthermore, Internet, DVDs/Videos and Audio CDs. The five respondents who reported using other materials did not actually volunteered any new alternative material other than those already stated as response options; three of them specified that information from specialist/stoma nurses as very helpful (Table 5.1.9; Figure 5.1.4). There were also notable numbers of 'no responses' and the implications of which will be discussed further in the Discussion chapter.

When asked about if having any alternative information materials other than those stated would have been helpful, ten respondents responded 'yes'; nine of them elaborated on their responses but no new material was actually suggested per se – they were more concerned with provision of more detailed information and/or personal consultation with clinicians involved in their care. One respondent reported being unexposed to any information material (Table 5.1.9; Appendix 17)

Table 5.1.9 Helpfulness level of information materials in decision making

Information materials	Very Helpful n (%)	Helpful n (%)	Neutral n (%)	Not Particularly Helpful n (%)	Not Helpful At All n (%)	Total	Material unavailable	No response
Internet (Websites)	8 (29)	12 (43)	4 (14)	1 (4)	3 (11)	28	16	22
Leaflets/booklets	27 (47)	21 (37)	5 (9)	3 (5)	1 (2)	57	5	4
DVDs/Videos	5 (36)	1 (7)	6 (43)	1 (7)	1 (7)	14	28	24
Audio CDs	1 (10)	0 (0)	7 (70)	1 (10)	1 (10)	10	30	26
Other materials	4 (80)	0 (0)	1 (20)	0 (0)	0 (0)	5	7	54

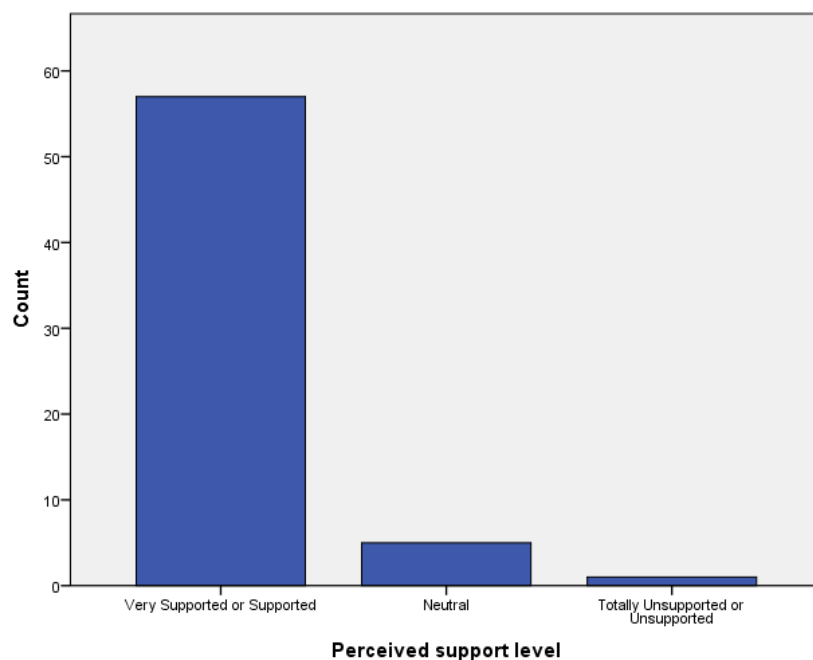
Figure 5.1.4 Helpfulness level of information materials in decision making



5.1.5 Perceived level of support during decision support

Most of the respondents reported that feeling supported or very supported during decision making (57/63 = 91%; no response = 3); another five respondents reported feeling neutral whilst one reported totally unsupported. There was no significant difference in the proportion of respondents who reported feeling supported or very supported between the two diversion groups (Chi-square test, $p = 1.00$, 1 d.f., 95% CI)

Figure 5.1.5 Perceived level of support during decision making



5.1.6 Feelings experienced when encountering the choice of diversion

Many respondents (N = 65; no response = 1) reported feeling 'positive' (50/65 = 77%) and approximately a third reported feeling 'relieved', 'wondering what would be important in life after surgery', 'worried about impact on self/significant others' and 'worried about what could go wrong with each choice (of diversion)'; relatively fewer respondents reported feeling 'distressed/upset', 'wavering', 'wanted to delay', 'physically stressed' and 'other feelings' (Table 5.1.10). Other feelings specified by the respondents were 'anxiety', 'self-assured about choice of diversion made' and 'total trust in responsible surgeon' (Appendix 17).

When the feelings were broadly grouped as positive and negative, most of the respondents reported experiencing either positive or mixed feelings (both positive and negative feelings) (58/65 = 90%) with the remaining reported experiencing only negative feelings (7/65 = 11%).

Table 5.1.10 Feelings experienced when encountering the choice of diversion

	Feelings	n/N (%)
POSITIVE FEELINGS	Positive	50/65 (77)
	Relieved	23/65 (35)
NEGATIVE FEELINGS	Distressed/upset	7/65 (11)
	Worried about what could go wrong with each choice (of diversion)	18/65 (28)
	Worried about impact on self/significant others	20/65 (31)
	Wondering what would be important in life after surgery	23/65 (35)
	Wavering	4/65 (6)
	Wanted to delay	1/65 (2)
	Physically stressed	3/65 (5)
	Other	7/65 (11)

Table 5.1.11 Feelings experienced when encountering the choice of diversion

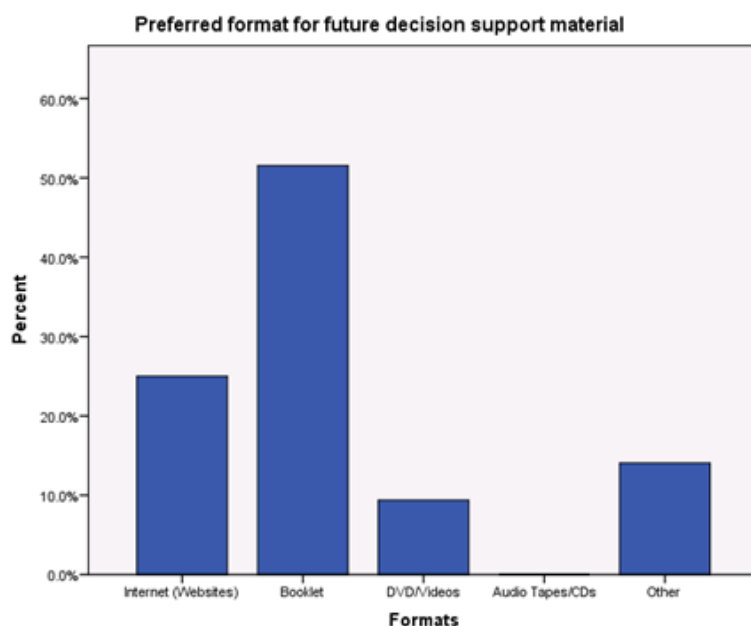
Feelings	Mixed feelings n (%)	Positive feelings only n (%)	Negative feelings only n (%)	Total N
	29 (45)	29 (45)	7 (11)	65

5.1.7 Preferred format for future decision support

Just over half of the respondents to this question reported their preference for the future decision support to be a booklet (33/64 = 52%), with another quarter of the respondents reported their preference for Internet (Website) (16/64 = 25%). Fewer preferred the format of DVDs/Videos (6/64 = 9%) whilst none of the respondents selected Audiotape/CD as the preferred format.

Nine respondents reported their preferences for other formats; of them three reported their preference for a combined format with booklet and one of the other stated formats (apart from Audio tapes/CDs); one respondent expressed preference for DVD/Videos with link to a support group formed by former patient; patient experiences (in audio-visual media) and other individualised support from healthcare professionals and former patients such as telephone helplines were also suggested.

Figure 5.1.7 Preferred format of future decision support



5.1.8 Degree of involvement and preferred role in decision making

Only one of the 65 respondents answering this question felt not being involved to the degree which he wished for, and indicated his preferred decision making role - 'making the final decision about the urine diversion method after seriously considering the opinion from the surgeon's and his/her team'. Twelve of the remaining 64 respondents who reported being involved to the degree which they wished for interestingly also reported their preferred role in the decision making process (Table 5.1.12)

Table 5.1.12 Preferred role in decision making among those involved to the point they wished

Preferred Role		n (N = 12)
Active role	Option 1: I would have liked to make the decision about which urine diversion method I would have	0
	Option 2: I would have liked to make the final decision about the urine diversion method after seriously considering the opinion from my surgeon's and his/her team	5
Shared role	Option 3: I would have liked to share with my surgeon along with his/her team the responsibility for deciding which urine diversion method was best for me	2
Passive role	Option 4: I would have liked my surgeon and his/her team made the final decision on which urine diversion would be used, but seriously considered my opinion	2
	Option 5: I would have liked to leave all decisions regarding urine diversion method to my surgeon and his/her team	3

5.1.9 Additional comments relevant to decision making

Many of the additional comments provided by the respondents were concerning their positive experiences in the decision making process, and with in-hospital care and life after surgery. However, a few respondents also highlighted some areas for improvement in the pre-operative counselling process, including the depth of discussion on the pros and cons associated with each diversion method; clinicians' understanding of patients' preferences, values and expectations of the outcomes associated with each diversion method; length of deliberation period for patients choosing between the two diversion methods; and lastly access to suitable former patients for support before surgery.

5.2 Clinician survey

5.2.1 Basic characteristics

The survey was forwarded to one thousand one hundred and seventy-six UK-based clinicians, including 768 full members of the British Association of Urological Surgeons (BAUS), 164 full members of the British Association of Urological Nurses (BAUN) and 244 full UK members of the World Council of Enterostomal Therapists UK (WCET UK). As mentioned in Methods, due to administrative reasons it was not possible to target the survey specifically at the full members who performed and/or being involved in pre-operative counselling on radical cystectomy and urinary diversion i.e. eligibility; therefore, the true response rate could not be ascertained. After exclusion of duplicates and those who self-declared as ineligible, the responses from 180 respondents remained for analysis (BAUS: n = 114; BAUN + WCET UK n = 66). For clarity, from this point onwards in this section, 'Surgeons' refers to the eligible surgeon respondents (full members recruited from BAUS) and 'Nurses' refers to the eligible nurse respondents (full members recruited from BAUN + WCET UK).

As demonstrated by Table 5.2.1, the surgeons were significantly older than the nurses ($p = 0.01$). There was also a male preponderance among the surgeons and the reverse was true for the nurses ($p < 0.01$). Over half of the respondents had 10 years or less of experience in their role ($85/154 = 55\%$); however, the differences in the percentages of respondents distributed across the groups of experience in years were insignificant.

In the year preceding this survey, each surgeon respondent reviewed on average 14 patients as radical cystectomy candidates (range 0 – 75), whilst the nurse respondents reviewed 11 patients (range 0 – 50). Nearly five times as many conduits as neobladders were performed (conduit N = 961; neobladder N = 199). There were also approximately five times as many patients counselled for conduit than for neobladder by the nurses (conduit N = 662; neobladder N = 123) (Appendix 18).

Table 5.2.1 Basic characteristics by respondent groups

Age Total N = 178; no response = 2	Mean = 48 years (31 – 64 years; sd 7)			
	Surgeons N = 114 Mean = 49 years (37 – 64 years; sd 7)	Nurses N = 64 Mean = 46 years (31 – 60 years; sd 7)	p* 0.01	
Gender Total N = 180; no response = 0	Surgeons N = 114	Nurses N = 66	P# <0.01	
	n (%)	n (%)		
Male	106 (93)	3 (5)		
Female	8 (7)	63 (96)		
Years of experience Total N = 154; no response = 26	Surgeons N = 103	Nurses N = 51	p† 0.774	
	n (%)	n (%)		
	0-5 years	25 (24)		11 (22)
	6-10 years	30 (29)		19 (39)
	11-15 years	18 (18)		9 (18)
	16-20 years	19 (18)		6 (12)
	Over 20 years	11 (11)		6 (12)

p* = p value from T Test, 95% CI; p# = p value from Chi-Squared Test, 95% CI, 1df; p† = p value from Chi-Squared Test, 95% CI, 4df

5.2.2 Information coverage

For both types of urinary diversion, recovery in hospital was the information area which most of the respondents reported to be discussed Very Often or Every time i.e. well covered (conduit = 94%; neobladder = 86%). Benefits (conduit = 94%, neobladder = 84%) and Technical Details (conduit = 92%; neobladder = 80%) were the other information areas very frequently reported to be well-covered. On the other hand, fewest respondents reported to have Employment well-covered (conduit = 59%; neobladder = 60%) (Tables 5.2.2 and 5.2.3).

With specific regards to conduit, it was significantly more well-covered in the information areas of Technical details, Benefits and Recovery in hospital than neobladder (p = 0.02, 0.03 and 0.01 respectively; Table 5.2.4). These three topics were consistently better covered again for conduit, as demonstrated by Wilcoxon Signed Ranks Test (p = 0.01, 0.03 and <0.001 respectively; Table 5.2.5); among the Surgeon respondents, the only information areas that was significantly more well covered for conduit than for neobladder was recovery in hospital (p < 0.001; Table 5.2.5); however, among the Nurse respondents, daily care, leisure/sports/travel and

bodily appearances were significantly better covered for conduit ($p = 0.02$, 0.03 and 0.02 respectively, Table 5.2.5), in addition to recovery in hospital ($p = 0.04$, Table 5.2.5).

Forty-five out of 107 respondents ($45/107 = 42.1\%$; 41 surgeons and 4 nurses) who answered both the questions 6 and 7 reported covering at least one topic less well (i.e. discussed 'Some Times' or 'Not Very Often' or 'Not Discussed'). Approximately a quarter of the respondents ($26/107 = 24.3\%$; 22 surgeons and 4 nurses) covered a greater number of topics less well when discussing conduit; eleven respondents covered all topics less well for neobladder and among them five reported that they did not discuss any of the topics for neobladder, due to their professional remit (Appendix 18).

With specific regards to conduit, significantly more nurse than surgeon respondents reported to have well-covered several topics, including recovery after discharge, daily care, employment, leisure/sports/travel and bodily appearance and sexual matters. As for neobladder, this was the case for employment and leisure/sports/travel (Tables 5.2.5 and 5.2.6)

Table 5.2.2 Information coverage for conduit

Coverage Level \ Information area	Every time n (%)	Very often n (%)	Sometimes n (%)	Not very often n (%)	Not discussed n (%)	Total N = 117; no response = 63
Technical details	94 (80)	14 (12)	4 (3)	2 (2)	3 (3)	
Benefits	95 (81)	15 (13)	2 (2)	1 (1)	4 (3)	
Adverse outcomes	82 (70)	23 (20)	5 (4)	2 (2)	5 (4)	
Probabilities of benefits	71 (61)	32 (27)	6 (5)	1 (1)	7 (6)	
Probabilities of adverse outcomes	72 (62)	32 (27)	5 (4)	0 (0)	8 (7)	
Recovery in hospital	106 (91)	7 (6)	1 (1)	0 (0)	3 (3)	
Recovery after discharge	88 (75)	16 (14)	9 (8)	1 (1)	3 (3)	
Daily care	67 (57)	18 (15)	25 (21)	1 (1)	6 (5)	
Employment	45 (39)	24 (21)	28 (24)	11 (9)	9 (8)	
Leisure/sports/travel	64 (55)	23 (20)	20 (17)	6 (5)	4 (3)	
Bodily appearance	80 (68)	17 (15)	11 (9)	6 (5)	3 (3)	
Sexual matters	69 (59)	27 (23)	12 (10)	5 (4)	4 (3)	

Table 5.2.3 Information coverage for neobladder

Coverage Level \ Information area	Every time n (%)	Very often n (%)	Sometimes n (%)	Not very often n (%)	Not discussed n (%)	Total N = 107; no response = 73
Technical details	76 (71)	10 (9)	10 (9)	3 (3)	8 (8)	
Benefits	79 (74)	11 (10)	8 (8)	1 (1)	8 (8)	
Adverse outcomes	79 (74)	10 (9)	9 (8)	1 (1)	8 (8)	
Probabilities of benefits	64 (60)	21 (20)	9 (8)	2 (2)	11 (10)	
Probabilities of adverse outcomes	69 (65)	20 (19)	8 (8)	1 (1)	9 (8)	
Recovery in hospital	77 (72)	15 (14)	6 (6)	1 (1)	8 (8)	
Recovery after discharge	73 (68)	17 (16)	7 (7)	2 (2)	8 (8)	
Daily care	65 (61)	17 (16)	12 (11)	3 (3)	10 (9)	
Employment	36 (34)	28 (26)	26 (24)	7 (7)	10 (9)	
Leisure/sports/travel	50 (47)	24 (22)	21 (20)	3 (3)	9 (8)	
Bodily appearance	67 (63)	13 (12)	15 (14)	4 (4)	8 (8)	
Sexual matters	62 (58)	18 (17)	16 (15)	2 (2)	9 (8)	

Table 5.2.4 Information areas well-covered by diversion type

Information area \ Diversion	Conduit N = 117 n (%)	Neobladder N = 107 n (%)	P*
Technical details	108 (92)	86 (80)	0.02
Benefits	110 (94)	90 (84)	0.03
Adverse outcomes	105 (90)	89 (83)	0.21
Probabilities of benefits	103 (88)	85 (79)	0.12
Probabilities of adverse outcomes	104 (89)	89 (83)	0.30
Recovery in hospital	113 (97)	92 (86)	0.01
Recovery after discharge	104 (89)	90 (84)	0.40
Daily care	85 (73)	82 (77)	0.60
Employment	69 (59)	64 (60)	1.00
Leisure/sports/travel	87 (74)	74 (69)	0.47
Bodily appearance	97 (83)	80 (75)	0.18
Sexual matters	96 (82)	80 (75)	0.24

P* = p value from Chi-Squared Test, 95% CI, 1 df

Table 5.2.5 Information areas well covered for conduit, by respondent group

Respondent group / Topics	Surgeons N = 75 n (%) N = 75	Nurses N = 42 n (%) N = 75	P*
Technical details	67 (89)	41 (98)	0.15
Benefits	70 (93)	40 (95)	1.00
Adverse outcomes	68 (91)	37 (88)	0.75
Probabilities of benefits	64 (85)	39 (93)	0.37
Probabilities of adverse outcomes	67 (89)	37 (88)	1.00
Recovery in hospital	71 (95)	42 (100)	0.30
Recovery after discharge	62 (83)	42 (100)	<0.01
Daily care	43 (57)	42 (100)	<0.01
Employment	31 (41)	38 (91)	<0.01
Leisure/sports/travel	45 (60)	42 (100)	<0.01
Bodily appearance	55 (73)	42 (100)	<0.01
Sexual matters	55 (73)	41 (98)	<0.01

P* = p value from Chi-Squared Test, 95% CI, 1 df

Table 5.2.6 Information areas well covered for neobladder, by respondent group

Respondent group / Topics	Surgeons n (%) N = 73	Nurses n (%) N = 34	P*
Technical details	57 (78)	29 (85)	0.54
Benefits	61 (84)	29 (85)	1.00
Adverse outcomes	60 (82)	29 (85)	0.90
Probabilities of benefits	56 (77)	29 (85)	0.44
Probabilities of adverse outcomes	60 (82)	29 (85)	0.90
Recovery in hospital	61 (84)	31 (91)	0.34
Recovery after discharge	59 (81)	31 (91)	0.28
Daily care	54 (74)	28 (82)	0.48
Employment	36 (49)	28 (82)	<0.01
Leisure/sports/travel	44 (60)	30 (88)	0.01
Bodily appearance	50 (69)	30 (88)	0.05
Sexual matters	51 (70)	29 (85)	0.14

P* = p value from Chi-Squared Test, 95% CI, 1 df

Table 5.2.7 Information coverage: conduit vs neobladder – all respondents and by respondent groups

Topics	All respondents N = 117		Surgeons N = 73		Nurses N = 34	
	Z	P*	Z	P#	Z	p†
Technical details	-2.59	0.01	-1.92	0.06	-1.71	0.09
Benefits	-2.14	0.03	-1.79	0.74	-1.20	0.23
Adverse outcomes	-0.51	0.61	-0.56	0.58	-0.31	0.76
Probabilities of benefits	-1.31	0.19	-0.55	0.58	-1.47	0.14
Probabilities of adverse outcomes	-0.40	0.69	-0.03	0.97	-0.50	0.62
Recovery in hospital	-4.11	<0.001	-3.57	<0.001	-2.04	0.04
Recovery after discharge	-1.80	0.07	-0.95	0.35	-1.81	0.71
Daily care	-0.13	0.90	-1.91	0.06	-2.21	0.03
Employment	-0.32	0.75	-1.47	0.14	-1.53	0.13
Leisure/sports/travel	-1.86	0.06	-0.49	0.62	-2.39	0.02
Bodily appearance	-1.78	0.08	-0.67	0.50	-2.20	0.03
Sexual matters	-1.04	0.30	-0.11	0.91	-1.67	0.10

Each level of coverage was assigned score, from 1 = not discussed to 5 = Every time. Each respondent's answer for that specific information for conduit was matched with the answer for neobladder provided by the same respondent. *p = p value from Wilcoxon signed rank test, 95% CI with 117 matched pairs. #p = p value from Wilcoxon signed rank test, 95% CI with 73 matched pairs. †p = p value from Wilcoxon signed rank test, 95% CI with 117 matched pairs. Ten respondents in total did not proceed to answer Question 7 (information coverage for neobladder)

5.2.3 Helpful individuals to patients in decision making

All Surgeon respondents selected their specialist/stoma nurse colleagues as helpful individuals to patients in the decision making process (n = 71). On the other hand, all apart from one nurse respondents selected their operating surgeon colleagues as so (40/41 = 98%). Many of the respondents also selected Former Patients (97/112 = 87%) and Spouses (88/112 = 79%) as the helpful individuals. Patient support groups, Relatives/friends and Others were selected as the helpful individuals by relatively fewer respondents. Oncologists, Radiologists and General Practitioners were specified as the other helpful individuals. All but three respondents reported both the responsible clinical team as well as those outside the team as helpful to the patients in the decision making process.

Table 5.2.8 Helpful individuals to patients in decision making

Respondent group	Surgeons N = 71 n (%)	Nurses N = 41 n (%)	P*	Total N = 112 n (%)
Helpful individuals				
Responsible clinicians: Operating surgeons OR Specialist/Stoma nurses	71 (100)	40 (98)	0.78	111 (99)
Spouse	57 (80)	31 (76)	0.73	88 (79)
Relatives/friends	26 (37)	18 (44)	0.58	44 (39)
Former patients	64 (90)	33 (81)	0.25	97 (87)
Patient support groups	32 (45)	19 (46)	1.00	51 (46)
Others	12 (17)	16 (39)	0.02	28 (25)

P* = p value from Chi-Squared Test, 95% CI, 1 df

5.2.4 Helpful information materials in decision making

Most of the respondents reported using more than one of the information materials (Appendix 18). Furthermore, most of the respondents reported using Pictures (N = 95) and Leaflets/Booklets (N= 94). Many also reported using Models/Appliances, Internet and DVDs/Videos (N = 84, 83 and 71 respectively). Fewest respondents reported using Audio CDs (N = 50). In terms of helpfulness, a majority of the respondents who reported using Pictures or Leaflets/Booklets rated each of these

materials as either Helpful or Very Helpful (88/95 = 93% and 90/94 = 96% respectively); on the other hand, just under half of the respondents who reported using Audio CDs (22/50 = 44%) rated them as Helpful or Very Helpful (Table 5.2.8 and Figure 5.2.6).

Unavailability was the main reason for non-usage of all materials, particularly for DVDs/Videos and Audio CDs. With specific regards to Internet, the other main reason for non-usage was concerns over inconsistency and reliability its contents. On the other hand, use of other additional information resources including counselling from local nurses and experiences shared by local patients as well as patients' refusal were the other main reasons for non-usage of DVDs/videos and Audio CDs (Table 5.2.8, Figure 5.2.6 and Appendix 18). Significantly more Nurse than Surgeon respondents rated DVDs/videos and Audio CDs as either Helpful or Very Helpful, but there was also a trend that more Nurse respondents rated Models/Appliances Helpful or Very helpful (Table 5.2.9). There were no new materials used reported.

Table 5.2.9 Helpfulness of information materials in decision making

Information material \ Helpfulness level	Very Helpful n (%)	Helpful n (%)	Neutral n (%)	Not particularly helpful n (%)	Subtotal using material N	Don't use - unavailable n (%)	Don't use - other reason(s) n (%)	Subtotal Don't use material N	No response n
Internet	12 (14)	33 (40)	31 (37)	7 (8)	83	11 (65)	6 (35)	17	97
Leaflets/Booklets	55 (59)	35 (37)	3 (3)	1 (1)	94	3 (50)	3 (50)	6	86
DVDs/Videos	20 (28)	33 (47)	15 (21)	3 (4)	71	22 (76)	7 (24)	29	109
Audio CDs	4 (8)	18 (36)	18 (36)	10 (20)	50	37 (74)	13 (26)	50	130
Models/Appliances	29 (35)	35 (42)	18 (22)	2 (2)	84	10 (63)	6 (38)	16	96
Pictures	52 (55)	36 (38)	7 (7)	0 (0)	95	1 (25)	4 (75)	5	85

Figure 5.2.6 Helpfulness of information material used in decision making

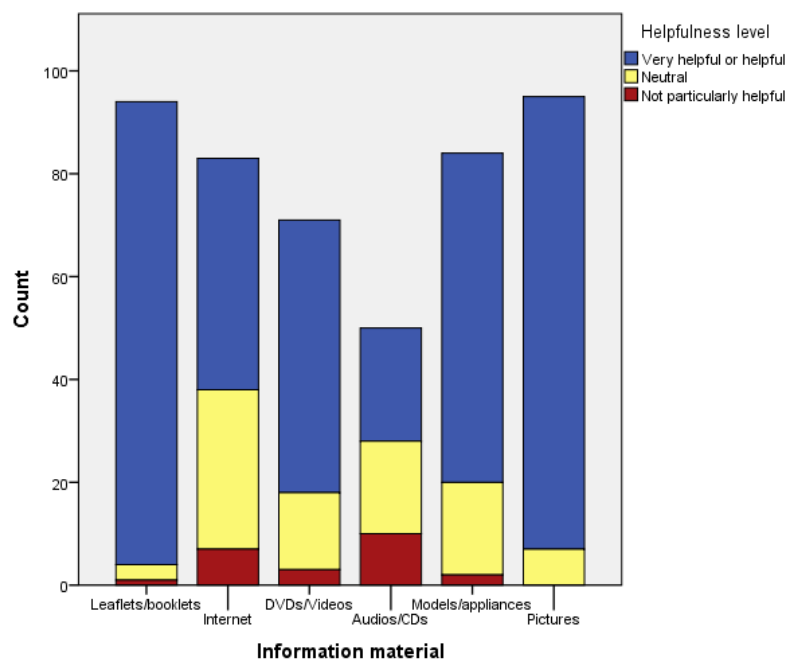


Table 5.2.10 Information materials rated Very Helpful or Helpful, by respondent groups

Respondent group / Information Material	Surgeons n (%)	Nurses n (%)	P*
Internet (Surgeon N = 45; Nurse N = 38)	23 (51)	22 (58)	0.69
Leaflets/Booklets (Surgeon N = 54; Nurse N = 40)	50 (93)	40 (100)	0.13
DVDs/Videos (Surgeon N = 37; Nurse N = 34)	23 (62)	30 (88)	0.02
Audio CDs (Surgeon N = 29; Nurse N = 21)	7 (24)	15 (71)	<0.01
Models/Appliances (Surgeon N = 45; Nurse N = 39)	30 (67)	34 (87)	0.05
Pictures Surgeon N = 55; Nurse N = 40)	49 (89)	39 (98)	0.23

P* = p value from Chi-Squared Test, 95% CI, 1 df

5.2.5 Preferred format for future decision support

Leaflets/Booklets was the format preferred by most of the respondents (42/99 = 42%), with the next most preferred formats being DVDs/videos and Others (21/99 = 21%); Audiotapes/CDs format was not selected by any of the respondents (Table 5.2.10). Others mainly included various combinations of all the other listed formats. Significantly more surgeon than nurse respondents selected Internet and DVD/videos as the preferred format ($p = 0.01$).

Table 5.2.11 Preferred format of a future patient decision support

Respondent group \ Preferred format	Surgeons N = 59 n (%)	Nurses N = 40 n (%)	P*	Total N = 99; no response = 81 n (%)
Internet	14 (24)	1 (3)	0.01	15 (15)
Leaflets/Booklets	20 (34)	22 (55)	0.06	42 (42)
DVDs/Videos	18 (31)	3 (8)	0.01	21 (21)
Audiotapes/CDs	0 (0)	0 (0)	Not applicable	0 (0)
Others	7 (12)	14 (35)	0.12	21 (21)

*p = p value from Chi-Squared Test, 95% CI, 1 df

5.2.6 Preferred patient role in decision making

All respondents reported a preference for a certain degree of patient involvement in the decision making process, with most of them (95/98 = 98%) reported that they preferred their patients to take on either an active (Options 1 and 2) or a shared role (Option 3) (Table 5.2.11). Approximately three times as many nurse as surgeon respondents selected Option 1 and this difference was significant ($p < 0.01$). On the other hand, significantly more surgeon respondents (nearly six times as many as nurse respondents) selected Option 3. Only three respondents, all surgeons, selected Option 4.

Table 5.2.12 Preferred patient role in decision making

Respondent group		Surgeons N = 59 n (%)	Nurses N = 39 n (%)	P*	Total N = 98; no response = 82 n (%)
Active role	Option 1: I would prefer to leave the decision about the diversion to my patient	6 (6)	20 (20)	<0.01	26 (27)
	Option 2: I would prefer that my patient makes the decision about the diversion, after seriously considering my opinion	18 (18)	13 (13)	0.94	31 (32)
Shared role	Option 3: I would prefer that my patient and I make the decision about the diversion jointly	32 (33)	6 (6)	<0.01	38 (39)
Passive role	Option 4: I would prefer to make the decision about the diversion, after seriously considering my patient's opinion	3 (3)	0 (0)	0.27	3 (3)
	Option 5: I would prefer to make the decision about the diversion	0 (0)	0 (0)	Not applicable	0 (0)

*p = p value from Chi-Squared Test, 95% CI, 1 df

5.2.7 Additional comments

Among the additional comments provided, two main points have been illustrated; one was that clinicians were generally inclined to leave the decision of diversion to the patients, as long as they are optimally informed and 'clinically suitable' to be considered for neobladder reconstruction as well as conduit diversion; the other was that supportive information materials should be available in various formats to suit the individual needs of patients.

5.3 Summary of survey

Below are the key points from the survey of both patients and clinicians which warrant further discussion in this thesis, in conjunction with the findings from the SWPHO-BAUS dataset analysis and the qualitative semi-structured interviews.

The patient respondents who reported to have had a choice of either conduit or neobladder as diversion options tended to be 69 years of age or younger at the time of surgery. Approximately half of these underwent neobladder, which was a much higher proportion than that demonstrated in the SWPHO-BAUS dataset analysis but perhaps this was due to the fact that the sample of the latter was much larger and more population-based. Many of the clinician respondents reported that they had 10 years or less experience in their role; this finding reflected the current responsible clinician workforce which is generally younger and less experienced. This could potentially ease promotion and dissemination the concept and application of SDM in the decision making process, as such a workforce is perhaps more aware of and receptive to use of SDM in their clinical practice.

The patient respondents were overall satisfied with the information provided on either diversion method; benefits, complications /risks and course of recovery were the three topics which most patient respondents were satisfied or very satisfied with. However, there remained a small number of cases where

respondents were not satisfied with or not informed about certain areas related to either urinary diversion method. Sexual matters appeared to be the topic which needed to be better discussed with patients for both diversion methods. In some instances, some or none of the information areas related to neobladder were not discussed by certain clinician respondents as such discussions were outwith their professional limits e.g. stoma nurses only counsel about stoma. However, in other cases the reasons for non-coverage of some or all information areas related conduit and/or neobladder were unknown. The fact that not all patients were at least satisfied with or informed about all certain areas related to either method of diversion were somewhat worrying; equally it was alarming to learn that not all information areas associated with each of the two diversion methods were covered every time by the clinician respondents, and not every instance of non-coverage was justified.

Conduit was generally better covered ('Discussed every time' or 'very often') by the clinician respondents. Furthermore, the nurse respondents appeared to cover the conduit and neobladder better than their surgeon colleagues in a number of areas pertaining to daily living with the diversion e.g. recovery after discharge, daily care, employment, leisure/sports/travel. The information areas which were most or least well covered did not necessarily correlate to the topics which most patient respondents were satisfied or dissatisfied with. The findings related to information coverage highlighted further the urgency of exploring into information exchange between patients and clinicians, regarding the choice of urinary diversion after radical cystectomy during the pre-operative period in the context of SDM.

A majority of the patient respondents valued their clinicians' input in the decision making process; surgeons and nurses valued each other's input. However, many patient and clinician respondents also valued the input from the individuals outside the responsible clinical team, especially spouse and former patients. Leaflets/booklets were the most popular additional material among both patient and clinician respondents, perhaps due to its availability and ease of use. More clinician than patient respondents found internet useful in the decision making process. Audio/CDs being deemed unhelpful by the greatest number of patient

and clinician respondents, perhaps due to the lack of visual feedback and access.

Most of the patient respondents felt supported during the decision making process; many also have mixed positive and negative feelings when faced with a choice between the two diversion methods. Only a few reported only negative feelings such as wavering and wanted to delay the decision. Positive feelings were probably linked with the sense of hope prompted by the availability of potential cure with the operation.

Printed format (leaflets/booklets) remained the most popular main format for a future formal decision support material among patient and clinician respondents. Many more surgeon than nurse respondents chose internet as a preferred current and future format which in itself was an interesting finding. As with a number of patient respondents, a number of clinicians stated that they would recommend a combination of different formats.

Almost all patient respondents reported that they were involved to the point they wished during the decision making process. All clinician respondents would prefer some degree of input from their patients, but among them many more nurse than surgeon respondents would prefer to leave the choice of diversion entirely to their patients, who were presumably suitably informed about their diversion options.

The findings from these surveys are cross-interpreted with the that from the SWPHO-BAUS dataset analysis and the qualitative interviews in order to obtain a collective understanding on the current decision making process related to choosing a urinary diversion after cystectomy.

Chapter 6 Qualitative Interviews with Patients: The Findings

6.1 The Five Emergent Main Themes

This chapter presents the findings from qualitative interviews with patients. Five main themes emerged from the data and are detailed as below:

1. **'Role of Responsible Clinicians in Decision Making'** describes the clinical encounters between the patients and their responsible clinical team (including surgeons and specialist nurses), including information on the two diversion options provided by the team and how this was delivered.
2. **'Role of Other Individuals in Decision Making'** describes the others outside the clinical team important in the decision making process, including the patients' families and extended social network, and former patients who had undergone cystectomy.
3. **'Use of additional information resources'** describes the additional information resources that the patients drew upon and how such influence in the decision making process.
4. **'Aspects considered in the choice of urinary diversion'** covers the main factors taken into account by the patients when choosing between the two diversion options, and how they deliberated over these aspects in order to reach a decision.
5. **'Engagement in the choice of urinary diversion'** describes the views of the patients on their involvement in the decision making process, their attitudes towards control over the choice of diversion and other healthcare decisions in general, as well as their suggestions on how to improve support for patients facing this decision over which diversion to proceed with in the future. Attitudes towards risk presentation are also briefly described.

All illustrative quotes in this chapter are indented, identified by the respondents' pseudonyms, age, gender and operative status (pre- or post-surgery and the elected type of diversion).

6.2 Role of Responsible Clinicians in Decision Making

The responsible clinical team serves as the main information provider for patients suitable for a conduit or a neobladder, before their radical cystectomy and urinary diversion. This information provision is predominantly verbal and takes place during clinical encounters between the team and the patients prior to surgery. It is sometimes supplemented by demonstrations with the actual diversion-specific appliances, such as urostomy bags for conduits and intermittent self-catheterisation (ISC) catheters for neobladders.

The data suggest that variations exist in the information delivered and the manner in which it is delivered. The main topics which the patients reported to be discussed by their clinical team included: external bodily appearance after surgery; the caseload, length and complexity of a given diversion procedure; and the risks and aftercare associated with a given diversion. With reference to Chapter 1 ('Introduction'), not all topics were covered or covered comprehensively, and indeed the patients at times appeared to be under-informed and/or misinformed.

6.2.1 Verbal Information Provision

6.2.1.1 External bodily appearance after surgery

A number of the patients reported on how their surgeons emphasised the near-to-normal bodily appearance after neobladder reconstruction as an advantage offered by this diversion option:

"[surgeon] said you will look perfectly normal [with neobladder]..."

(Ian, 68M, chose neobladder but post-conduit)

6.2.1.2 The caseload, length and complexity of diversion

A number of the patients recounted how their clinicians presented a conduit as the proven standard diversion method by quoting the relatively larger annual local caseload for this diversion:

"...[the responsible clinical team said conduit] is accepted as a standard operation – I think they [the responsible clinical team] said there was...how many...sixty was it in a year they had performed, so there's a lot of question-marks around that other operation [neobladder] still isn't there?"

(Terry, 63M, post-conduit)

A number of respondents reported on how their responsible clinical team cautioned about the

protracted nature of the neobladder procedure, by quoting the maximum number of hours it could take to complete:

"[surgeon] said that in both cases [conduit or neobladder] you remove the bladder you remove the prostate...with the neobladder...it takes anything up to 10 hours to do the job, it's a much longer operation..."

(George, 67M, post-conduit)

Furthermore, the data suggest that the neobladder procedure often appears to be presented to patients as being the more complex diversion method. The account below shows that some clinicians not only illustrate the neobladder procedure as more complex when compared to the conduit procedure, but they also appear to explicitly advise their patients against choosing neobladder. It was difficult to ascertain if the clinicians were considering the complexity of neobladder only in relation to the surgical techniques involved, or to the recovery period and aftercare, or to both.

"The stoma nurse had explained in more detail... and she said if you've got any doubt whatsoever, don't go in for a more complicated operation [neobladder]..."

(Terry, 63M, post-conduit)

6.2.1.3 Risks and aftercare associated with diversion

Some of the patients reported on how they were reassured of their survival through the neobladder procedure due to their age and fitness, by their responsible clinicians:

"[surgeon] was going on about like a bag was for someone of an older age...because I was younger and [surgeon] said it was quite dangerous for someone older to go through this operation [neobladder] if they were not fit, but because I was fitter [surgeon] said 'I think you'd get through this..."

(Steve, 47M, post-neobladder)

There were other patients reported on how their responsible clinicians illustrated a 'worst case scenario' for urinary incontinence after the neobladder procedure, by quoting maximum number of years before a patient would regain control over continence and a single patient story to highlight some of the dramatic measures undertaken by the patients to manage urinary leakage:

"...during the night particularly he [surgeon] referred to somebody whose practice was to go and have a few pints on Friday night and almost invariably leaks and wore a big nappy... most of the time though he said the sort of leakage that you're susceptible to can be solved just by a small pad tucked down in the underwear... he[surgeon] said you'll probably be able to be dry enough to resume a fairly normal life after about six months but you could be leaky up to a couple of years..."

(George, 67M, post-conduit)

Re-operation was another common risk to both diversion procedures. A number of the patients reported being informed of a higher risk of suffering from complications with a neobladder, which would necessitate a re-operation to convert the neobladder to a conduit:

"[surgeon] said that a few people actually change their minds after a while and after they have had the reconstruction finish up having the stoma [conduit] because he said there was more chance of things going wrong with that operation..."

(Greg, 59M, post-conduit)

Regarding diversion-specific risks, some of these can be life-threatening, difficult to rectify, as well as having far-reaching impact on quality of life. One of such risks is neobladder rupture. In the account below, the patient recalled this being emphasised by his responsible surgeon and the irreversible damage caused by neobladder rupture:

“[surgeon] said if you end up with a [neobladder] rupture it isn’t something that we can go in and fix...”

(Jim, 68M, post-conduit)

Parastomal hernia is a documented risk specific to conduit. A number of the patients reported not having discussed the risk of a parastomal hernia with their responsible clinical team. The account also shows how some patients have trivialised the impact of parastomal hernia as it was not discussed or discussed sufficiently with their responsible clinicians:

“[Have they [clinicians] spoken to you about the chance of getting parastomal hernia?] No they have not gone into that...but I can appreciate that... [doesn’t that bother you?]. no I guess that’s a revisit and stitch it back together sort of thing...”

(Martin, 63M, pre-conduit)

The aftercare of urinary diversion is another main topic that was discussed with the patients. In order to establish optimal functioning of a neobladder, patients are advised by their responsible clinicians to follow a highly regimented care routine especially during the initial few months after surgery, however despite this in the longer term the neobladder may still fail to empty efficiently and has become ISC dependent for emptying (see Chapter 1 ‘Introduction’). Several of the patients recalled their responsible clinicians portraying the regular emptying of neobladder through day and night for an indefinite period and the life-long necessity of performing ISC:

“He [surgeon] said after the operation you will have to wake up through the night, every two hours to empty the neobladder...for about I don’t know how long it was, it seemed forever and that’s a must you have to do

that, 'cos we don't want your [neobladder] to just get full and then stretch and not function at all' "

(Carol, 62F, post-neobladder)

"I think they [clinicians] gave me enough to be going on with but the self-catheterising for the rest of my life – that was the big influence on my decision-making... you know I've got to carry these sticks [catheters used for ISC] with me wherever I go..."

(Dave, 58M, post-conduit)

Some of the patients were also cautioned by their clinicians about the potential negative impact of ageing on one's capacity to manage ISC, as illustrated by the account account below:

"[surgeon] saying if you had a bladder reconstructed then you had to be reasonably agile to manage it... it was fine now but may be in older age when you can't see and your fingers don't work properly you might not be able to cope with it then if you have got to catheterise then you might not be able to manage..."

(Fred, 59M, post-conduit)

6.2.1.4 Responsible clinicians' opinion on patients' suitability for diversion

Some of the patients recounted how their responsible clinicians, especially their surgeons, provided their opinion on which diversion procedure to opt for when asked, as illustrated in the account below:

"[surgeon] did tell me that about 80% of the younger patients... he was saying sort of below 60 would opt for [neobladder] reconstruction... I'm always one for asking someone, 'well, if you were in my situation what would you do...?' he's a similar age and he'd go for [neobladder] reconstruction."

(Ed, 53M, post-neobladder)

6.2.2 Demonstrations with care products for diversion

Demonstrations by the responsible clinicians with diversion-specific care products (urostomy bags and ISC catheters) before surgery allowed their patients to imagine, if not to have a ‘taster experience’ of living with and caring for a given diversion (e.g. wearing a urostomy bag to bed, being supervised to perform ISC). These demonstrations played a role in managing patients’ expectations of a life with either a conduit or a neobladder and in assisting patients to reach their choice of diversion:

“...she [specialist nurse] give me some [urostomy] bags ... to fit and wear myself with some water in so I’d become accustomed to what it felt like to wear this bag... it’s not a disadvantage really ... it’s not even uncomfortable except if you crouch or bend ... but you get used to wearing it ... even in bed ...”

(Mike, 72M, post-conduit)

“...they stuck it [urostomy bag] on where it was going to be, and I had to come home and have it on for a couple of days and fill it with water... I was in bed, so you were moving about and you had a bit of leakage out of this water... at first I was determined that I was going to get the bag on... when I put the bag on when they showed me the bag... I changed my mind instantly... I don’t want the bag on, I didn’t expect them to be as big...”

(Steve, 47M, post-neobladder)

The timing of demonstration also matters in the decision making process. Ample time between the demonstration and surgery allow a patient to become more adjusted physically and psychologically to performing a given care routine, especially with an invasive routine like ISC. Consequently, a patient may find the routine more acceptable and therefore be more compliant with it:

“I went along with the stoma nurse just to make sure that I was capable of doing it [ISC] you know physically and mentally... I did start doing it for about a month or so before surgery and to be honest I didn’t like it at all... I would almost be dreading going to bed... thinking I’m going to have to catheterise myself... now I just accept it it’s like anything you can get

used it's like diabetics having to get used to injecting themselves all the time..."

(Ed, 53M, post-neobladder)

Due to the anatomical differences, female patients may find it more difficult to perform ISC. For some of them, to perform ISC independently and competently remains a struggle initially, even after learning with their responsible clinicians. Whilst this struggle can provide a more realistic picture of life with ISC, it can also provoke anxiety about the chosen option of a neobladder:

"... it [ISC catheter] was slippery... very hard to get hold of. You're not used to looking down there and if it goes into the wrong place you've got to discard it... it's so embarrassing to start with because you're trying to do this in front of the nurse... I had to have a mirror, she explained – I understood what I had to do exactly. But manually doing it as opposed to the theory of doing it were two different things...when I did it at home I had to sit on the bathroom floor with a mirror to do it and I really started to panic, it was that close to the operation..."

(Arlene, 54F, post-neobladder)

Many patients like Ed and Arlene above, are shown how to carry out ISC by their responsible specialist nurses in person. However, there are other patients who do not perform ISC in front of their specialist nurses, and therefore their competency in doing so is not evaluated before surgery:

"...[did anyone go through with you how to do the self-catheterisation?]... they gave me the booklet... [but you have to learn yourself...]... I think I can do it I have seen it anyway... [Have they checked you can?] They haven't checked but the booklet is self-explanatory and [...they are going to train with you [in hospital]?] Yes they are... because I will have the catheter on anyway because it's not the stoma [conduit] you know you understand..."

(Bill, 51M, pre-neobladder)

6.3 Role of Other Individuals in Decision Making'

6.3.1 Families

The decision on which diversion to proceed with can be influenced by the interactions between patients and their families. The decision is often reached after some negotiations between the two parties, and the spouse/partner appears to be particularly influential. Patients and their spouses/partners usually acknowledge each other's views on, and preferences for, the respective diversion options; however, as expected they are not necessarily in agreement with each other before the decision is made. Some patients proceed with their preferred diversion option despite their spouses'/partners' concerns over it, as demonstrated below:

"... my partner was actually pushing me towards the bag [conduit]... just go for the bag [conduit] she was saying, it's less messing about but I said no, it's my decision, I said I'm going to have that bag on for the rest of my life, I didn't like it, I wasn't comfortable with it, so I said I'm going to opt for the [neobladder], and once I'd told her she stood by me..."

(Steve, 47M, post-neobladder)

According to Steve, his partner voiced her views against his choice, although in other cases spouses/partners were more reticent with their views about the diversion options and supported patients deciding for themselves, as demonstrated by the account below:

"... he [Mike] wouldn't have a bag [conduit] ... well we [wife and family] liked the idea of that [conduit] for you, didn't we ... but I said to him [Mike], whatever you decide ... we'll go along with it but it must be your choice ... so we [wife, family and Mike] talked about it... and then finally he decided that he would have this operation [neobladder]"

(Mike's wife; Mike, 72M, pre-neobladder)

Sometimes the spouse/partner and family members facilitate the decision-making process by acting as the patients' advocates. They proactively gather additional information about the diversion options, raise queries with the responsible team, and clarify some information with the team:

"...my wife's always there... anything I don't ask or I forget to ask... she asks..."

(Ian, 68M, post-conduit elected for neobladder)

"My son was there as well... which was good because I might mishear something or have a different take and he [son] was like "what he [the surgeon] meant was"..."

(Terry, 63M, post-conduit)

Those family members who are more technologically inclined may look to the internet for information; however, from the data it is unclear how they judge the relevance and credibility of this information. Sometimes, through family members' extended social networks, patients can also acquire additional information about the diversion options which can prove to be helpful in the decision-making process, as demonstrated by Carol's account below:

"... she [daughter] had heard of somebody who had a neobladder and she'd gone on the internet and sifted the information that she thought I should know about really... and her boss... his mother had the neobladder operation 16, 17 years ago and so it was him [daughter's boss] who got her [boss's mother] in touch with her [daughter]... and that's how I started to think [about neobladder]."

(Carol, 62F, post-neobladder)

6.3.2 Former Patients

Pre-cystectomy patients are often put in contact with former patients through the responsible clinical team and/or their own family and social networks. The lived experiences after surgery told by former patients are a powerful agent in shaping a patient's decision concerning diversion after radical cystectomy; patients can either be persuaded towards or deterred from one of the two diversion options on the basis of these 'former patients' stories'. A former patient's portrayal of a seemingly positive life after a certain diversion introduces a degree of positive bias in the decision-making process; such a portrayal reassures a patient about his/her preferred choice of diversion and encourages him/her to proceed with it:

"... he [a former neobladder patient] is leading now a normal life and he had the operation about sixteen month ago... he said it took him a couple of months to become accustomed afterwards but he was able to control his urine function just using his pelvic floor muscle ... although he still has to wash out the new reconstructed bladder ... but he said that's really not a big thing ... he made me feel much better..."

(Mike, 72M, pre-neobladder)

Patients may also find the portrayal of life after radical cystectomy and urinary diversion more credible if told by former patients deemed to have similar characteristics, background and personal values. As a result, the stories from these former patients reassure some of the pre-surgery patients of their preferred diversion being appropriate for them:

"He was a climber and his biggest concern was dehydration but he gave me some confidence that he could climb on fairly serious stuff in France with the colostomy... and so speaking to a fellow climber was pretty positive and pretty handy... it [climbing] was something that was feasible [with a stoma]"

(Jim, 68M, post-conduit)

As expected, there are variations in former patients' post-surgery experience but from the data it remains uncertain how such would influence patients' ultimate choice of diversion:

"Now the neo-bladder lady [specialist nurse] put me onto a guy [fellow neobladder patient] who agreed to talk to me... we spent best part of an hour talking over the telephone, which was very useful... it might not be as bad as I thought it was but even five years later he was still having problems... if he drinks alcohol he can still be incontinent and he is wearing pads to protect himself at night..."

(Martin, 63M, pre-conduit)

"But the one who was five months in surgery and who was catheterising himself morning and night and another one who was ten years post-surgery who doesn't catheterise at all..."

(Ed, 53M, post-neobladder)

In order to gain a more comprehensive insight into life with either type of diversion, some patients may actively seek to speak with both patients living with a conduit and those with a neobladder. However, this may not be possible as there are relatively few patients living with a neobladder, as highlighted in the account below:

"She [nurse] said 'I really think you ought to speak to someone who's had the neobladder as well so you've got a balanced view' and I said yes... she [nurse] said I'd ask about it but maybe there's no-one available."

(Sharon, 56F, pre-conduit)

Some patients who are aware of the varying former patients' experiences chose not to hear about such, in order to avoid wavering between the two diversion options once the decision regarding diversion has been made:

"... I've already got me mind set on it [neobladder] ...if you talk to other people, he might say he is really glad he had it done, he is brilliant, fantastic... but you might talk to somebody else who didn't go so well and pee himself all day and put you off..."

(Brian, 53M, post-neobladder)

6.4 Use of Additional Information Resources

There is a wealth of resources which contain information pertaining to the decision over urinary diversion, which is in addition to the information (usually verbal) obtainable from the responsible clinical team and other individuals. These resources vary in formats and authors. Common formats include printed literature, internet websites and some audio-visual aids such as DVDs. Non-profitable organisations (e.g. a local NHS trust), commercial companies (e.g. stoma bag manufacturers) and patient support groups can all be involved in the compilation of such information resources; consequently, these resources may differ from one another in terms of wording, format, applicability and credibility. Patients are often introduced to resources before surgery, again by their responsible clinicians; however, sometimes patients seek such resources by their own initiative, with at times the help of families

and friends. The data suggest that these resources can influence the decision making process, and the format and authorship particularly impact on their perceived usefulness by patients.

Some patients find sifting through such additional information resources before discussing the diversion with their responsible clinical team helpful, as this stimulates them to question further regarding the decision on diversion. Moreover, these resources act as an *aide memoire* for patients on the salient points of previous discussions with their responsible clinical team. Bob and his wife recalled how the printed literature provided by their responsible clinical team assisted them in the decision-making process:

“[Wife: ... [nurse] have given us those booklets and then to go back and re-read everything that he’s told us... you just can’t take everything in ‘cause you are thinking I’ve got cancer I am going to die... so to be able to have the information in front of you written down and then you have a cup of tea, think about what’s going to happen...] we were reading beforehand so it meant that we had the right information, the right questions to ask [the responsible surgeon]”

(Wife of Bob; Bob, 54M, post-conduit)

With the recent advances in technology, the internet has become an important portal for accessing health information. Mixed feelings on internet-based information were reported by some of the respondents, with the trustworthiness of this kind of information a particular concern:

“...my experience of the internet is there are masses of information...you can drown yourself in the information and end up with information you’re not sure what its source is...you might really spook yourself by reading something from somebody who is a nut case...”

(Jim, 68M, post-conduit)

Additional information resources which are more technologically-based may pose issues of access and utility for some patients. These patients may simply not have the means to access them, or do not know how to negotiate through the technologies and make use of the resources. Bill explained his difficulties with the more technologically-based information resources:

"I could go through the internet because I've got a library...I don't have it [internet] where I live because I haven't got a phone line..."

(Bill, 51M, pre-neobladder)

The layout and language of a particular additional information resource can also influence its acceptability and perceived usefulness by patients. One respondent found the language used in an information website hosted by a certain national cancer charity condescending. She also found the layout of the website 'non-user friendly', since it would not allow her to directly access the information relevant to her own condition:

"...I just think it hooks you into all other sorts of cancer...I wanted something which was just about my area of interest...straight in. Parts of the website which I think – I'm going to use the word 'patronising' – I just want the facts, I don't want to be told 'please don't worry about this'. I'll worry if I want to, you know?"

(Sharon, 56F, pre-conduit)

To some patients, having information concerning both types of diversion contained in one single resource would allow for an easier, fairer comparison between the two, as noted in Pete's account below. He asserted that having information on each diversion presented side by side would allow an immediate and more balanced comparison between the two types of diversion:

"I don't think you should have a booklet that just concentrates on one [diversion]... you can't really have a booklet that's telling you to have a stoma... that's more or less saying this is what you need... the balance [of information on both diversion options] is probably better in one book even if it's a thick one... rather than have it [information on a diversion option] here and the other one over there and not bothering to go and read that one..."

(Pete, 69M, post-neobladder)

Although the additional information resources have their functions in the decision-making process and are generally appreciated by patients, but to patients the clinical encounters between themselves and their responsible clinicians, with the information transfer which occurs during these encounters, remain far more influential on the decision making process. In his account below, Brian explained how he viewed these encounters as irreplaceable, affording immediate opportunities for patients to address their queries and concerns:

“... so obviously computer is as good as any assets definitely, but at first you were bit... until you talk to somebody face to face... computers are brilliant way of getting an information to people, but there’s always a question people want to ask ain’t it...”

(Brian, 53M, post-neobladder)

The concordance between the information acquired from the additional information resources and that from the responsible clinical team provides reassurance to patients on what they understand about the diversions and the competence of the team, and they become more positive about the prospect of their chosen diversion:

“For me having them [the responsible clinical team] to explain to me over and above the written is very reassuring because you feel confident that these are the people who are going to be dealing with me... ... to me seem like they know what they’re talking about... it’s invaluable that face-to-face contact and explanation above and beyond paperwork... they confirmed all that you’d read about it either online or wherever you got that information from...”

(Tony, 64M, post-conduit)

6.5 Aspects Considered when Choosing between Ileal Conduit and Orthotopic Neobladder

From the data, there are three emergent aspects considered by patients when they choose between the two options of diversion, namely: external bodily appearance; history of success, duration, complexity and risk of re-operation related to diversion procedural outcomes; and managing urinary leakage. These aspects largely overlap

with what was mentioned in the first two main themes, and the ways in which patients deliberate about these aspects have a direct bearing on the final choice of diversion. Patients' deliberation processes are largely influenced by their encounters with the responsible clinical team and the other individuals who have a role in the decision making process; and in turn these encounters shape the knowledge base for deliberation. As exemplified by a number of accounts in this section and the rest of chapter, this knowledge base is often insufficient for making the decision on diversion.

6.5.1 External Bodily Appearance

The urostomy and urostomy bag are viewed by some patients as a disruption to their usual anatomy, whilst an intact abdominal wall with a scar better resembles 'the normal body' and instils a relatively stronger sense of 'the normal body'. The desire to preserve the sense of 'normal body, normal self', and the avoidance of potential stigmatisation by society following a urostomy compel many patients to select a neobladder, as illustrated in the accounts below:

"The idea of clanging something on your body outside is... it's not what you would expect to see in a mirror... I think there's a bit of vanity comes into it as well...that you want to look just the same."

(Ian, 68M, post-conduit but elected for neobladder)

"... you are working in a factory you carry a [urostomy] bag and [it's like] hang on be careful he's got some... you'll be liked disabled now because you've got something missing that other people have... when you don't have [a] bladder... maybe tomorrow you meet a nice woman as well... I'd rather not be with the [urostomy] bag."

(Bill, 51M, pre-neobladder)

Some patients are more accepting to the idea of living with a conduit and consequently choose a conduit over a neobladder for a number of reasons. By successfully concealing the conduit with under-garments, these patients are able to retain a sufficient degree of a sense of normal self which persuaded themselves towards a conduit:

"...body image is important... I like to dress well, I take care of myself... but I think I can conceal it [conduit/urostomy bag]... when I had the trial [urostomy] bag on actually I felt quite relieved that it didn't look so awful... I'm also appeasing myself by thinking nowadays these pouches [urostomy bags] you can get them in different sizes... and you can get underwear and stuff that you run in... like a sports bra kind of keeps you in place..."

(Sharon, 56F, pre-conduit)

6.5.2 History of Success, Duration and Complexity and Risk of Re-Operation Related to Diversion Procedure

As mentioned previously, the conduit procedure has well established evidence base of success, as measured by a range of outcome parameters. This is reassuring for many patients and as a result, they view a conduit as the 'gold standard' diversion to have and err towards it during the decision-making process, as shown in Terry's account below:

"...there were thousands of people that had a bag fitted [conduit] without any visible signs of torment or trouble, and it was a well... sort of well recognised form of operation."

(Terry, 63M, post-conduit)

Duration and complexity, as well as the risk of re-operation associated with a diversion procedure are also important considerations to patients. When compared to the conduit procedure, the neobladder procedure is relatively lengthier, as well as often being described and viewed as more complex. To some patients, a perceivably longer and more complex procedure such as that for neobladder would translate into a higher risk of suffering adverse outcomes (including mortality), and subsequently being deterred from the neobladder option:

"I mean a 10-12 hour operation [cystectomy and neobladder reconstruction] if I survive it you know... whereas stoma [conduit] solution is probably half that I guess...well I think the length of it [operation] must increase you risk."

(Martin, 63M, pre-conduit)

"...it [conduit] just seemed a lot simpler procedure, recovery rate was a lot quicker, probably the success rate is a lot higher... that's basically why I went for it... I thought it [neobladder] was a more intricate operation... I think you're more prone for things to go wrong in later life..."

(Ken, 63M, post-conduit)

Together with some of the other accounts in the first and this current main theme, the ones below highlight the issue of patients reaching a decision on diversion based on inaccurate information and /or misunderstanding of information on the two alternative diversion procedures; specifically in the accounts below, the respondents made their choice on diversion with erroneous ideas about the surgical anatomy and the technical details concerning either diversion procedure (e.g. how the internal organs are involved) :

"...and then when I asked [the responsible surgeon] she explained everything to me, I said I was just a bit worried about having like, messing about many things inside me, with my bowels and everything else...but she said well I 'am going to have to take a piece of your bowels anyway to make a stoma [conduit] so I thought, I might as well go for the other [neobladder]"

(Steve, 47, post-neobladder)

"...when we came out we both talked about why they would want you to have a new bladder [neobladder] made out of something that has cancer cells in it. If it is affected why would we want to do that?... I think we had already made our minds up that there was no way that you wanted anything affected [by cancer] staying in your body, you wanted it all out..."

"

(Wife of Fred; Fred, 58M, post-conduit)

At any point in time a diversion created can malfunction to the point where a reoperation is warranted; the reoperation may involve a revision of the existing

diversion or conversion to an alternative type of diversion. The data suggest that a number of the respondents were aware of this risk with both conduit and neobladder; and ultimately it would be their understanding of, and attitudes towards this risk that would influence their final decision on diversion. To some of the respondents the prospect of re-operation was too bothersome and perhaps even daunting:

"... sometimes you know, if you go with the internal reconstruction of the bladder [neobladder] you have got to finish up with a second major operation to have that [neobladder] remove and have the conduit done so to me, I think one was easier than having two done as well."

(Greg, 59M, post-conduit)

However to the others, re-operation was akin to a 'safety-net' measure, an opportunity to rectify problems with the existing diversion. Interestingly, according some of the respondents' understanding there would be no available measure to rectify the issues brought upon by a malfunctioning conduit:

"...if things went drastically wrong then you can still have the stoma [conduit] anyway, probably have to have another big operation which won't be very nice, but whereas once you have the stoma [conduit] it's over and done with ain't it... "

(Pete, 69M, post-neobladder)

6.5.3 Managing Urinary Leakage

Leaked urine can be difficult to mask due to its visibility and smell. It is associated with many negative feelings and connotations which patients would like to avoid, including feeling and being stereotyped as a dependent and/or unwell individual:

"... he [GP] said you can mask a lot of things in what you do behind toilet doors or with clothes, he said what you can't mask is the smell, you know with a urine leak... he articulated what had been playing on my mind... it's the smell and obviously being wet ... also there's an association [of urinary leakage] either with being a child or being geriatric... I don't want to think that I'm not fit and well"

(Sharon, 56F, pre-conduit)

Patients hold varying expectations on and attitudes towards the level of urinary continence achievable post-surgery. Some of them look to regain total continence within a relatively short timeframe, whilst others accept a certain degree of leakage even in the longer term. Various measures exist for controlling urinary leakage as described before (e.g. pelvic floor exercise, ISC and well fitted urostomy bag hidden under specialist undergarments and ISC). In determining which diversion procedure to proceed with, patients weigh up the likelihood of achieving their desired/acceptable level of continence, against their anticipated time required and perceived invasiveness of the aforementioned measures to be used.

Some of the respondents who chose conduit had expressed the view that neobladder would fail to guarantee complete urinary continence (and the risk of urinary leakage would be ongoing), despite much time and effort had been invested into ensuring its optimal functioning:

“I would be prepared to do that [pelvic floor exercises needed to establish a well-functioning neobladder] for a limited time... but not do it forever. I would want to do that and think ‘Okay I’ve done my pelvic floor exercises, I’ve done this, I’ve done everything, but now can I just get back to normal’ and yet there seems to be no guarantee... what I’m picking up is there is a greater expectation of being dry with the [urostomy] bag than with the neobladder...”

(Sharon, 56F, pre-conduit)

On the hand, some of the respondents who chose neobladder appeared to be much more optimistic and confident about regaining complete continence, with some of the measures used in controlling for urinary leakage from the diversion:

“... the thing is that I am confident I can sleep through the night without leaking because I think with these pelvis exercises or something like that I feel like back in control... I am going to need [intermittent self-catheterisation – ‘ISC’] maybe for the first year, the second year...but I am hoping that I can get control of it [neobladder]...”

(Bill, 51M, pre-neobladder)

The measures employed to control urinary leakage may be effective, but may also interfere patients' usual lifestyle. A patient's level of acceptance of such interferences is implicated in the final choice of diversion. For instance, toileting, especially in a more public setting, seems to generate concerns among the male patients in particular; how accepting these male patients of being seen emptying urine from a urostomy bag versus that of carrying out ISC in a public setting seem to be the crux of their choice of diversion. To some male patients, being able to void into a urinal constitute part of their known normality/sense of normal self:

"...if I'm out in company and go to the toilet now I can either go into a cubicle and empty my [urostomy] bag in private or if there isn't one available I can actually stand at the bowl and I can just zip myself down, put the valve out...if I've got to start self-catheterising in front of people... I just didn't want to [do so]."

(Ken, 63M, post-conduit)

"...there's no stoma [conduit] there's no bag and I can still go and stand in a public toilet, you know stand at a urinal, I have to be quiet as ...if I had a stoma [urostomy] bag I wouldn't want to do that I'd have to go into a cubicle and empty it... so that straightaway is affecting the quality of life and freedom I would have..."

(Ed, 53M, post-neobladder)

Sleep disturbance caused by one urinary leakage control measure is also implicated in patient decision-making. The recommended need to regularly empty the neobladder throughout a 24-hour period (at least initially after surgery) dissuades many patients away from the diversion option, particularly those who are already suffering from poor quality sleep:

"I am an insomniac...the thought of having to get woken up every two hours through the night to go to the toilet, all parts of the training the [neo]bladder until you get the volume...up to where it should be, I was just not happy with that at all..."

(Martin, 63M, pre-conduit)

The perceived practicality of ISC in the context of work and leisure by patients also influenced their decision on diversion. Some patients find the urostomy bag a hindrance, whilst others find ISC an inconvenience in their lives:

"I'm never clean [to perform ISC]... [Wife: farmers and wagons...you can't always just stop and wash your hands] I mean if I put me hands in me pockets and there'll be bits of hay and straw and such like comes out..."

(Bob, 54M, post-conduit)

"I still cycle, I'm a keen cyclist and I go mountain biking and the thought of you know I was forever thinking if I had a stoma here and a bag there and I'm leaning over me bike..."

(Ed, 53M, post-neobladder)

As reflected by the above accounts, the acceptability of ISC to patients is strongly implicated in the final choice of diversion. From the data it appears that the respondents who were motivated towards neobladder would attempt to adapt to the idea of ISC through reading about it and practising it, in order to make ISC more acceptable to them:

"I mean the catheter [ISC] in itself is a frightening prospect, I don't like it at all do you understand that... and to have to do it... I can get used to the idea better."

(Bill, 51M, pre-neobladder)

The data also suggest that the respondents considered a number of issues related to ISC, including their anticipated frequency and duration of ISC; the potential impact of advancing age on their competence to carry out ISC; their previous experience with urethral catheterisation; and the potential interferences brought on by ISC with their work and leisure, as well as the dependence on ISC in avoiding serious complications associated with a neobladder.

In general, the respondents appeared to be aware of the possibility of ISC after a neobladder, but they held differing expectations of the frequency and duration of ISC required. Patients balanced such expectations against other perceived advantages and disadvantages associated with either diversion option, before reaching a

decision on which option to proceed with. For a number of respondents, ISC was already an unappealing prospect for a neobladder, and the anticipated frequency and duration of ISC and the associated inconvenience to their lifestyle made neobladder even less appealing to them when compared to conduit:

"... this [ISC] is actually quite common, and some people have to just do it every day...and I thought ouch hang on, what am I gaining?...let's say I'm average or worse than average I might have to fairly frequently self-catheterise... if it [neobladder] gets bunged up a lot, I'm then prone to lots of urinary tract infections 'cos the damn thing [ISC catheter] going in and out all the time."

(George, 67M, post-conduit)

"when I found out what it [neobladder] entailed for the rest of my life...self-induce yourself with a catheter for passing water, four or five times a day...I didn't fancy doing that for the rest of my life..."

(Dave, 58M, post-conduit)

Eye-hand co-ordination, dexterity and memory are all required in order to perform ISC satisfactorily, and all of which could deteriorate with age. Some patients hold concerns over their own capacity to manage ISC with advancing age and be dissuaded some from selecting neobladder:

"I would have been able to cope with it a lot easier, it [ISC] is something I would have grown up with and I would have managed it a lot better... I don't think I can manage it now; I'm thinking you know in 10 or 15 years' time I don't know what's going to happen, I might have rheumatism in my hands, I might not be able to [self-catheterise]"

(Ken, 63M, post-conduit)

A previous negative experience with indwelling urethral catheters, usually encountered after initial less radical surgery to treat bladder cancer, also impacted upon some respondents' views about catheterisation in general. In the account below, Tony spoke of his unpleasant experience with an indwelling urethral catheter after having undergone previous endoscopic surgery to control for his bladder cancer:

"The two operations I've already had I had extreme, excruciating pain to do with a catheter... then one nurse came on the night shift who had the golden answer to it and she just got the tubing and wound it all up and went like that and created a vacuum and all these clots came out... [anyone showed you what the ISC catheter looked like?]. No..."

(Tony, 64M, pre-conduit)

Another concern for patients when choosing between conduit and neobladder was their dependence on ISC and its use to avoid life-threatening complications, such as rupture. There are occasions where it is very difficult, if not impossible, to perform ISC; the worry about rupture on these occasions deters some patients from the neobladder option; moreover, they may feel this worry is limiting on their known lifestyle. In their accounts below, Jim and Dave discussed the relative safety of living with conduit against that of neobladder, in the context of their leisure activities:

"... if you are tied onto the rock on a belay and you need to empty your bag it is relatively easy to do...to self-catheterise and to remain clean with it all is quite awkward under those circumstances... if you are on a long pitch... it's taking quite a long time and you are certainly not going to think about emptying your bladder [neobladder] when you're hanging on for life...and so you can do without that being at the back of your mind; when you're mountaineering one of the benefits of or pleasures of it is that everything, your concentration is fully on what you're doing then."

(Jim, 68M, post-conduit)

"The fact that there's a possibility of it [neobladder] it could all disintegrate inside you, or break up inside of you if it gets too full, if you don't do this thing [ISC] three or four times, five times daily...I enjoy a couple drinks, so what happens when I've had three, four, five, six, eight whiskies...and it [neobladder] builds up...and if you forget [to empty], then what happens?"

(Dave, 58M, post-conduit)

From the accounts above, a number of aspects were given particular consideration in the patient decision-making process, namely: external bodily appearance; history of success, length, complexity and risk of re-operation related to diversion procedure;

and urine leakage and its impact. The data show that ultimately, the decision was associated with the personal importance placed upon these aspects:

"With the reconstruction [neobladder] the upside is you don't have the [urostomy] bag, the downside is it doesn't just automatically work you have to make it work... the clear upside [of conduit] is it's simpler, it's a much briefer time in hospital... the only things you have to learn to do are all the very simple things like how to put the thing [urostomy bag] on and take it off... I've been retired for four years and I love it, and I just want to get on with it, I've seen a lot less mucking about [with conduit] than reconstruction [neobladder]"

(George, 67M, post-conduit)

"I just remember thinking it [cystectomy + neobladder] was going to be a huge operation, and he [surgeon] did say if I went for the reconstruction [neobladder] it was a lot of work after the operation... I just thought well... 'I can do it, I can whatever he [surgeon] tells us to do, I'm sure I can do it'... as I say I just really didn't want to have a bag on if I could help it."

(Arlene, 53F, post-neobladder)

6.6 Engagement in the Choice of Urinary Diversion

After the initial few interviews, it had come to light that it was not always possible to distinguish between respondents' preferred and perceived control over the decision on diversion, with the use of Controlled Preference Scale (CPS). As reflected in Jim's account below, two potential reasons are: 1) the respondent's recollection about the decision making process was not entirely accurate 2) the level of the respondent's preferred control indeed matched with that of the respondent's perceived control; there are other possible underlying reasons which will be further discussed in Chapter 8 ('Discussions and Conclusions'). Nonetheless, the CPS stimulated some thought-provoking responses from the respondents and therefore, its subsequent usage was maintained, although primarily for eliciting the views of the respondents about their engagement in the decision making process:

"[B] is a bit of a contender but because the way I'd remembered it, he explained it in detail... I don't remember him in any way saying 'I think you should have this rather than that'... I remember him saying now you have the information you need to go away and think about it."

(Jim, 68M, post-conduit, Preferred/perceived role = B)

6.6.1 Patients to make the final choice of diversion

For a given healthcare decision there bounds to be varying levels of patient engagement. For example, some patients may be engaged with the decision-making process throughout, but wish to delegate the final decision to their responsible clinical team. In general, the respondents reported that the ultimate decision on diversion should rest with them, but at the same time the decision-making process should be a joint venture between themselves and their responsible clinicians. There was a power imbalance which stemmed from the existing medical knowledge gap between the two groups, and as reflected in Steve's account below this gap was acknowledged by some the respondents and at the same time, they entrusted their responsible clinical team's expertise to guide them towards a decision:

"...it was my responsibility to go for the decision, but I wouldn't like to think I was just going to make the decision... you'd want to speak to your consultant about it... to know all the pros and cons... they know the best... at the end of the day it's my decision that counts but it would be nice [for the surgeon] to go through everything with you and sit down and talk to you..."

(Steve, 47M, post-neobladder)

Some respondents reported the view that, it was acceptable for the responsible clinical team to finalise the decision on which diversion on patients' behalf, so long as the team had held dialogues with the patients concerned and taken into account their clinical and personal circumstances; moreover, making the decision could prove to be onus for these patients, and thus forcing them to have the final say might be ethically unsound:

"... maybe we [patients] are not in the best position to decide... because you [surgeons] have all that expertise... listen to my circumstances

personally and socially and of course medically and you tell me what you think it's the best thing – what's wrong with that? Stop sitting on the fence... choice is a tyranny often... it can be a burden; it confuses people and they could take the wrong decision..."

(Sharon, 56F, pre-conduit)

On the other hand, some respondents reported the perspective that, careful, detailed counselling provided by the responsible team was key in empowering patients to finalise the decision on diversion for themselves, and even when the patients were unkeen to do so the team should refrain from finalising the decision for patients:

"He [the patient] definitely wants a little bit of guidance on he's got to know both sides of it [conduit/neobladder]; someone [from the responsible clinical team] must seriously sit down and talk with him and say this will be the best option and explain why... it can't be left up to the doctor to decide what's best for him... frankly tell him you're not going to do the operation until they make a decision..."

(Ken, 63M, post-conduit)

The societal-cultural context in which patients have been brought up may be implicated in their willingness to make a certain healthcare decision and to engage in the decision-making process; certain groups of individuals, such as the elderly, are perhaps more accustomed to the authoritarian model for the patient-clinician relationship. Acknowledgement of this potential influence on patient decision making in general by patients is reflected in Ed's account below:

"...some people just won't have the confidence or the willingness to want to get involved in... probably an older generation is probably more used to being told this is what you need... I don't think it's necessarily right to

try and force people to take more responsibility for that decision if they really don't want to."

(Ed, 53M, post-neobladder)

6.6.2 Enhancing Patient Decision Support and Patient Engagement

Many respondents reported the view that, the additional time and efforts invested by their responsible clinicians in discussing the diversion options would be the key to enhance patient engagement in the decision-making process. One respondent, Ken, thought that even when a patient is willing to delegate the responsibility of final decision-making to a clinician, the clinician should nonetheless explain the rationale behind the suggested option:

"He [patient] definitely wants a little bit of guidance on he's got to know both sides of it and someone must seriously sit down and talk with him and say this will be the best option for you rather than that and explain why... if I went into the hospital and turned around and said I'm not bothered... and then a year or so further on... and I think 'oh I don't want this I should have had other, I'm going to sue them because they didn't give me a choice'..."

(Ken, 63M, post-conduit)

As Sharon highlighted in her account below, being in a private environment and made to feel at ease meant that she was subsequently more enthused to ask questions and explore concerns:

"but [registrar] has given me two long sessions to take me through the options and both of those sessions were in private... Instinctively I think he understood that privacy was important to have such a conversation because I had lots of questions... so people have given me time, but I have felt more able to ask questions when I've been private"

(Sharon, 56F, pre-conduit)

The dynamics between patients and clinicians during their encounter also have a crucial role in patient decision making related to diversion and other healthcare

decisions. For some respondents, the responsible clinicians' ability to evaluate individual patient information needs would be essential in enhancing patient engagement:

“The role of the professionals who get face to face contact is in sensitively picking away through how to counsel that particular patient... there are some broad principles that he [Surgeon] and colleagues would need to apply which they would need training on... what patient is in front of them and then gauge what style, what kind of information should be given to them...”

(George, 67M, post-conduit)

Some patients are certain about which diversion method to proceed with by the time they meet with their responsible clinical teams, and how the teams illustrate the other diversion method, given the knowledge of their patients' prior preference, is also influential in patient decision-making. Tony felt that his clinicians should have better maintained the balance between the information given on a conduit and that on a neobladder, in terms of the amount and depth:

“Probably deeper explanation of the non-stoma alternative [neobladder], I know I had already made my mind up [about conduit] by what I'd read about... and I think that came across to [Nurse] and to [Surgeon]... they didn't try to put me off it but I wonder if I hadn't been as certain in my own mind when the process started whether they would of spent more time explaining the alternative...I'm aware of how the alternative works but it wasn't given to me in like a clinical way... if you're talking about this engine is better for you than that one you would say this engine has got this and that engine has got that...”

(Tony, 64M, pre-conduit)

However, as explained by Ken, sometimes, depending on how firmly a patient stands by his/her choice of diversion, further efforts from the clinical team to engage a patient regarding the alternative option is futile:

“... he [operating surgeon] asked me basically had I really made my mind up on which way I was going to go... and I said yes... giving my

explanations...They [reconstruction nurses] rang me up to try and get me back to have another talk about reconstruction to make sure I was really clear in my mind and I said no I'm not coming because... we're 100% committed to this [conduit] what we want..."

(Ken, 63M, post-conduit)

With respect to the proposal of formalised decision support for patients in the future who are facing the two choices of diversion, respondents were generally supportive. They also made a few suggestions for future decision support, one of which was to incorporate information into a decision tree. The timing of delivering decision support before surgery was also considered to be important, and Ken felt that it would be helpful to provide patients with support when they were first informed about a radical cystectomy and the two options of diversion methods:

"...I said I call it a decision tree...these are the basic decisions that you need to make and these are the advantages and disadvantages with these options...it directs you to where all the support and information is..."

(Ed, 53M, post-neobladder)

"I think a question and answer session which could be given out to a patient when they are first diagnosed with whatever, especially if you have got a choice of what you want to do, a tick box, if you went down this route this is what's going to happen..."

(Ken, 63M, post-conduit)

It is often said that a picture paints a thousand words, and many respondents regarded the realistic, graphical information available for a conduit to be helpful in their decision-making. One of the reported reasons for this was that many were unfamiliar with a conduit, and the visual presentation of a conduit and its management, perhaps via an audio-visual aid, helped patients to picture what a conduit would be like and to mentally rehearse the care routines required:

"...how do you deal with another orifice that you have never had before and perhaps a video, perhaps some more diagrams showing what a

stoma [conduit] looks like, photographs of stoma...the fitments that go onto the stomas..."

(Jim, 68M, post-conduit)

However, audio-visual information was not welcomed by everyone. Some respondents, like Carol and Bob's wife, were apprehensive about the operational aspects of viewing audio-visual information such as a DVD, as referencing back to information on a DVD can become bothersome:

"I think it's an age group thing...I would rather read about something but I think I'm quite technically minded but not as technical as the generation coming through... "so if I've got a CD I wouldn't have put it on..."

(Carol, 62F, post-neobladder)

"[Wife: No well we wouldn't put a DVD and watch it...I need to, I need things to be written down ...I need to be able to go back to it and flick back through it, were you 'd have to keep shoving a DVD in wouldn't you and recording and rewinding...]"

(Wife of Bob, 54M, post-conduit)

6.7 Summary

This chapter provides an insight into how patients choose between the two diversion methods, an ileal conduit and a orthotopic neobladder. Both the responsible clinical team and other individuals outside this team are significant in shaping a patient's preference for and ultimately the decision concerning the diversion to proceed with.

From the first meta-theme, 'Role of the responsible clinical team', the team most often inform patients about the two diversion methods verbally, sometimes supplemented through the use of diversion-related appliances, such as urostomy bags and ISC catheters, to help inform the patients. A range of topics pertaining to the choice of diversion have emerged from the data, and the delivery of such by the responsible clinicians was often injected with clinicians' opinions, as reflected in the respondents' accounts. Demonstrations with appliances assisted a number of respondents to build a more realistic picture of living with each diversion method, and

based on this expectation some then adhered to or revised their initial choice of diversion. These demonstrations also helped to build a patient's confidence in caring for his/her chosen diversion.

The influences of some individuals outside the responsible clinical team on the decision-making process, such as spouses/partners, family members, and former patients, are highlighted in the second meta-theme, 'Role of the individuals outside the clinical team'. The opinions of family members can impact upon a patient's decision on diversion; moreover, the decision-making process can be facilitated by family members who advocate for patients in a number of ways. Family members can retain information from clinicians which might have otherwise forgotten by patients, raise patients' concerns with the responsible clinical teams, and seek additional information on diversion on behalf of patients. The information provided by former patients is concerned with their individual experiences of living with a particular diversion. As demonstrated by the data, positive experiences with a certain diversion method can sway patients towards that method. Meeting both former conduit and neobladder patients can provide a more balanced picture for pre-surgery patients on what life can be like with either method. However, the number of patients who have undergone a neobladder formation remains relatively small, and the 'availability' of former neobladder patients can be an issue. Some patients did not want to take up the offer to meet with former patients in order to avoid wavering between the two options of diversion.

There is also a wealth of additional information resources related to diversion, which are available in a range of formats. It is outside the remit of this study to formally evaluate the quality of these resources. Nonetheless, some respondents shared their views on some of these resources in the third meta-theme, 'The use of additional information resources'. From the data, some of the resources facilitate a dialogue between patients and clinicians, regarding radical cystectomy and diversion.

Collectively, the first three meta-themes illustrates that apart from what information is presented, the manner in which it is presented is highly influential in patient preference development for a diversion method. This point gains further ground from some of the accounts presented in the next meta-theme, 'Aspects considered when choosing between ileal conduit and orthotopic neobladder'. This meta-theme presents the main emergent aspects under three sub-themes, relating to what

patients take into account when they are deciding between a conduit and a neobladder. These sub-themes are: external bodily appearance; history of success, length, complexity and risk of re-operation related to diversion procedure; as well as urine leakage and its impact. They largely mirror the information topics reported under the first meta-theme of 'Role of the clinicians'. From some of the respondents' accounts, the information gathered formed the basis for respondents' further deliberations about a particular aspect, e.g. one respondent understood from his clinician that ISC was a long-term necessity, and he then considered how this would impact upon his social life.

For the respondents, one of the most obvious advantages that a neobladder presented over a conduit was the absence of a conduit opening and urostomy bag. Preservation of an intact abdominal wall was of prime importance to some patients, as this would maintain their sense of 'normal self', while others were more willing to endure an indefinite period of disruption caused by certain measures employed in establishing and maintaining a well-functioning neobladder. However, for some these measures were too overwhelming, compounded by the lack of guaranteed continence from these measures, and these respondents steered towards a conduit instead. Moreover, the relative lack of a track record of success, the length and complexity of the neobladder procedure, as perceived by many respondents, were associated with their belief of having a higher chance of experiencing adverse outcomes. As a result, these respondents were more cautious regarding the option of a neobladder. Essentially, respondents tended to consider all three emergent aspects when choosing between a conduit or a neobladder. Patients assessed their personal values and preferences together with the various risks and outcomes associated with each diversion, before finalising their decision on diversion.

The last meta-theme, 'Engagement in decision-making', demonstrates some overall influences on patient decision-making. The data shows that in general, patients would like to be engaged in the decision-making process, and they highly valued the input from clinicians, with many of them wanting to take ownership of making the final decision. A few respondents found it acceptable for by their responsible clinicians to recommend or even choose the diversion to proceed with on their behalf, providing that the clinicians had taken into account their circumstances holistically and explained the rationale for their choice. Many respondents also appreciated that

enforcing engagement on some patients to come to a decision could be burdensome and possibly ethically wrong, in this decision and in a wider context.

The respondents also offered suggestions to enhance patient engagement, some of which were based on their personal experience during the decision-making process. These suggestions mainly concerned training clinicians to better evaluate an individual patient's information needs, and to be more mindful in providing balanced, neutral information about the two diversion methods. As regards the format of future decision support, respondents suggested the use of a 'decision tree' and a realistic representation of a conduit and its management, potentially through the use of audio-visual aids. The data provides an insight into patients' varying attitudes towards risks, and their responses to different risk presentations can impact upon decision-making. Survival through cancer is the top priority for patients, and whilst they would like to be informed of the risks associated with the diversion methods, the numerical probabilities are of less concern to them than undergoing prompt surgery for removal of the cancer. Those who have experienced rarer medical conditions may also have less regards for numerical probabilities of risks.

Chapter 7 Qualitative Interviews with Clinicians: The Findings

7.1 The Five Emergent Main Themes

This chapter presents the findings from qualitative interviews with patients. Five main themes emerged from the data and are detailed as below:

- 1. Patient's Suitability for Choice** illustrates how clinicians' views on certain patient characteristics, surgical experience, and inter-professional relationships that can impact upon decision-making concerning urinary diversion in the UK
- 2. Role of Clinicians in Pre-operative Counselling** describes the contents of the discussions and the varying manners in which they were conducted
- 3. Role of Individuals outside the Clinical Team** illustrates the clinicians' views on the potential influences of the individuals outside the responsible clinical team on patient decision-making
- 4. Supplemental Information Resources** encompasses the clinicians' views on the various existing resources used during pre-operative counselling as an adjunct to the face-to-face discussions between the clinicians and their patients
- 5. Patient Engagement in Decision Making** highlights the clinicians' attitudes towards engaging their patients in the decision making process and to making a decision; their opinions on how to improve the current decision-making process and their explanations for their preferred format for future formal decision support are also described.

7.2 Patient's Suitability for Choice

7.2.1 Age of Patients and Their Capacity and Motivation to Manage a Neobladder

The data suggests that a patient's age is a relative contraindication taken into account by many clinicians. The respondents were generally less inclined to offer neobladder formation to patients who were over 70 years old; nonetheless, a few respondents did acknowledge that a patient should not be denied the option of a neobladder solely based on their chronological age, and other aspects should be taken into account:

"... once they're [patients are] over 70 we would tend to veer them a little bit more towards conduit than orthotopic [neo]bladder, [however] if they have very good performance status and are very motivated we would not refuse them a neobladder."

(William, surgeon)

The data suggests that clinicians were generally sceptical of older patients' capacity to cope with a neobladder; such scepticism was seemingly founded upon evidence available concerning certain neobladder outcomes and a degree of stereotyping of older patients as less capable in managing the consequences of a neobladder:

"A lot of the very elderly patients that will not understand the ins and outs of a complex continent urinary diversion... you need to have complete mental faculties to know when to empty your [neo] bladder, how to empty and you need to be able to catheterise yourself or increase abdominal pressure ... I think a lot of them [older patients] would have problems coping with them [neobladders] and I think there is some evidence to say that the continence rates are not as good in the older patients with the orthotopics [neobladders]."

(James, surgeon)

There is also some degree of ambivalence among clinicians regarding neobladder formation as a diversion option with advancing age. This is perhaps evoked by the lack of evidence on certain longer-term outcomes of neobladder formation compounded by concerns over age-related deterioration of the physical capabilities impacting on care for a neobladder:

“... what I’m getting at is that the oldest neo bladder [patient] we’ve got is about 77/78 now... we don’t know what’s going to happen to neo bladders when they’re 85 and some of them will be frail.”

(William, surgeon)

“I’m more than happy to do it surgically ... that’s an interesting operation to do and when it works well there’s undoubted major benefits ... the other thing I do worry about them is... as people age ... their eyesight ... dexterity ... memory ... I think we are maybe storing up quite major problems ...”

(Karl, surgeon)

The above statements reveal some clinicians’ concerns when considering whether to offer older patients a neobladder based on assumptions about a patient’s current and future physical ability to manage the diversion and its malfunctioning.

Another aspect many clinicians take into account when determining a patient’s suitability for choice is a patient’s apparent motivation to care for the diversion, as perceived by them. The data suggests that typically, this judgement on a patient’s motivation is again mainly on the basis of clinicians’ intuition, with the feedback from a patient’s outward appearance and their body language, verbal feedback and questions they ask about a neobladder during the consultation:

“There is the halo effect... A patient walks into a clinic and I get a sense of what things are like. I mean clearly those who are very disinterested, ‘I have got cancer I just want it out of my body if it means a bag so be it if it is quicker’... I think the motivated person is one who would show interest and say ‘tell me more about this and more about that and how it is going to impact on my work and my lifestyle, relationship and so on’...”

(Anil, surgeon)

“... you are just observing their body language and of course with reconstruction [neobladder] you always have to sort of underline how much more is needed from them in terms of looking after themselves and you will need to come back into hospital it is more care of the bladder, you will may be need to use a catheter and sometimes these things are

deal breakers straight away... you can see them thinking 'oh my goodness no...'”

(Emma, nurse)

Some clinicians also make assumptions concerning a patient's ability to cope with diversion care in relation to certain health behaviours, such as alcohol excess, which would go against offering a patient a neobladder:

“...one of my youngest cystectomies who just turned 50 and he was otherwise reasonably fit and well... but he was a known alcoholic... had a tendency to relapse as alcoholics often do and that was the one reason why I didn't offer him an orthotopic [neobladder]... I told him that I had serious worries about his ability to cope with it...”

(James, surgeon)

Given the risk of patients with a neobladder being required to perform ISC, clinicians are averse to offering neobladder formation if there is a physical inability to perform ISC, even when a patient expresses a preference for a neobladder or when there is a carer to perform the intermittent catheterisation:

“... the spouse may drop dead from a stroke or a heart attack the next year and if they do that guy is stuffed he's either got to have an indwelling catheter, or get a district nurse in four times a day which is unreliable you cannot rely on that...”

(Jane, surgeon)

7.2.2 Surgical Expertise and availability of Post-operative Support for Neobladder Formation

With reference to the SWPHO-BAUS chapter, there is unexplained variation in neobladder formation across cancer networks, centres and among consultants. Some centres serve a wide area, which in itself presents challenges for follow up and ongoing specialist care and advice. This factor was also raised by clinicians when explain why they did not offer neobladder formation:

“...we do a fair number of patients from [smaller city] and beyond... we don't tend to offer those patients a bladder reconstruction [neobladder]... even there is a fairly big district general hospital they don't have

continence advisors that are trained in dealing with patients with bladder reconstruction so if they [patients] get into a problem and have a complication they could have 80 to 100 miles to travel to get back here for us to see them.”

(Peter, surgeon)

The likelihood of a patient being offered a neobladder as an alternative to a conduit can also be related to the experience of a surgeon and/or a centre as a whole in achieving favourable outcomes from this surgery. Surgeons establishing the procedure in their practice are appropriately careful in their approach. During establishment of being able to offer neobladder formation, some surgeons may preferentially select certain patients whom they believe would fare better, thus helping to start and sustain a local track record of satisfactory outcomes:

“... if I have had an elderly patient, say 70/72 who wanted a neo-bladder I would have probably sent them off to [centre 1] or [centre 2]... when we start... we have got to pick winners, we just wanted the young patients.... because we don't want to start doing this procedure [neobladder] and end up with all sorts of complications and then our confidence will fall...”

(Niran, surgeon)

In contrast, surgeon respondent Peter described how he had become increasingly comfortable with offering neobladder formation to a wider range of patients, as his experience with the diversion was maturing with a record of satisfactory outcomes:

“...and what became very clear sort of three years ago was that the peri-operative complication rate actually for neobladders was no higher than it was for the ileal conduit and the functional outcomes that we were getting were very good and so the way I talk to patients and my threshold changed. I would say that doing a neobladder is almost a default position and then you are looking for reasons not to do it...”

(Peter, surgeon)

Following on from Niran's comment above, the willingness of surgeons less experienced in neobladder formation to refer to colleagues at other centres also impacts on whether patients are offered a neobladder. For some clinicians their

feeling is that this may be more related to a patient's desire to have all their care locally:

"I think to be good at anything you need to be basically doing it every other week... I have only done one [neobladder] in three years you know is that justifiable that I should do them, I can do them competently... I am quite happy for patients to go down to [a larger unit at a fair distance away], I have not got a problem with that. Patients don't like it, you know..."

(James, surgeon)

7.3 Role of Clinicians in Pre-operative Counselling

7.3.1 Information Exchange Regarding Diversion

Much of the influence on patients' choice appears to be exerted through the exchange of information between clinicians and their patients, as well as amongst clinicians themselves. Both sets of clinicians seem to show an awareness of each other's impact in terms of guiding patients' diversion choice:

"I think when they [patients] come to speak to us they have been already filtered down... they may have a tip off from the consultant or the registrar as to which one [diversion] to choose so they have already had that seed planted..."

(Emma, nurse)

It appears from the nurses' perspective that surgeons have a primary impact on a patient's choice of diversion, but there were occasional surgeon respondents reporting their recognition of nurses' significance in influencing patients' choice:

"I think the nurses can influence the patients a lot because I have sent patients to see my nurse practitioners being pretty sure that they would choose a reconstruction and after they've spent an hour with the nurses they've come back and said they want an ileal conduit because I think up until probably a couple of years ago our nurse practitioners here were quite negative about bladder reconstruction... may be by the fact there

were another couple of surgeons who did reconstruction who had a fairly high complication rate..."

(Peter, surgeon)

Several nurse respondents portrayed themselves as advocates for patients' preference for one or other diversion option, and fed this back to their surgeon colleagues. A number of nurse respondents explained that the potential power imbalance between patients and surgeons might lead patients to settle with a diversion which corresponds more to their surgeon's preference, rather than their own:

"... [and the patient said] 'I want to have a stoma'... and I'll say [to the patient] 'well, is that your decision?' ... and if they say 'yes' then I'll tell the consultant... [the patient said] 'Well, I'm a bit scared in case he's [the operating consultant is] angry with us...' "

(Nancy, nurse)

The nurses can help address this imbalance, but this is dependent upon their readiness to feedback patients' preferences to surgeons and the working relationship between these two groups of healthcare professionals:

"... it helps if you've worked with the surgeons before because they kind of think 'well she does talk a bit of sense'... sometimes the ones that you've worked with for years, sometimes the ones that are very experienced can get a bit egotistical and say 'Well actually' you know 'I know what's right'; whereas the young ones who haven't got the experience, you can say 'Listen' you know 'I appreciate where you're coming from and I understand what you're saying but, in my experience, this is what I feel...' "

(Freda, nurse)

On occasions, general practitioners were also mentioned by the respondents as influential in the decision-making process:

"Well GPs have got a lot of input with it especially in the small valley areas like you know the GP is part, is a very big part of these communities and a lot of patients after they've been told will go to their GP to have a chat..."

(Ena, nurse)

There are suggestions from the data that both surgeons and nurses do clarify their patients' knowledge regarding the diversion options available to them. Although the preference for one or the other has usually been mooted by the surgeons, a number of nurses emphasised that they would re-establish patients' awareness that both options were open to them:

"... I would say to the patient 'right, I've come to talk to you today about having your bladder removed, did the doctor talk about having a bag on your tummy or has he talked about having a reconstructed bladder?' Some of the patients may say 'well, the doctor talked about both...'"

(Nancy, nurse)

The timing of when patients engage in the initial consultation with a nurse can impact on their capacity to retain and understand the relevant information, given the potential psychological turmoil resulting from the diagnosis of bladder cancer and the need for major surgery such as a radical cystectomy and urinary diversion. In general, the nurse respondents reported that from their perspective, the information on diversion delivered at an initial consultation with a patient should be tailored and guided by what a patient is deemed capable of taking about or wished to hear at this point:

"... so that would be the initial consultation. We don't like to do this the same day [of meeting the operating consultant] as they're told the information from the consultant because it just isn't productive because they're too stressed out to take on any more information...."

(Abigail, nurse)

"ideally I would like to see the patient [straight]after they've seen the consultant... either just to say 'hello, this is who I am...' and then either give them the option there and then to talk about the surgery in whatever depth they want to. But then have the opportunity to either bring them back again just to reinforce what we've talked about... the sooner we have first contact with the patient the better because they know who we are and they know what we stand for..."

(Nancy, nurse)

When a patient is not clinically suitable for neobladder formation, a number of respondents reported that they would be transparent in explaining to the patient why a neobladder was inappropriate; according to Linda, she did this in order to ensure that the patient felt that all options had been considered:

“... even if it’s a patient who can’t have one of the diversion options –... I would say ‘there is this option [neobladder] but I really don’t think it’s for you because you’ve had radiotherapy...’ So I say it to dismiss it... I don’t want to cause distress at a later stage when a patient comes along and says ‘why wasn’t I offered this?’”

(Linda, surgeon)

Given the amount and complexity of the information, as well as the potential emotional distress experienced by the patients, a number of respondents described the actions they took in helping their patients to be more informed. These mainly focused on checking patients’ understanding and retention of information during and after a consultation:

“I like them to come back on a second occasion so I can answer their questions, because sometimes people haven’t understood, they almost always haven’t taken it all in... on the second occasion we’ll go through their specific concerns and I’ll run through it again to make certain that they understand what the decision they’ve made really means, and they they’re happy with that...”

(Linda, surgeon)

“...I go through with them [patients] the very salient points about reconstructions [neobladder]... then ask them if they’ve got any questions and I will also ask them if they understand what I mean about pelvic floor muscle training... so sort of checking back they’ve listened... I wouldn’t say I formally assess it.... If at the very end they ask me a really obvious question that we’d talked about the whole way through that would probably tell me that they haven’t understood a word I’ve said....”

(Helen, nurse)

One respondent spoke of providing a document with the points discussed at the consultation for a patient to take away with them, in order to reinforce the information discussed:

“We’ve got some proforma we use which are sort of just tick boxes of all the different things we discuss and then they’d [the patients would] have a copy of those to take home with them... they have so many things to retain they’re not going to retain everything...”

(Sue, nurse)

Sometimes a patient is given the contact details of the responsible clinical team and encouraged to approach the team to resolve outstanding questions:

“So we always give them written information to take away with them, with our contact details anyway. I normally say to them you’ll probably forget a lot of what I’ve told you today, but if there’s anything that comes into your head phone us straightaway, don’t sit and worry about it.”

(Nancy, nurse)

As mentioned in Chapter 1, there are a number of benefits and risks associated with the two diversion options. In addition, outcomes after each of the two diversions may vary from one centre to another. A discussion of the centre-specific rates of complications may influence patients’ choice of diversion, and a few of the surgeon respondents reportedly used their local outcome figures and recognised the difference in organisational experience as impacting on the outcome:

“I’d say the complications are high but I don’t offer any figures mainly because the absolute outcomes with those orthotopics [neobladder]... I would say that there are centres of excellence that describe certain outcomes... they have a very unique set of outcomes which we have to be honest about that we’ve struggled here to truly recapitulate that... they tend to have a more authoritarian very strict driven approach to getting their patients doing their catheterisations.”

(Kumar, surgeon)

Several nurse respondents noted that they sometimes felt their surgeon colleagues ‘down-played’ the incidence and duration of some complications, and therefore patients could form unrealistic ideas about such complications:

“...what I don’t think the doctors emphasise strongly enough is the return to continence and what I find is that sometimes the doctors give a very false idea to the patients of how long it takes for them to be continent post operatively...”

(Sue, nurse)

One problem for patients with a neobladder is not being able to empty it efficiently with straining alone, and when such a situation arises ISC is needed. The clinicians interviewed had diverse views on whether ISC should be taught prior to surgery, and this was influenced by a number of factors, including personal opinion or local evidence on ISC rates, a patient's gender, staffing and time constraints, and the anticipated ability of a patient to cope with ISC:

“... we don’t always do that [teach the patient ISC before surgery]... because the proportion of men who do ISC after a neo-bladder is only about 10% [local figure] so I’ve not felt that it was essential to do that really. But I mean we warn more about it and if they show any concern about it then we get them to do it. Women we do because the hyper-contenance [i.e. unable to effectively empty neobladder formed]...”

(Stephen, surgeon)

“... very often you don’t have much time because they [the patients] may have already got their date very quickly and it’s very difficult to fit it [ISC teaching] in... sometimes if they’re highly symptomatic with low urinary tract symptoms it’s not always appropriate to go sticking catheters in and upsetting them.... I would ideally definitely teach all the women because it’s far more difficult for a woman to learn than a man...”

(Helen, nurse)

The respondents who did require ISC teaching pre-operatively as part of the assessment of suitability for neobladder formation reported on their perceived benefits of this practice, including helping a patient to obtain a more realistic idea about ISC and thus hopefully being better informed of their reaction if this became necessary:

“... I try to get [the patient] at the same appointment [initial consultation] if you can get rid of that fear... they’ve never heard of it [ISC]... so if I can take away some of the myths and worries then they’ve got a much fairer way to make the argument... if you send them away from that appointment and they’ve never done it already in their mind is ‘Well that seems a lot of hassle...’”

(Freda, nurse)

In order to enhance patient acceptability of the possible need for ISC, a few respondents deliberately sought to portray it in a more positive light and offered pragmatic solutions to anticipated associated problems:

“... if you tell them that it’s [ISC is] a little trick that they have to learn, and it is very easy to learn and you know once they’ve learnt it and it will not be a problem to them... what we say to all of them if they want to consider bladder reconstruction [neobladder] we teach them how to do intermittent self-catheterisation before the operation anyway... that usually allays most of their fears.”

(Peter, surgeon)

Similarly, simulated experience of life with a conduit by wearing a prosthetic urostomy or by wearing and handling urostomy appliances can also influence a patient's choice of diversion:

“...so it's like a little pretend stoma that sticks onto their skin and they [the patients] can have a try of putting a bag on... we let them handle them [urostomy bags] and feel them and often they might think oh, it sounds a bit crunchy, but normally once it's warmed against the skin and it's got urine in it doesn't make that crunchy like crisp packet noise... but we have had some hysterical outbursts, you know patients have looked at them [urostomy bags] and it's actually the reality of what's happening to them has actually just hit them...”

(Nancy, nurse)

“... I stuck it [urostomy bag] onto his abdomen and he went ‘well I’m not loving it...’ and I said ‘now I just want to talk to you [about ISC]’ [and he said] ‘No not interested.’ I said ‘I’ll just show you the catheter just so you

can see it', so I opened the catheter and I just seen his eyes change...and he ended up having his neobladder."

(Donna, nurse)

A few respondents described actively engaging their patients in the decision-making process; this included asking patients to share the reason(s) for their preference of diversion option:

"The things that you think are going to be important as a clinician, aren't always the same as what the patient counts as important... I always ask them when they make their choice (of diversion), why they made their choice. Just to try and educate myself as to how they are making their choice."

(Anne, surgeon)

Some surgeon respondents reported that they would urge their patients not to commit to a diversion option too early and encourage them to carefully consider their choice:

"[After seeing you how many of your patients proportionately speaking... have made up their mind about which diversion to go for?] What, after the first consultation? I tell them I won't accept a decision then. I say 'Now is not the time to decide'... the time of the first clinic appointment is not the best time to make a decision even if it is just go away and think about it overnight and ring me tomorrow if you are pretty convinced."

(Norman, surgeon)

Several respondents stated that consultant-led and specialist nurse-led consultations could differ in terms of the emphasis placed on certain topics, the time allocated for the consultation, as well as the perceived dynamics within the consultation. Consultants usually went into greater detail regarding potential complications, whereas specialist nurses would concentrate more on the recovery after surgery and the day-to-day practical management of a diversion:

"... I can concentrate much more on the complications and the operative problems just basically because I don't like it being thrown in my face afterwards that you didn't tell me about this... where the specialist nurses try to be I think reassuring to some extent..."

(Jane, surgeon)

“... we tell them [the patients] what to think about between now and coming into hospital, what will happen in hospital, as close as we can, give them an idea day by day what will be expected and then obviously we need to talk about continuity of care, follow up, support ...”

(Emma, nurse)

“...we can tell them more about is the functional day to day managing... the consultant's got lots and lots of, other things that they've got to be dealing with... ...”

(Abigail, nurse)

A specialist nurse-led consultation appears to provide a better environment for considered decision-making since a patient would feel less pressurised by time. Moreover, the dynamics between specialist nurses and patients can be more relaxed and as a result, more open to deeper discussion about the surgery:

“... nurses do tend to find more out about the patients... you can actually talk to them a little bit... more openly... and of course they [the patients] always say the doctors haven't got any time but they think... obviously we've got to give them a lot more time...”

(Karen, nurse)

However, it should be noted that such impressions may simply be speculation amongst the clinician groups, as only one respondent reported observing a consultant colleague talking to patients:

“... the big mistake I've made is I've not sat in with them [specialist nurses], so I don't know what their chat really involves all I guess, I've seen what they've recorded [in medical notes] and I see what they've dictated but erm they don't sit in with me and I don't sit in with them which is probably a real problem...”

(Oscar, surgeon)

“...I tend to go in with the consultant when they are talking to the patient so the consultant will talk about the two types of diversion... I think it is important for me to be involved when the consultant is talking to them

about a cystectomy so that I know exactly what the patient's been told and then I can measure what the consultant said and what I can see that the patient has understood..."

(Donna, nurse)

Some respondents seemed to believe that the degree of patient involvement in healthcare decision-making varied from one local population to another, and that this could be attributed to the 'local patient attitude' towards healthcare decision-making. Certain populations were less proactive and respondents considered that such patients would prefer being directed into a decision; moreover, they also attributed regional variation in neobladder use to the 'typical local personality' of patients:

"I think they [patients] like to be guided... some yes would definitely make their own decision no problem but a lot of them like to be guided, whether it's just the attitude of people in the [region name]..."

(Donna, nurse)

"... [a particular patient's] demographic makes you feel, well let's just do the conduit and get it done sort of thing I ... seriously I think that your average [person from local area] is less likely to be bothered about continence and more likely to [go for] the simplest thing [conduit]... 'get it over and done with, doc..'"

(Karl, surgeon)

7.4 Role of Individuals outside the Clinical Team

Clinicians' views on the role of others outside of the clinical team in decision-making was noted; these could be individuals asking questions about the diversion options, as well as expressing their own views about each option:

"...well definitely their partners, their wives or their spouse... because it depends if they could actually cope with them [patients] having a stoma or having a reconstruction. Because I have had gentlemen say 'I couldn't have the stoma because my wife said she would, you know, she wouldn't be in the same room as me..."

(Nancy, nurse)

“... this particular lady in talking to her we had a translator, we had her [patient’s] three sisters and her husband so it was a big crowd... I got the impression from the women’s face that she wasn’t liking what was being translated and the husband spoke quite good English and he said to me that what’s happening is they [the translator and three sisters] are trying to tell her that she should have the operation where you can’t see anything [neobladder]”

(Sue, nurse)

Former (peer) patients are another group who may influence the decision-making process, and indeed clinicians have actively sought to engage former patients by facilitating contact, but some were careful who they chose to introduce:

“...you need [former] patients that you can talk to, to discuss how they have got on with their conduit or with their neobladder... you have just got to be a little bit careful with those that they are not over enthusiastic... having spoken to a couple of patients that have come through who said ‘that guy was yeah, it’s [conduit or neobladder] the best thing since sliced bread you must have this.’ I want them just to be honest so you have to be a little bit careful with your volunteer patients...”

(Norman, surgeon)

In contrast, others said they welcomed having former patients who had experienced complications talking to patients prior to surgery:

“I mean I have had patients who have had complications and I really don’t mind that at all because I think it gives them [pre-surgery patients] a better understanding about well they have had complications.”

(Niran, operating consultant)

However, negotiating access to former patients can be problematic, particularly those who have undergone neobladder formation as they are fewer in number:

“It’s not an easy process for the orthotopic [neobladders] as well ‘cos there’s not many... [former patients] not always willing and there is not always a suitable person to speak to... you’ve got to have someone in the right stage of their recovery and give a balanced opinion of things...”

(Abigail, nurse)

7.5 Supplemental Information Resources

A variety of information resources are used by clinicians to supplement their pre-operative consultations with patients, and these are provided when patients have an idea that they are to be treated via a radical cystectomy and urinary diversion. These resources vary in content, format, accessibility and authorship, and thus their utility applies only in certain contexts. As informative as these resources seem at times, generally speaking the clinicians feel that face-to-face discussions that patients have with them and/or those outside the responsible clinical team, continue to hold primary importance in decision-making regarding diversion:

“... when I did a patient satisfaction audit [on utility of a DVD on urostomy and its care] they didn’t think that was very good; what they felt was the most beneficial part was talking to myself, taking to another patient who’d experienced it [urostomy]...”

(Ena, nurse)

Geographical variation in the availability of relevant supplemental information resources also appears to exist, and is particularly problematic for neobladder formation. The clinicians from some centres have produced supplemental information resources for neobladder formation for use in their local practice. In contrast, others use resources produced by other centres, with or without adaptation to their local organisational and demographic contexts; copyright issues are implicated in these instances:

“... the cystectomy and neobladder leaflets, I actually wrote in conjunction with the surgeons here... I did used to get phone calls from people saying ‘is it alright if we borrow it [the leaflets]?’... I was doing something last week and the [organisation] have got a leaflet on neobladders... and I am reading it thinking some of those sentences are my sentences.”

(Carla, nurse)

“... some pamphlets about the orthotopic [neobladder] procedure... we don’t have our own ones... I’ve previously just pinched the ones from

[another centre] off the internet when I've wanted to discuss it with patients..."

(Tim, surgeon)

Leaving the copyright issues aside, the use of supplemental information resources already produced is understandably attractive to some clinicians; however, the utility of these when used in another centre may not be appropriate due to variation in local organisational frameworks, surgical expertise, as well as patients' demographics and collective health states. There is also no evidence of the assessment of the utility of a 'borrowed' resource by the 'borrowing' clinicians. Clinicians who have produced local resources tend to feel it is their duty and it is more useful to share their local data concerning the diversion(s) on offer to their local population, as explained by Norman in his account below:

"I think you've got to produce your own for local use because I don't know translate or something or go to some big American hospital and use theirs but does that actually apply to what we are doing locally... I think you need to explain what you're able to offer for your local patients."

(Norman, surgeon)

Some clinicians noted that the relative lack of information on neobladder formation, as highlighted above, can lead to biased decision-making concerning diversion choice. This issue can be further compounded by not only the relative abundance and availability of information available on a conduit/urostomy, but also by the appealing, commercialised presentations of such information which is presented by the stoma care products companies. Although widely adopted, some clinicians are aware that this company-packaged information may be commercially biased, thus affecting the quality of the decision-making process concerning a diversion:

"... there is a really good [conduit/urostomy] diversion booklet that we use by [stoma product company]... you can send them [patients] away, there's a very good booklet for urostomy, but you can't send them with anything for reconstruction so they're biased already in some ways because they've got this lovely book that tells them all about the stoma and a very good picture of a stoma, it tells you about the appliances... You have to retain everything about the reconstruction in the head..."

(Freda, nurse)

“[...information for patients] to make a balanced decision, I think it’s appalling. I don’t think there is any information that I have read... that provides balanced information, they all have some sort of vested interest... there’s nothing to sell an orthotopic reconstruction [neobladder]... it’s more complicated surgery so the surgeon has to be better...”

(Oscar, surgeon)

As mentioned previously, supplemental information resources differ in their formats. Many are written and printed, and some include pictures/photos. There are also resources which are more technological in nature, such as audio-visual and internet based presentations. Clinicians may use a particular item of supplemental information on the basis of its format in order to, in their opinion, better convey certain salient aspects of a diversion procedure

From the data, the respondents appeared to use pictures and photos to mainly illustrate the anatomy related to a diversion procedure; the use of such to help patient decision-making was somewhat less obvious:

“... there’s a nice article in the BJUI [British Journal of Urology International]...that actually shows the how to do the surgery and it just does nice pictures of how the thing works so you just show it as a, as a kind of an aide memoire...”

(Paul, surgeon)

According to some of the respondents, DVDs/audio-visual aids provide patients with a more realistic idea about living with a certain diversion in a more time-efficient manner. However, it was apparent that the DVDs used were primarily orientated around conduit/urostomy, and these are most often produced by stoma care product companies:

“we use the [stoma product company] care pack [with video on urostomy care]... and I think nothing helps better than seeing it [conduit/urostomy] because it could take you three hours to do that [counselling about urostomy and its care] but you show a patient a video of somebody changing the urostomy pouch and in seconds you save yourself two thousand words because you patient is actually seeing what is going to be...”

(Abigail, nurse)

Although potentially useful in helping patients to choose between a conduit and neobladder, the use and utility of these supplemental information resources in audio-visual formats may be limited in certain organisational and demographic settings. For instance, some centres do not endorse the use of educational DVDs, and some patient groups simply have no experience in the use of DVDs. These limitations are acknowledged by clinicians and they still very much value resources in the written/printed format, as explained by Freda's account below:

"I do think written literature is extremely important because then they can take it away, they can read a little bit, they can put it away; they can read it again, put it away again. And they can pass it round their relatives as well who then have a different idea and can put their own point of view in as well... DVDs I think are useful, [but] there's patients who won't sit through all of that whereas they will look at a book... some patients in this area haven't got DVD players... there is a massive elderly population so they're just not familiar with that type of thing..."

(Freda, nurse)

There is also a wealth of internet-based supplemental information resources, some of which are accredited whilst others are not. Respondents were generally more cautious in recommending use of these resources, due to concerns over discrepancies in the information quality:

"I am very careful about this I don't encourage or discourage people from going into the internet. I'm just worried that they might go to sites that wouldn't be ideal to go into; if somebody wants to go into the internet and say 'Where do I go and see?' I will ask them to go round to the BAUS [British Association of Urological Surgeons] website..."

(Niran, surgeon)

"I think it has its place but it's an absolute logistical nightmare for nurses and doctors. There's no quality assurance. They go onto blogs, and there's sites like Samantha's Stomas and things like that, they have pictures of their stoma – 'I've had a really bad day, I've had lots of

problems, I've been in hospital' and the patients are like, 'oh, I'm not going to have that because you have loads of bother...'"

(Nancy, nurse)

Clinicians' main concern over 'authorship' (e.g. commercial vs non-profitable, professional body) of supplemental information resources seems to relate to its impact on the quality of decision-making concerning urinary diversion. From the clinicians' perspective, information from a non-profitable or professional organisation may not always be conducive a quality decision-making process. This may be due to a number of reasons, for example the make-up of the membership of an organisation and whether it includes a balanced representation of conduit and neobladder patients:

"The [registered charity] and the leaflets that they [patients] get out...but that's more towards promoting stoma [conduit/urostomy] and that's very positive... we don't have an orthotopic [neobladder] or a reconstructive association so it's not equal...the [registered charity] make a good job of minimising the problems associated with the stoma [conduit/urostomy], selling it, marketing it shall I say..."

(Tim, surgeon)

7.6 Patient Engagement in Decision Making

7.6.1 Attitudes towards Patient Engagement

With reference to the earlier meta-themes of 'patient suitability for a conduit and a neobladder' and 'clinicians' role in pre-operative counselling', clinicians make a judgement on whether both a conduit and a neobladder should be offered to a patient on the basis of the clinical grounds, as well as their rather subjective evaluation on a patient's capability in caring for either type of diversion. Clinicians in general appear to appreciate and are willing to include patients' input when there is a choice to be made between a conduit and a neobladder. None of the respondents reported not taking into account a patient's opinions regarding his/her decision, when a patient was deemed suitable for both diversion options and perceived to be optimally informed about the options:

"[So leave it [decision on diversion] all to the patients?...]... assuming that they're suitable for both and the patient is furnished with the correct

information... I'm presuming they've spoken to me about it, as part of that decision I wouldn't be happy for them to make their decision unless they were fully aware..."

(James, surgeon)

The surgeons in particular explained that in reality, a patient's choice of diversion may not be honoured always based on good clinical practice, and they make the ultimate decision on which diversion a patient is to undergo. Some of the issues leading to such a situation may not be apparent in the pre-operative period, such as urethral involvement with bladder cancer and intra-operative patient safety concerns. However, this does not necessarily mean that these clinicians have not engaged with their patients in the decision-making process:

"... intrinsically if you were doing the operation, you have to be happy that it is the right thing for the patient and even if you know ideally what you want is the patient to be on board, you're doing the operation that the patient wants... and I think the surgeon has to in the end say yeay or nay because if the patient dies on the operating table it's the surgeon who gets sued... in the end no matter how much adequate counselling you give it doesn't countermand clinical decision-making."

(Jane, surgeon)

"Because I'm the guy doing the operation and I have to make a decision at the time of the surgery as to whether it's an appropriate thing to do or not and that's 100% my decision... But it's based on what they want. They've told me what they want and I will do what they want as long as it's possible; as long as I think it's safe, but sometimes it isn't..."

(Stephen, surgeon)

As previously illustrated by the second meta-theme, 'clinicians' role in pre-operative counselling', a patient's suitability for the choice of diversion sometimes is less clear-cut to clinicians than that exemplified above. Clinicians then tend to rely on their professional experiences, sometimes backed by empirical evidence, at other times hunches, to make the judgement. For a patient who does not have an absolute

contraindication for the formation of a neobladder, it appears that his/her suitability for making a choice is often further evaluated according to his/her apparent willingness to make the decision and/or engage in the decision-making process. This willingness is often regarded by clinicians as a reflection of a patient's motivation to look after their own diversion, whichever one it may be. To some clinicians the neobladder becomes less suitable, if not unsuitable, if the patient concerned is seemingly less/unwilling to engage and/or decide. As has been highlighted, the demand on a patient to develop and maintain a functional neobladder is higher than for a conduit. Clinicians' views may be founded on their concerns over the anticipated increase in certain neobladder-specific risks, their seriousness and manageability with such a patient:

"[...but there are people would say "you decide..." what would you do in that instance...I try very hard to sway them to one side if I think they are not suitable for neobladder... I think everybody should have the choice but as healthcare professionals [we] had a lot of experience in dealing with patients... we have got good inclines on how patients are going manage... if you have a poor stoma [urostomy] you're wet all the time... but 9/10 times I normally can get a bag to stop you from being wet.. I haven't got patients out there who have problems with major leakage [with conduit]..."

(Ena, nurse)

"... and if they're taking that attitude then you know fine well they are just not going to cope. They're not going to involve themselves in their care, they're not going to pay attention to their neobladder; they're better off with something [conduit] that just blows the [urostomy] bag off [when the urostomy bag overfills]...['... it's very much about patient safety, isn't it?']... Oh, yeah..."

(Jane, surgeon)

A surgeon respondent who was early on his learning curve for neobladder formation, admitted his concerns over the expected increase in the risk of adverse post-operative outcomes with a patient in the context of his personal (and organisational) morbidity and mortality track record associated with neobladder formation:

“... the one patient I remember [who said] ‘Do what you want I don’t want to hear about anything’....even if he [patient] was suitable he would not have got a neobladder, I wouldn’t have offered a neobladder. Unless they show tremendous commitment [to look after neobladder]... especially since we have just started doing it [neobladder]... we don’t want to start doing this procedure and end up with all sorts of complications.”

(Niran, surgeon)

As reflected by Ena’s account above, some clinicians may guide or persuade a patient towards usually a conduit when they are less/non-engaging in the decision-making process and/or the decision itself. However, it remains obscure as to how these clinicians do so in reality. One respondent reported of his recognition of this as a far from ideal situation, at least in the context of decision-making, due to the further introduction of his own biases on the matter of the decision:

“...if they’re [patients are] uncomfortable with that [making the decision on diversion] then you have to help them make the decision, which is not ideal because then it’s not really their [patients’] decision because no matter how hard you try [not to], you are influencing them...”

(Peter, surgeon)

There are clinicians who are persistent in their efforts to obtain a decision from a patient and refrain themselves from disclosing their preferred diversion. Time spent discussing the decision with a patient, time for a patient to deliberate over the two diversions, and the amount of information on a diversion given, appear to be commonly regarded the as keys in assisting a patient to take ownership of the decision. Referring to the second meta-theme again, another factor according to some nurses is to encourage and advocate for a patient’s voice on the matter of the choice of diversion:

“...if they say ‘nurse, what would you have? And I say we’re not here to talk about me, and I don’t know what I would decide so we’ll go through the options again... the lifestyle so that you can make your decisions and you can sit there in front of me and say this is the right thing [diversion] for me to have done...”

(Nancy, nurse)

“... the patients often say “oh I’ll leave it [decision about diversion] to you”. What they mean is ‘I don’t particularly want to engage with this issue; I don’t want to have to stop and think about it, I just want you to get on and deal with me’ and what that requires is for you to spend more time with them... I don’t think that I’ve ever had a situation where having spent more time with them and having had the chance to talk it [decision about diversion] through with the specialist nurse, where someone [a patient] has still not been able to make the decision...”

(Stephen, surgeon)

7.6.2 Improving the Current Decision-making Process

A number of ways to improve the current decision-making process were suggested by the respondents. Some of these ‘remedies’ for the shortcomings in the current process tend to orientate around time for patients, patient knowledge, and patient advocacy, and mirror practices already adopted by clinicians in enhancing patient engagement in the decision and decision-making process; however, there was no direct mention of assisting patients to form their preferences:

“... to give them the time and to give them as much information...and to allow them to know that it is okay that they can just go down the route that they want to go down and you will support them as long as they know what they are taking on. As long as they take on board the differences between the two [diversion options].”

(Emma, nurse)

“... it’s giving them as much information as you possibly can that they can understand not just coming from me, but coming from nurse practitioners, coming from other patients as well so that they can then make a considered decision at the end of that process...”

(Peter, surgeon)

As discussed in Chapter 1, formal DS is aimed at improving the decision-making process for a given healthcare choice. Some respondents welcomed the use of such support for the decision concerning diversion and they appeared to understand this support as primarily a patient knowledge enhancer:

“...anything that informs the patient better has got to be an advantage... I think it [decision tool] puts it in a clearer way of understanding because I can talk to them for an hour, they can come back and talk again about it later on but if you’ve got a decision tool they can go back to it as many times as they want and there’s no bias there... often am concerned that I get to a point where I say ‘Look you’ve got to make your decision here, time’s running on’.”

(Freda, nurse)

Far fewer neobladder formations are performed overall and less is known about their ‘natural history’ or outcomes. This can adversely impact upon the decision-making process through biased counselling. According to one surgeon respondent, an antidote to biased counselling would be ensuring optimal patient counselling by clinicians with the relevant specialist knowledge on neobladder formation:

“...What he [a cyctectomist colleague from the same unit] would say ‘this [conduit] is an hour job, this [neobladder] is a three and a half hour job...’... it might take me three hours to do an ileal conduit, it might take me exactly the same time to do an Indiana pouch [a sub-type of neobladder] and patients come and say ‘actually I don’t think I want to stay under the knife or the anaesthetic for 6 hours.’ That was their reason [for not choosing neobladder]. So it was totally inappropriate for the person who is not doing the diversion to say anything about [neobladder] and we have rectified this now...”

(Anil, surgeon)

One respondent suggested that providing information about both a neobladder and a conduit prior to the consultation with the operating consultant would be beneficial to decision-making, as the patient would have more time to think over each option before discussing it. Moreover, the referring clinicians who did not perform the neobladder formation should make a point of discussing a neobladder as a viable option:

“I think they [the patients] need better information but they need longer to get their information they probably need more publicity at the lower level so as I said if our referring clinicians would be more upbeat about an orthotopic [neobladder], then you’d see more referrals in for it. All the

clinicians around the country to be pushing this at a lower level or to be talking about this at a low level of the districts referring him but in an ideal world that's what you would do..."

(Tim, surgeon)

Promoting access to former patients from similar backgrounds was also suggested as a means to improve current decision-making:

"I think it would be good to have easier access for patients to speak to other patients if they wish to 'cos sometimes... it's not always an easy process and it's not an easy process for the orthotopic bladders as well cause there's not many you know that's where it's a bit more difficult, too... [former patients] they're not always willing and one might so there not always a suitable person to speak to you..."

(Abigail, nurse)

Finally, a nurse respondent suggested that a stronger identity amongst bladder cancer patients as a group might be able to promote patient engagement in the decision-making process concerning cystectomy and urinary diversion:

"[...how can we encourage patients to be more involved in this decision-making process... (Sighs) I don't know because I don't think there is a strong identity in bladder cancer patients ... there was some research done from [university name] about bladder cancer patients not attending support groups [so is it a sense of belonging to a group that may make patients take more ownership [of their condition and management] I think it often does yeah..."

(Carla, nurse)

7.6.3 Preferred Format of Future Decision Support

When asked about the format of future DS, many of the respondents were in favour of a range of formats being available, but that these should not replace face-to-face consultations:

"... you need all of them I am afraid I think you need a written thing that they can take away that's written in plain language they can read at their leisure. You probably need a DVD or a You Tube site or something like

that, that they can have a look at. And nothing will replace the need for people to talk to so nurses, people who have had this experience before something like that...

(Tim, surgeon)

A few respondents elaborated on their perceived benefits of having a DVD as an integral part of future DS:

“... it would be good to have a DVD for patients to say actually I have had this operation and this is what I’m like and this is how you pass urine... I think it is quite powerful isn’t it? If you listen to a few patients talking about their experience of their operation and their management afterwards... you could get a balanced view from people who have had conduits and people who have had neobladders, both giving experiences of what they felt their operations were... [...but you have also got to be honest with them that some patients have very negative experiences of both...] But you will get that pretty well balanced won’t you?”

(Donna, nurse)

One surgeon suggested an interactive format to elicit patient’s preferences for longer-term outcomes:

“if we start putting together some kind of standard gamble kind of approach to this in an interactive way, it is quite feasible that we could come out with a result at the end in your position 4 out of 5 people have chosen this, or 3 out of 5 chosen this, these are the problems they have, this is why, these are the problems they suggested...”

(Oscar, surgeon)

However, although seemingly supportive of alternative formats for information, clinicians also noted possible challenges:

“... most of our patients are generally a bit elderly I think, we don’t get very many spring chickens here... I think internet alone for them will be a no go, a lot of them don’t even have a computer.... let alone the internet. And the younger ones from leafy [local area] I think that they will all be on internet and they will have no problems but from [City] don’t think that will watch much at all so I think they need booklets. They need individual

attention, they need to be told about everything, sat down and things gone through....”

(Niran, surgeon)

7.7 Summary

This chapter has reported on the findings from the qualitative interviews with clinicians. Clinicians determining the appropriateness of offering a patient neobladder formation as an option take into account a number of aspects, but patient age, surgical expertise, and organisational factors appear to be most prominent. Clinicians' judgement appears to be partly informed by the empirical evidence on the relevant outcomes, and partly by their own assumptions about a particular patient's capacity to care for a neobladder.

It is clear from the accounts that both surgeons and nurses consider themselves to be crucial sources of information for patients on the choice of diversion options after a radical cystectomy. Various measures are employed by clinicians to help patients retain and understand information on each diversion, which is predominantly provided during face to face consultations. Consultations led by surgeons differ from those led by nurses, with the former placing much focus on indications, contraindications and outcomes associated with a neobladder, and the latter tending to emphasise the daily care routine for each diversion. Nurses can also sometimes act as the advocates for their patients' preferences regarding diversion choice. There are clues from the accounts that not all clinicians feel that teaching of ISC pre-operatively is necessary and that it may not be in a patient's best interest.

Both surgeons and nurses acknowledged each other's influence on patient decision-making. In addition, both groups of clinicians found spouses, close family members and former patients as being individuals who can exert a significant impact on patient decision-making, sometimes for the better but not always.

Aside from face-to-face counselling, additional information materials are used and are regarded as helpful in promoting patient informed decision-making. Clinicians find various formats helpful, although written material was consistently utilised as the main tool to supplement face-to-face counselling. Not all clinicians were happy with the quality of the information currently available regarding diversion options.

Clinicians also appear to conflate informed choice with shared decision-making at times, with many respondents quoting that by increasing the amount of information available on diversion and improving its quality would lead to better patient engagement. Many of the proposals to improve the current decision-making process largely mirror that used in current practice; nonetheless, some new suggestions were made, such as promoting a bladder cancer patients' collective identity. Finally, for future DS printed material is preferred, although a number of respondents acknowledged that different formats, such as audio-visual, are needed to suit individual patient requirements.