An exploration of the experiences of people living with Pelvic Radiation Disease

Submitted in accordance with the requirements for the degree

of

Doctor of Advanced Healthcare Practice (DAHP)

Helen Ludlow

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This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any other degree or award

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Abstract

The number of people being diagnosed with cancer is increasing year on year and it can therefore be assumed that the number of people living with late effects of the cancer treatment is also increasing. Using a descriptive and exploratory qualitative approach, this study considers the experiences of those people with late gastrointestinal effects of cancer treatment. Using this knowledge recommendations will be made to improve future awareness and support for this group of people.

Cancer treatment can cause problems which may be evident during or after the treatment is completed, even many years later. Those that occur four to six months after treatment are referred to as late effects, or consequences of treatment. Radiotherapy for pelvic cancer can affect organs within the pelvis, including the gastrointestinal (GI) tract. Therefore, although the cancer treatment may be successful, the person may then be living with late GI effects that can have a significant impact upon their life. These symptoms are collectively known as pelvic radiation disease (PRD).

Using a qualitative approach, nine participants were involved in interviews, five of whom also had their spouse present. Framework analysis (FA) was used to analyse the interview transcripts. Through the process of familiarisation with the literature the issues that people with PRD were experiencing began to emerge and thus formed the basis of the framework. When applied to the interview transcripts, the framework developed further to highlight three main areas of concern: feelings of stigma, experiences of contact with healthcare services and the need of, but occasional lack of, support from family and friends.

This study shows that there is a significant physical, psychological and social impact upon quality of life (QoL) for people with PRD. It is therefore anticipated that the knowledge gained from this study will contribute to improving the care that people with PRD receive, by increasing awareness of PRD, and the affect upon patients, amongst healthcare professionals (HCPs). In addition, this study developed recommendations to

encourage the identification of people with PRD, through the use of existing guidelines and assessment tools.

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Contents

List of abbreviations

ALERT-B: Assessment of Late Effects of Radiotherapy- Bowel
ARS: Anterior resection syndrome
BAD: Bile acid diarrhoea
BAM: Bile acid malabsorption
BSG: British Society of Gastroenterology
CTAE: Common terminology criteria for adverse events
EAGLE: Evaluating and Addressing the Gastrointestinal Late Effects of radical treatment for prostate cancer
EBRT: External bean radiotherapy
EORTEC: European Organisation for Research and Treatment of Cancer
EORTC-C30: European Organisation for Research and Treatment of Cancer C30 Questionnaire
FACT: Functional assessment of cancer therapy
FA: framework analysis
FI: Faecal incontinence
GCP: Good clinical practice
GI: Gastrointestinal
HB Health Board
HCP: Healthcare professional
IBD: Inflammatory bowel disease
IBD-Q: Inflammatory bowel disease scoring tool
IMRT: intensity-modulated radiotherapy
LENT-SOMA: Late Effects on Normal Tissue (LENT)- Subjective, Objective, Management and Analytic (SOMA) questionnaire
MOS: Medical outcomes study
NHS: National Health Service
NMC: Nursing and Midwifery Council
ORBIT: Optimising Radiotherapy Bowel Injury Therapy study
OT Occupational Therapists
ROTG: Radiation Therapy Oncology Group

PIS: Participant information sheet

PORTEC: Post-Operative Radiation Therapy in Endometrial Cancer trial

PROMS: Patient reported outcome measures

PRD: Pelvic radiation disease

SeHCAT: Selenahomocholic acid-taurine test

SIBO: Small intestinal bacterial overgrowth

TI: Terminal ileum

UK: United Kingdom

QoL: Quality of life

VBT: Vaginal brachytherapy

WHO: World Health Organisation

WHOQOL-100: World Health Organisation- 100 question tool

WHOQOL-BREF: World Health Organisation Management of Substance Abuse tool

Chapter 1: Introduction

The number of people being diagnosed with cancer is increasing year on year. With 19,088 new cancer diagnoses in Wales in 2015, this was a 10% increase from the previous ten years (Welsh Cancer Intelligence and Surveillance Unit 2017a). Cancer survival in Wales also continues to grow, with an average increase of approximately 3% for both one and five year survival (Welsh Cancer Intelligence and Surveillance Unit 2017b). Of these new diagnoses, the two disease origins with most new cases were prostate and bowel and both frequently require pelvic radiotherapy as part of their treatment.

Radiotherapy causes cell death, which although necessary to treat the cancer, results in collateral damage to healthy tissue within the radiotherapy beam area. As well as the initial tissue damage, there is progressive ischaemia and stem cell loss, which can result in long term loss of function of the affected tissue (Denham and Hauer-Jensen 2002).

Gastrointestinal (GI) symptoms are the most commonly reported side effect following treatment for prostate cancer (Bacon et al 2002), gynaecological cancer (Dunberger et al 2010) and colorectal cancer (Downing et al 2015). The range of GI symptoms identified include diarrhoea, abdominal pain and rectal bleeding, although due to the role and function of the GI tract, different pathological changes caused by the radiotherapy can display differing symptoms, thus making a simple diagnosis of the medical conditions, very difficult. (Andreyev 2007). The term used to describe this group of symptoms is Pelvic Radiation Disease (PRD)

The literature review within this thesis, demonstrates that quality of life (QoL) in people with PRD is often negatively affected. Many of the studies which looked at potential effects of cancer treatment, also measure QoL to some extent. The World Health Organisation (WHO) (1997) recommends that any study examining a care intervention should also include an assessment of QoL. They went on to develop two assessment tools, WHOQOL-100 and WHOQOL-BREF which are unique in that they include assessment of the patient's own perception, which can then be used by HCPs to guide care interventions (WHO 2018). As demonstrated in the Literature of Quality of Life Tool's review table (Appendix 1), none of the studies identified, used these recommended QoL assessment tools. This is not to say that the tools that were used are any less adequate, and this will be further discussed in sections 3, 4 and 5 of the literature review which looks at studies of PRD amongst prostate, gynaecology and colorectal cancer patients.

The lack of studies involving patient perception and understanding of the patient's experience of PRD was noted throughout the papers looking at the various pelvic cancers. There was a high level of recognition of physical symptoms, but little in way of how these symptoms impacted on the patients' lives, even though the term QoL was prevalent throughout. This suggests a gap between what QoL means to researchers, HCPs, patients and their families, and subsequently how this is assessed and translated into meaning.

In the United Kingdom (UK) there are very few sites offering specialised care for people with PRD, with just one GI service in Wales currently doing so. Whereas these few specialist services have recognised the need to identify people experiencing consequences of pelvic radiotherapy, such as Ludlow et al (2017), there is still an underlying lack of awareness amongst healthcare professionals (HCPs) (Henson et al 2011, 2012). This results in patients initially not being made aware of the potential of such problems once their treatment finishes and then, if they do present with bowel symptoms, it is unlikely that the necessary appropriate investigations and treatment will follow.

If, as discussed, awareness of PRD is poor amongst HCPs who manage people with and after cancer, this would suggest that there are a significant number of people living with PRD and its inherent difficulties. The actual number is unknown, but Gami et al (2003) and Denton et al (2000) argue that the incidence figures reported in some studies, such as over 50% of patients developing chronic GI symptoms (Andreyev 2005), is underestimated in clinical trials. Davidson and Faithful (2006) suggest that a possible reason for this perceived lack of incidence data is due to the difficulty in defining bowel symptoms and the subjectivity between patients and HCPs over what is a problem and to what extent they become bothersome enough to mention.

The literature review demonstrates that people who have symptoms of PRD often experience a reduction in QoL, although it will be shown that frequently the actual symptoms are what are measured and recorded, rather that the effect of the symptoms on the person’s life. Therefore, the aim of this study is to gain an insight into the participants’ experiences of living with PRD. To achieve this, the objectives are:

- To explore the current literature surrounding PRD and to identify gaps in knowledge

- To provide an insight into the experiences of living with PRD. This will include the physical, psychological and social impact, examining what this means for the person and their friends and families

- To develop recommendations aimed at identifying people with PRD through the use of existing guidelines and assessment tools.

Thesis structure

The search strategy for the literature review (Chapter 2) will be discussed, including search terms, which databases were used and how the quality of the papers was assessed. The resulting literature will then be presented and critiqued, offering an analysis of the contribution to the impact of PRD on peoples’ lives. The literature review will be clearly laid out to categorise the papers into the identified themes, and this will be defined in the literature review overview.

The Research Paradigm, Chapter (3), will discuss how a qualitative approach was identified to be the most appropriate methodology for examining the experiences of people with PRD. This will include the author’s personal views on the production of knowledge and how this led to the structure of the study. In the Method, Chapter (4), the structure of the research study itself will be presented, including participant selection, the reasons for the choice of method of information gathering, i.e. through interviews, and how the method of analysis, framework analysis (FA), was identified as a beneficial way to analyse the transcripts obtained from the interviews. The findings will then be presented, (Chapter 5,) using the three main themes developed from the FA: stigma, healthcare and support. The Discussion, Chapter (6), will then link the findings to current theory and identify how they impact upon peoples’ experiences of PRD.

The Conclusions, Chapter (7), will consider the limitations of the study, the contribution to knowledge offered and recommendations for further study to be carried out. A personal reflection will conclude the thesis, with a discussion of the impact the Professional Doctorate journey has had on a personal level, and the changes it has already afforded.

Chapter 2: Literature review

Chapter overview

The aim of the literature review is to undertake a thorough enquiry into the current evidence surrounding PRD and people's experiences of it. The review will be presented under headings to clarify what is already known and where there are gaps in the literature. The literature search strategy will be discussed, including search terms and databases used, followed by how the quality of the papers was evaluated. The literature will then be discussed in the following order:

1. The development of the recognition of Pelvic Radiation Disease as a consequence of cancer treatment
    - PRD- diagnosis frequently made following investigations into symptoms of PRD
    - PRD- defining the problem
    - PRD- addressing the problem, through the ORBIT study
    - PRD- improving recognition of those who may have PRD

2. PRD following treatment for prostate cancer
3. PRD following treatment for gynaecological cancer
4. PRD following treatment for colorectal cancer
5. Quality of life scores- a help or hindrance?

6. Current awareness of PRD by healthcare professionals
7. The effect of faecal incontinence
8. Conclusions and gaps in the knowledge

Following each of the subject sections there will be a summary discussion where the literature will be synthesised and observations made.

Literature Search

The main body of the literature review, as seen in sections 1-4 and 6, was undertaken at the very beginning of the development of the research process, prior to formalising the study protocol. This used the broad search terms associated with PRD. Later on in the study development and after the first few interviews had taken place, the Patient, Exposure and Outcome (PEO) format, as described below, was utilised to ensure a thorough search was performed, using the wider range of search terms. This additional review data was necessary after identifying comments and themes that had arisen during the early stages of the interviews, and so subsequent literature searches were made to examine papers concerning QoL and the effects of faecal incontinence, as seen in sections 5 and 7. The additional review findings were then considered and added to the final literature search and review process.

To ensure appropriate literature was found, the aims of the research question were considered in a PEO format- Patient, Exposure and Outcome, as described by Bettany-

Saltikov (2012). Table 1 shows how the PEO format was used to ensure that all the elements of the questions were included in the literature search.

Simplified research question: what is the experience of people, their friends and families of living with PRD?

Table 1 - PEO to develop literature search

P Population and their problems	People who have PRD and their relevant family members and friends
E Exposure	PRD after pelvic radiotherapy, gastrointestinal symptoms, faecal incontinence
O Outcomes or themes	Experiences, quality of life, stigma, taboo, shame dignity

With guidance from the librarians, search terms were then developed from the PEO framework and included pelvic radiation disease, gastrointestinal symptoms/disease/disorder, quality of life, faecal/fecal incontinence, patient experience, stigma, taboo, shame and dignity. Boolean operators AND, OR and NOT were used, as were * and / symbols to widen potential key word detection. Due to the relatively recent awareness of the consequences of cancer treatment, date boundaries were not set.

Following advice from the librarians it was initially decided to limit the search to just OVID-Medline and Cinhal, but then PyscINFO was included to check for papers regarding psychological issues. Table 2 below shows which databases were searched, the terms used for each of the databases, how many potential papers were initially found and checked, how many were discarded and how many then went on for further in-depth reading and consideration for inclusion once duplicates had been identified and removed. An alert service was also set up for Ovid Medline with the terms "pelvic radiation disease" and "consequences of cancer treatment" to access newer publications as they were released.

Whereas table 2 demonstrates in more detail the individual results from each search term, the quasi PRISMA diagram below summarises the process of the literature review. This is divided into the 2 main groups of search terms used, as well as the individual database results.

1. Terms associated with PRD/GI Symptoms
2. Terms associated with QoL/FI/experience/stigma

Diagram 1 Literature search quasi PRISMA Diagram

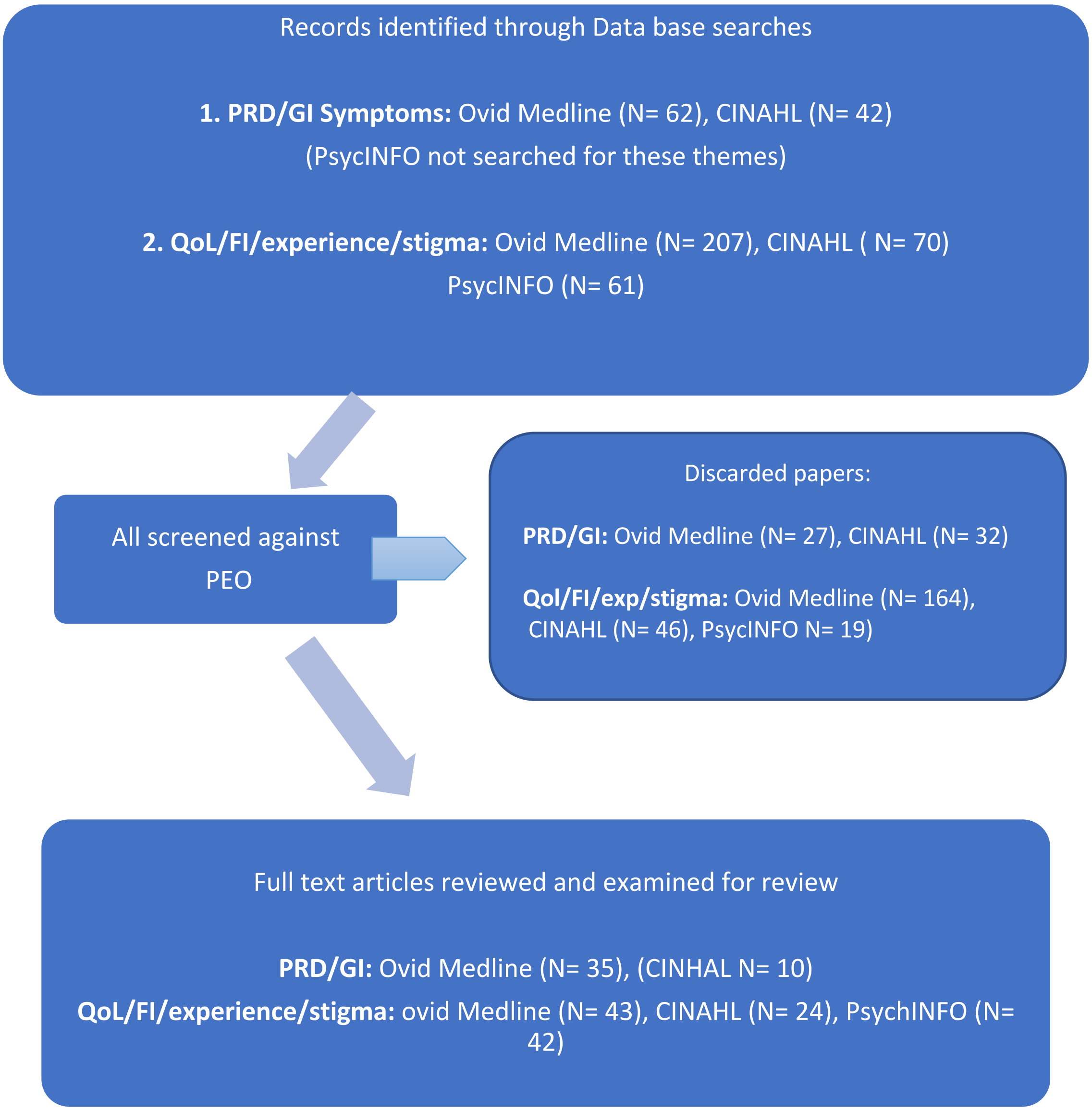


Table 2 - Database Search

Ovid Medline Search

Search	Search term	Found	Checked	Discarded	Reviewed
1	pelvic radiotherap*	1258			
2	gastrointestinal symptom*	9289			
3	Gastrointestinal disease*	40945			
4	Gastrointestinal disorder*	5700			
5	Gastrointestinal diseases/	36858			
6	2 OR 3 OR 4 OR 5	51978			
7	1 AND 6	62	62	27	35
8	“quality of life”	247095			
9	“Quality of life”/	161200			
10	8 OR 9	247095			
11	faecal incontinen*	10125			
12	Fecal incontinence/	9112			
13	fecal incontinen*	10125			
14	11 OR 12 OR 13	10511			
15	10 AND 14	1752			
16	patient experience	2985			
17	Experience	501945			
18	social stigma/	5261			
19	stigma*	25249			
20	taboo/	779			
21	taboo*	2170			
22	Shame/	2047			
23	Shame	4158			
24	Dignity	5277			
25	16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24	533707			
26	15 AND 25	207	207	164	43

PyscINFO

Search	Search term	Found	Checked	Discarded	Reviewed
1	“quality of life”	69491			
2	“quality of life”/	37432			
3	1 OR 2	69491			
4	faecal incontinen*	59			
5	fecal incontinence/	616			
6	Fecal incontinen*	706			
7	4 OR 5 OR 6	735			
8	3 AND 7	51	51	14	37
9	patient experience	1054			
10	Experience	367948			
11	Stigma/	10776			
12	stigma*mp	28246			
13	Taboos/	520			
14	taboo*	3225			
15	Shame/	3764			
16	shame*mp	12073			
17	Dignity.mp	4670			
18	Dignity/	555			
19	9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18	405583			
20	8 AND 19	10	10	5	5

CINAHL

Search	Search term	Found	Checked	Discarded	Reviewed
1	pelvic radiotherap*	488			
2	gastrointestinal symptom*	3025			
3	gastrointestinal disease *	8771			
4	(MH“gastrointestinal diseases”)	6144			
5	gastrointestinal disorder*	1921			
6	2 OR 3 OR 4 OR 5	12051			
7	1 and 6	42	42	32	10
8	“quality of life”	139041			
9	(MH “quality of life”)	86619			
10	8 OR 9	139041			
11	faecal incontinen*	2968			
12	fecal incontinen*	2968			
13	11 OR 12	2968			
14	10 AND 13	512			
15	patient experience	29381			
16	experience	252832			
17	(MH “stigma”)	11588			
18	Stigma*	18848			
19	Taboo*	946			
20	Shame	3197			
21	(MH "Shame")	1580			
22	Dignity	5274			
23	(MH "Human Dignity")	2621			
24	15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23	285,979			
25	14 AND 24	70	70	46	24

Selecting relevant papers

As the database search outcome shows, the number of papers identified was significant, although these were reduced to a more manageable number through the combining of search terms. Articles found from the final combined searches were then assessed for suitability for inclusion in the literature review. This was undertaken using elements of the original PEO format, as described by Bettany-Saltikov (2012). There is also a section in the table on quality and for comments. Whereas there are strict guidelines for assessing quality in quantitative literature, with randomised controlled studies being of the highest standard, the criteria for qualitative is somewhat different. For qualitative studies *"authenticity and trustworthiness"* Bettany-Saltikov (2012, p. 91) are considered valuable. Caldwell et al (2011) provides further examples of differences when assessing what to consider for quality in qualitative papers, which includes:

- Has the philosophical background and study design been identified, with rational for choice of design evident?
- Are the major concepts identified?
- Is the participant selection process described, along with the sampling method?
- Is the method of data analysis credible and confirmable?
- Are the results transferable?

Caldwell et al (2011) p. 4

Some articles were more opinion presentations; although not research-led, they enabled a wider understanding of experiences of living with, or supporting those that live with, PRD. Although not fully transferable, many of the elements suggested by

Caldwell et al (2014) were used to assess the appropriateness for inclusion of these non-study, or opinion articles, many of which were found useful within this study. Reasons for discarding papers included those involving paediatrics, surgical and non-surgical treatments of FI including biofeedback and tibial nerve stimulation, as well as FI related to genetic conditions.

Table 3 below uses two papers, one quantitative and one opinion-led, as examples to show how these aspects were applied to the papers identified on the search.

Table 3 - Example of PEO application to literature

Paper: Algorithm-based management.. ORBIT.. RCT Andreyev et al (2013)	**Which Inclusion criteria met?**	**Include?**	**High quality? Comments**
P: People who have PRD and their relevant family members and friends	People with bowel symptoms are cancer treatment (no family opinions)	Yes	RCT, no qualitative elements
E: PRD after pelvic radiotherapy, gastrointestinal symptoms, faecal incontinence	GI symptoms descriptions, clear overview		
O: Experiences, quality of life, stigma, taboo, shame dignity	Effects on QoL		

Paper: GI consequences of cancer treatment… a bad gut feeling Muls (2014)	**Which Inclusion criteria met?**	**Include?**	**High quality? Comments**
P: People who have PRD and their relevant family members and friends	Clear description of who might be affected	Yes	Trustworthiness of author, lots of experience in area
E: PRD after pelvic radiotherapy, gastrointestinal symptoms, faecal incontinence	Examples of GI symptoms, importance of systematic assessment		Examples, clear discussion
O: Experiences, quality of life, stigma, taboo, shame dignity	Social/psychosocial impact, QoL		Examples, clear discussion

For papers that were considered likely to be appropriate, the abstracts were read and assessed using the PEO and quality criteria. Those selected as suitable, (as described above, and once duplicates were identified), were then downloaded, printed and thematically analysed using coloured marker pens, a useful step to highlight those areas identified in the PEO, and any further areas considered useful, such as interventions to improve assessment and/or QoL. It is noted that electronic methods for saving and reviewing papers are available, but it was found to be helpful to have physical printouts available to aid study comparisons and cross-referencing.

The articles were then placed in groups according to the topics they covered and where there was cross-covering, notes were written on the front page to keep track. For example, Andreyev et al’s (2013) paper presenting the ORBIT trial discussed an overview of PRD, the symptoms it causes as well as the effect on QoL. The paper then went on to discuss the trial and its conclusion that a specialist nurse is effective in assessing and managing people with PRD. Therefore, on the front page of that article, the following notes were made: RCT, PRD symptoms, QoL, and PRD management. This was helpful to keep track of appropriate papers when writing the review.

Literature review

Pelvic Radiation Disease- the development of the recognition of PRD as a consequence of cancer treatment

This section will examine the literature surrounding the initial recognition that radiotherapy cancer treatment can cause long term health problems and will include studies that have tried to address this problem.

Radiotherapy has been used to treat cancer for over one hundred years and uses high dose x-rays to damage cells by stopping their growth and multiplication (Gianfaldoni 2017). Although an effective cancer treatment for tumours involving the urological, gynaecological and colorectal anatomy (Gami et al 2003), there is growing acknowledgement that the collateral damage to surrounding healthy tissue can result in chronic health problems for many years after treatment has finished (Andreyev et al 2012).

Although this literature review will demonstrate that there is a growing number of studies looking at the symptoms of PRD and what impact they may have on QoL, there are very few that consider how this affects the patients' daily lives, a point that was recognised over eleven years ago by Gillespie et al (2007), yet has changed little to date.

Diagnosis frequently made following investigations into symptoms of PRD

The document “The Practical Management of the Gastrointestinal Symptoms of Pelvic Radiation Disease” (Andreyev 2014), provides a systematic process for investigating each of the GI symptoms commonly experienced. A step-wise initial management plan for each of the symptoms is also described but the aim of the document is to facilitate, where one exists, a firm diagnosis of specific physiological conditions in order that they may be successfully treated.

Appendix 2 presents the literature discussing each of the more frequently encountered conditions, how they are diagnosed and the current recommended treatments for them. It is important to note the potential symptoms a person may present with, which may lead to the subsequent diagnosis, as well as an appreciation of the treatment options where available.

Pelvic Radiation Disease- defining the problem

In one of the first articles describing the symptoms suggesting PRD, Andreyev (2005) calculated that about 12,000 people in the United Kingdom (UK) had received pelvic radiotherapy. Considering the aforementioned rise of cancer diagnoses year on year, then this figure is now likely to be much higher. He goes on to describe how up to 80% of these patients are likely to experience acute bowel problems during or shortly after treatment and that although many of these will settle within 3 months, studies have shown that up to 78% of patients may develop chronic GI symptoms significant enough to affect their QoL (Potosky et al 2000 and Kollmorgen et al 1994). In the closing paragraph of his article, Andreyev (2005) states that

> *"What we have still failed to address systematically is how best to care for the patient who is cured of their cancer but living with the physical consequences".*
>
> Andreyev (2005 p. 1053)

The GI symptoms that develop following pelvic radiotherapy have become known as Pelvic Radiation Disease. Although a collection of symptoms, rather than a specific disease, Andreyev, who developed the term, was heard to present at the British Society of Gastroenterology 2005 conference that he felt the term 'disease', rather than 'syndrome' was more likely to gain the professional interest he felt was deserved, such as that held by inflammatory bowel disease (IBD). He followed up his concern that other diseases such as IBD were given far more attention in one of his early papers, shortly after his initial presentation (Andreyev 2005). He believed that perhaps due to this perceived lack of awareness, and/or interest, people experiencing such late GI effects may not receive the treatment they require.

The main charitable organisation linked with IBD, The National Association for Colitis and Crohn's Disease (now known as Crohn's and Colitis UK), also recognised the growing disparity between what was known about IBD compared to PRD. They therefore commissioned a study to look at the issues surrounding living with bowel problems following radiotherapy (Wilson 2006). This study was one of only a few found in the literature search that provided participants with a chance to tell their story and to talk about their individual experiences. For this study, nine people with a median average age of 54 were interviewed either by telephone or by giving a written response. This qualitative work provided patients' stories about their experiences and identified a significant impact upon their lives. The study concluded that there was a lack of voice from people living with PRD, and that experiences from other chronic diseases, such as IBD, could be used to support people living with PRD. Considering that this study was undertaken over twelve years, this literature review highlights that there has been little further study into people's experiences of living with PRD, as opposed to a number of studies looking at the symptoms.

Following Andreyev's growing awareness of the increasing number of patients with GI symptoms following radiotherapy, being referred to the clinic, he and the team at The Royal Marsden Hospital in London, have undertaken a number of studies to develop the knowledge base surrounding PRD. This work culminated in the document "The Practical Management of the Gastrointestinal Symptoms of Pelvic Radiation Disease" (Andreyev et al 2014). With the publication of this document, Andreyev addressed his perceived lack of a systematic assessment and treatment plan. It is also noted that many of the articles examined in the following literature, list him as one of the co-authors. Therefore, a potential suggestion of an over-use of his work in this thesis is unavoidable without ignoring much of the current knowledge surrounding PRD.

In a further paper examining the symptoms experienced by people with PRD, Andreyev (2007a) discusses how the toxicity of the treatment appears only indirectly linked with dose and volume and describes a complex mix of many factors, both patient and treatment related. In a second paper, later that year, Andreyev (2007b) details such factors which include genetic variations, smoking and pre-existing medical conditions. The first paper (Andreyev 2007a) highlights the importance of the HCP having a full history of any presenting bowel problems the patient has, such as pre-existing problems before the radiotherapy treatment began. A clear understanding of what the presenting problem actually is, is also vital, as people may have different understanding of different terms- for example, diarrhoea may mean a loose stool once a day to one person whereas to another the term may actually describe the passage of watery stool 10-15 times per day; clearly the two scenarios are very different and require clarification.

It is interesting to note in the papers over the years, the growing recognition of the need for a systematic approach to assessing a patient's symptoms. Andreyev (2007b) quantifies that a third of patients may experience QoL affecting bowel changes after pelvic radiotherapy. The paper lists 38 different symptoms that patients describe although Andreyev does not explain if these were elicited during any studies or simply mentioned during clinical consultations. In a later research paper (Andreyev et al 2013), which is described in more detail below, he supported the development of the Guideline, using two further studies (Gami et al 2003 and Olopade et al 2005) to refine the list of symptoms to a more manageable 23. He then describes how the timing of the development of the symptoms can vary enormously, from soon after the radiotherapy has been completed, to many years later. He goes on to highlight that patients mostly did not report symptoms but that equally, HCPs did not enquire about them, often resulting in a delay in symptom assessment and subsequent treatment. Further on in this thesis, it will be discussed how a lack of awareness is an important reason for the failure to identify people with PRD (Henson et al 2011, 2012), which then results in ongoing GI symptoms, with the physical, psychological and social impact that this entails.

Pelvic Radiation Disease- addressing the problem, through the ORBIT study

As discussed, PRD has a significant impact on the person experiencing it. To assess and demonstrate if a suitably trained HCP could appropriately use an algorithm to assess and treat patients with PRD, the ORBIT (Optimising Radiotherapy Bowel Injury Therapy) study, described by Andreyev (2013) was developed. This important study would form the basis for the theory behind the later guidelines (Andreyev et al 2014), to manage care for people with PRD. Over a four-year period, 218 patients were identified, who were still experiencing GI symptoms at least six months after completion of pelvic radiotherapy. The study steering group also included patient representatives. Involving patients in the study development and data discussion not only acknowledges the importance of their opinions but also improved reliability and validity of the findings.

Using computer generated randomisation, which included stratifying for the tumour sites, participants were allocated to one of three groups. One group received a self-help booklet, which was then current practice. Another was managed by a Consultant Gastroenterologist using the algorithm. The third was managed by a specially trained nurse, also using the algorithm. The primary end-point of the study was improvement in the patient's GI symptoms, which was assessed using the IBDQ-B tool at baseline, six months and one year. The study showed that using the algorithm, irrespective of whether by the Consultant Gastroenterologist or a trained nurse, resulted in a clinical improvement in the patient's GI symptoms, compared against using the self-help booklet alone, which was found to be less effective. With the final assessments being undertaken at one year, the study was also able to demonstrate that the improvements continued if the algorithm had been used. This is an important point and is relevant to current practice as it suggests that the benefits are longer lasting only when management is undertaken by a specialist team. It is important to note that this study, as per the majority of studies in this review, concentrates on symptoms of PRD, and little to no exploration of the person's experiences of living with the symptoms.

The ORBIT study showed that correct use of the algorithm is likely to involve costly investigations such as endoscopy, scans and breath tests. The purpose of the algorithm is to request only investigations identified as necessary, and to do this early on in the assessment process. In this way, the symptoms' causes can be identified and treated promptly, avoiding the long term clinical care of managing chronic bowel symptoms, with multiple hospital visits that was, up to then, the norm. Clearly however, these investigations will have financial implications and unfortunately an economic evaluation of the ORBIT study did not show that it was cost effective despite the evidence that it was extremely beneficial for the patients themselves (Jordan et al 2017). It was calculated that although algorithmic care demonstrated an improvement in IBDQ-B scores, this comes at a cost of approximately £1,000. The evaluation concludes that using generic health related QoL instruments may not capture the full patient benefit and that when the cost of treating the original cancer can be up to £15,000, then the additional cost to manage the consequences of that treatment should be considered acceptable.

Pelvic Radiation Disease- improving recognition of those who may have PRD

Identifying those people who may be experiencing PRD is the first step to ensuring they receive the appropriate treatment. The need to acknowledge that recognition of those experiencing consequences of any cancer treatment is also important for future cancer care delivery plans. Not only will this inform clinicians of the size of the problem, but it will also enable future patients to be more aware of the potential of consequences of their cancer treatment.

Following a recognition that treatment centres were using different assessment tools, a working party was set up to develop a tool aimed at standardising symptom reporting, thus reducing variability in study data collection and outcome (Pavy et al 1995). Involving two large trial co-ordination groups (European Organization for Research and Treatment of Cancer (EORTC) and the Radiations Therapy Oncology Group (RTOG)), the sub-group developed a new scoring system which included data regarding the grades of toxicity and patient perception of the severity of their symptoms. What would become known as the LENT-SOMA (Late Effects of Normal Tissue and Subjective, Objective, Management and Analytic) assessment scale was so developed. These tools were designed to be simple to apply whilst providing accurate and comparable data (Rubin et al 1995).

There is disagreement however, whether the LENT-SOMA is practical to use in clinical practice. Routledge et al (2003) evaluated the tool in eighty-nine patients post radiotherapy for cervical cancer. Not only did they believe it to correctly represent the clinical data but also claimed to find it "f*easible to use … in a busy cancer centre"* (p. 509). Within their paper however, they noted that postal questionnaires were also used, due to the reluctance of patients to return to the hospital to complete the assessment tool. This would indicate that it was not always possible for the questionnaires to be fully completed during the clinic appointment and may therefore not be particularly simple to complete as per the original aim of the development group. Taylor et al (2016a) also identified that other current symptom-based scoring systems also had issues surrounding ease of use. They identified that the Gastrointestinal Rating Scale (GSRS) was too long at fifteen questions and the IBD-Q was even longer with thirty-two questions. Another assessment tool, the Vaizey incontinence questionnaire, focused on only faecal incontinence and would therefore not provide detailed information on other symptoms. Therefore, Taylor et al (2016a) believed that for use in a clinical situation, in the case where patients had received pelvic radiotherapy, a simpler assessment tool was required; entitled ALERT-B (Assessment of Late Effects of RadioTherapy- Bowel), the tool was developed in four phases:

Phase one: A consensus meeting was held that included those involved in the original Guidance: The Practical Management of the Gastrointestinal Symptoms of Pelvic Radiation Disease (Andreyev et al 2014), along with a patient representative who had been treated for PRD. *Phase two:* Twelve patients underwent cognitive interviewing which assessed participants' understanding of the screening tool questions, and whether their judgment regarding their responses was appropriate. Both inductive and deductive analyses were used to assess the interview transcripts. *Phase three:* A final consensus meeting was held to develop the tool in readiness for use in clinical practice. *Phase four:* A psychometric validation of ALERT-B was undertaken against GSRS, which had been used in the EAGLE study (Taylor et la 2016b).

The completed ALERT-B tool consists of the following three questions, where a positive "yes" answer will encourage discussion between the patient and their HCP and a referral to specialised gastroenterology services where appropriate.

1. Do you have difficulty in controlling your bowels (having a poo) such as:
    i. Having to get up at night to poo?
    ii. Having accidents such as soiling or a sensation of wetness?

2. Have you noticed any blood from your bottom recently?

3. Do you have any bowel or tummy problems that affect your mood, social life, relationships or any other aspect of your daily life?

This tool is now being used to screen patients who have received pelvic radiotherapy at the local cancer hospital. Patients with positive results, where further assessment is considered necessary, are then seen by the GI/PRD CNS.

This section has discussed how the recognition and subsequent naming of PRD was only acknowledged in the last two decades despite radiotherapy being used for the past one hundred years (Gianfaldoni 2017) and that the late effects of radiotherapy are a growing problem. Development of a simple to use assessment tool, ALERT-B, has enabled large cohorts of patients to be quickly assessed for PRD, with identification of those requiring further follow-up clearly recognisable. It is noted however, that for more detailed symptom data collection, as required by the Cancer Therapy Evaluation Programme (Common Terminology Criteria for Adverse Events (CTAE) (National Cancer Institute 2017) then the longer assessment tools may be necessary, but for patients with PRD recognition, the ALERT-B is a valuable tool than can be used to trigger a GI referral where appropriate. Again, it is important to note that each of these studies and data collection tools have concentrated on the participants physical symptoms, and very little attention, if any, has been paid to the effect that the physical symptoms may be having upon the patient’s life.

The following sections will look at the issues of PRD in the three main pelvic cancer groups: prostate, gynaecological and colorectal cancer. The literature identified through the search was generally split into one of these three categories.

Pelvic Radiation Disease following treatment for prostate cancer

In 2015, the most recent cancer statistics available, prostate cancer was the most common cancer in men in Wales (Welsh Cancer Intelligence and Survival Unit 2017b). Radiotherapy is a common treatment for prostate cancer and late effects following this treatment are noted to be significant (Gami et al 2003). Up to now much of the knowledge of PRD has come from Dr Andreyev and the team at the Royal Marsden Cancer Hospital. However, there are many other reports from both the UK and across the world, highlighting that awareness and interest in this topic is growing. Problems following radiotherapy for prostate cancer are perhaps one of the largest areas where research into both the causes and treatment for late effects is noted. This section of the literature review will examine the available papers looking at what is known about PRD in men following treatment for prostate cancer. This will include how PRD is identified, what symptoms occur and whether impact on QoL or patient experience was considered, and if any work is being undertaken to manage the problem.

TrueNTH is a worldwide initiative partially funded by the charitable event, Movember, where men are sponsored to grow a moustache throughout the month of November and the money is donated to fund research into prostate cancer. The main aim of TrueNTH is to improve survival rates for men with prostate cancer. As well as supporting research into treatment for prostate cancer and so improving survivorship rates, they also aim to improve the quality of that survivorship. One of the UK based projects of TrueNTH has been developed specifically to investigate the late effects of radiation treatment of men with prostate cancer and part of this is the EAGLE study- Evaluating and Addressing the Gastrointestinal Late Effects of radical treatment for prostate cancer (Taylor et al 2016b). The aims of this study were to raise awareness of PRD and the treatment available for PRD following prostate cancer. To do this they used the assessment tool developed by Andreyev et al (2014) and monitored the participants' progress and healthcare utilisation over a one year period.

The study involved consented participants being screened at their follow-up oncology appointments. Screening was performed using GSRS and also the DESIGNER tool, which subsequently evolved into the ALERT-B tool, through which this tool was then validated. Those who were screened as positive for bowel symptoms were then referred to one of the three specialist PRD centres for further assessment. At the PRD clinic, patients were further assessed using the Guidance: The Practical Management of the Gastrointestinal Symptoms of Pelvic Radiation Disease (Andreyev et al 2014). The guidance follows an algorithmic approach whereby each individual symptom identified results in a number of investigations being suggested. For example, abdominal bloating/cramps would suggest the following investigations are appropriate: a full blood screen, abdominal x-ray, dietary and drug history, oesophageal gastroscopy or breath test to look for small intestinal bacterial overgrowth or carbohydrate intolerance. If all return normal, then a USS, CT or MRI may be indicated. As with all symptoms, positive findings were then to be treated and followed up for further assessment. As part of the EAGLE study, participants, their families and the HCP were regularly interviewed to discuss process acceptability and to discuss and identify issues. The financial evaluations also included costs such as those to the participants, such as incontinence protection, travel costs for hospital appointments and lost working hours and also the costs to the NHS of the HCP and investigational costs. Although the full outcome of this study is still awaited, three specialist PRD services have been developed as a direct result, which continue to provide care for those with PRD following treatment for a range of pelvic cancers.

Crook et al (1996) developed and used their own self-administered questionnaire to investigate the effect on bowel, bladder and sexual function following radiotherapy treatment for prostate cancer. Their 20-point questionnaire was developed using previously used questionnaires by Fowler et al (1993) and Jønler et al (1996). Fowler et al (1993) stated that their questionnaire was evaluated for participant comprehension but it was not formally validated. Jønler's et al (1996) study said that they utilised a previously validated questionnaire, although upon further reading this was the one used by Fowler et al (1993) that was merely evaluated for understanding and was not formally validated. This highlights the need to examine the tools used for studies, particularly if the validity of the questionnaires used is a vital part of a review. In a study by Crook et al (1996), 92 patients responded to an invitation to take part, and of these 11% reported a "severe change" in their bowel function. They noted that patients reported an improvement over time in rectal bleeding, with 17% experiencing this in years 1-3 but a reduction to just 4% in years 4 and onwards. This is a useful study if considering when PRD symptoms are likely to be most prevalent, however, although the questionnaires enquired about effects on bowel, bladder and sexual function, the study did not look at what effect these function problems may have on the men's lives, such as did it stop them going out, has it affected their mood and so on. The experience of what it is like to live with these functional difficulties is not examined although this would have provided valuable data on men's experiences of living with PRD.

A similar study based in Texas, United States of America, also looked at the late effects on radiotherapy in men with prostate cancer. Nguyen et al (1998) utilised patient administered questionnaires and found a higher than expected level of symptoms reported. 101 patients from an existing randomised trial using differing doses of radiotherapy were asked to complete questionnaires enquiring about bladder and bowel function. They also developed their questionnaires from the ones used by Crook et al (1996), Fowler et al (1993) and Jønler et al (1996), again highlighting how un-validated questionnaires can be utilised numerous times, which may then affect the quality of evidence the paper produces. The participants would have completed their radiotherapy at least 2 years prior to the study. 29% reported that urinary incontinence was a current problem and 21% noted at least a moderate change of bowel function. As these patients were already part of a radiation dose randomised trial, it was possible to note which dose each of the patients had received and to consider if this affected the severity of their symptoms. Interestingly, those patients who had received the higher treatment doses actually reported slightly less late effects although no comment on statistical significance is mentioned. This observation is perhaps unexpected yet concurs with Andreyev et al (2007a, 2007b and 2012) who notes that the radiation dose alone is insufficient to define expectation of late effects and that others factors such as genetic factors and co-morbidities may also have a role. It is anticipated that newer radiotherapy techniques will minimise normal tissue exposure to radiotherapy and so reduce late effects (Macmillan 2016) although Andreyev et al (2012) believes that more targeted treatment will only alter the timing and severity of effects in the GI tract. Again, Nguyen's et al (1998) study focussed on symptoms; what was their experience and to what extent of severity. There is no mention of the impact of these symptoms on the men’s lives, even though in their conclusion they comment on lifestyle impact and use urinary leakage as an example. This study lacks information on the impact of something like urinary leakage such as did it stop them going out and further work in the area is necessary and will be addressed by the study presented in this thesis.

Cameron et al (2012) also explored men’s experience of symptoms following radiotherapy for prostate cancer although used a much earlier time scale of just 1 month following completion of radiotherapy. Using a prospective descriptive survey, 73 men from the Canadian Cancer Centre were recruited to study both their symptoms and their perceived health state prior to and following radiotherapy. Symptoms were assessed using a modified Expanded Prostate Cancer Index Composite (EPIC) tool, that was designed and validated by Chang et al (2011) to specifically measure urinary, bowel, sexual and hormonal function and to encompass health related QoL issues in men receiving prostate cancer treatment. Statistical analysis was used to compare the scores, which demonstrated that each of the functions deteriorated during the first month after treatment although did not necessarily bother the patients. This may be because patients are often told to expect some changes during their treatment and so find them easier to tolerate. Specifically, bowel symptoms did not appear to cause enough distress to impact upon the men’s perceived health state, but it is important to note the short time scale, and this is likely to be non-representative over a longer period of time. Although the assessment tool used measured QoL, the short time period again results in difficulty in applying the data to men over a longer period of survivorship. There are many things which could alter the men’s perception of their QoL being measured so close to completion of cancer treatment, such as relief that their cancer was found and that the treatment is over and this is likely to impact of their general idea of well-being and contentedness with their lives, at that exact time period. The authors conclude that men need to be informed about the likelihood of symptoms post-radiotherapy, although accept that their findings should not be used to inform longer-term time frames or different types of treatments due to the limited time frame of their study.

In an attempt to further address the issue of identifying when and which patients are more likely to develop late symptoms, Pinkawa et al (2010) undertook a longitudinal study of 298 patients in a German cancer hospital who were receiving radiotherapy for prostate cancer. Also using the EPIC assessment tool, they identified that those who received >70gy of radiotherapy were more likely than those receiving lower doses to develop acute toxicity symptoms and that this group were more likely to go on to develop chronic late effects. Although QoL was measured as part of the EPIC tool, there were no examples given as to how this was demonstrated in the men's' lives such as what effect any symptoms might have upon them. They believed this was due to acute damage to the intestinal mucosa and that this non-healing response is more likely to be a predictor of subsequent long-term problems. These findings are in contrast to Nguyen et al (1998) who did not find an obvious link with increased symptoms and higher radiation dose and are also in conflict with Andreyev et al (2007a, 2007b and 2012) who identified that the radiotherapy dose did not directly correlate with severity of symptoms. Also noted within the study was a mention that steroids and/or Mesalazines may have a treatment role, although Andreyev (2005) had highlighted five years previously that due to the biological process causing PRD, such treatments would be ineffective. This disparity of findings merely identifies that knowledge in this area requires further study and that for now all patients receiving pelvic radiotherapy should be considered at risk of developing late GI effects.

Andreyev et al (2012) address the issue of time frames, which has been demonstrated in the literature above, identifying that acute, sub-acute and chronic symptom presentations, are very different. Acute symptom presentation may result from infection, neutropenic enterocolitis, haemorrhage, perforation, ischaemia/infarction, thrombosis and bowel obstruction. These are medical/surgical emergencies and require prompt assessment by appropriate and experienced HCPs. He identifies that often, the more chronic the symptoms, the more difficult they are to detect, possibly because patients do not report them and HCPs may not enquire of them, possibly due to lack of awareness. This paper does not define time scales for chronic/long-term/late-effects but does comment that when patients attend cancer follow-up clinics, they should be assessed for such problems. In his earlier paper however, Andreyev (2007) does cite Olopade et al's (2005) data suggesting that up to 90% of patients receiving pelvic radiotherapy, develop permanent changes in their bowel function. Olopade et al's (2005) data is produced using 2 previously validated and commonly used questionnaires in looking at bowel and incontinence problems in people with inflammatory bowel disease (IBD) and faecal incontinence (FI). The IBD Questionnaire (IBDQ) and Vaizey incontinence score are both simple and quick to use tools that assess not only the symptoms but also the effect these have on the patients' QoL (Guyatt et al 1989 and Vaizey et al 1999). Results using both of these tools were then compared against the Late Effects on Normal Tissue (LENT)- Subjective, Objective, Management and Analytic (SOMA) questionnaire (Pavy et al 1995) to see if they were comparable in assessing the effects of pelvic radiotherapy on GI symptoms. Their study concluded that all 3 questionnaires were useful in determining GI symptoms following pelvic radiotherapy and that the IBDQ and Vaizey tools were perhaps more sensitive in identifying patients who may benefit from specialist gastroenterology input.

Macmillan (2014a) has developed a booklet which provides information and advice for men who have developed late GI effects following pelvic radiotherapy for prostate cancer. In it, they describe the differing types of symptoms that men may experience and suggest that they talk to their HCPs about any concerns they may have. The booklet mentions that once the man has discussed his problems with the cancer specialist, they will be offered assessment and advice (p.11). However, Henson et al (2011) identified that oncologists struggle to appropriately manage these patients or to refer them to a specialist gastroenterology service. Indeed, of the 190 oncologists who responded, 91 said that they refer less than 10% of their patients for specialist gastroenterologist support. Studies including Olopade et al (2005), Potosky et al (2000) and Kollmorgen et al (1994) show that up to 90% of patients may experience late GI effects following pelvic radiotherapy, these referral figures are likely to be inadequate.

Each of the studies examined has demonstrated a consideration of the effects of pelvic radiotherapy on men's lives, through symptom assessment and QoL scores. The TrueNTH organisation and subsequent study recognises that PRD has a significant impact on the participants, their families and the NHS. Although the full report is currently awaited, the study has already shown that it has met part of its aim in improving access for men with PRD post prostate cancer treatment with the development of the new clinics as its legacy. Studies by Crook et al (1996) and Nguyen et al (1998) solely concentrated on the physical symptoms of PRD. Although it is important to be aware of the symptoms men present with, the study did not contribute to the knowledge of what it means for the participant to live with these symptoms. If there is no discussion of the impact upon lives then it is unclear how important these symptoms may be to the men. The study by Cameron et al (2012) went further in evaluating the impact of symptoms upon the men's lives, although used a timescale of one month following treatment, which does not meet the generally accepted criteria of late effects of treatment. They acknowledged this time-scale discrepancy in their discussion, noting that it may not be applicable to those with longer-term symptoms. Their conclusion was however, similar to most of the papers' findings; people should be informed of the possibility of late effects of the treatment before commencing, and HCPs should be aware of the possible effect on patients at follow-up. Pinkawa et al (2010) looked at a longer time frame than the Cameron et al study (2012) although their suggestion of using steroid or mesalazine treatment, that had previously been described as unsuitable, calls into question the authors' knowledge and prior research. QoL was measured within the EPIC tool they used, although again, no mention was made of how this then correlated with the impact upon the men's lives.

Andreyev et al (2012) summarised that the lack of knowledge of the significant impact of PRD upon people's lives was contributing to a perceived lack of care. Patients are unlikely to report symptoms if HCPs do not raise the subject and HCPs are unlikely to enquire about problems if they themselves are unaware. Andreyev recommends that it should become standard practice to raise the subject with patients at their follow-up clinics and suggests that assessment tools are utilised.

Although some of the papers discussed do examine QoL, even those that mention it, do not go on to discuss the effect upon the lives of the men in their studies. The literature surrounding men with PRD following prostate cancer, notes that late GI effects are not uncommon after treatment but also reveals a significant gap in the knowledge about the experience of what it is like to live with PRD, the effect that symptoms of PRD has on their lives and how the person sees their future whilst living with these issues.

PRD following treatment for gynaecological cancer

Female cancers in Wales have the second highest cancer rate in the UK, and the 7th highest in the 22 European Countries (Welsh Cancer Intelligence and Surveillance Unit 2017a). Of these female cancers, after breast cancer, uterine then ovarian cancers have the highest incidence. Due to female pelvic anatomy, radiotherapy to treat cancers of the ovaries, uterus, cervix or vagina, is highly likely to affect surrounding tissues, which includes the small and large bowel and which will inevitably receive doses of radiotherapy (Andreyev 2007). This section of the literature review will examine the papers that report on studies of women with PRD. As well as a critical analysis of the papers, this review aims to look at the recognition of PRD as an issue, the suggestions for either avoiding or improving PRD and which studies consider QoL or take patient experience into account.

Danielsson et al (1990) noted that following pelvic radiotherapy for gynaecological cancers, diarrhoea was a common problem in women attending their oncology clinics. In their prospective study of 173 women attending follow-up for cervical and ovarian cancer in a Swedish hospital, they utilised a questionnaire to assess the patients' bowel habits and gastrointestinal symptoms, although did not say if this was a pre-validated tool or one they had developed themselves. They identified 20 people who had chronic or intermittent diarrhoea that was significant enough to affect their daily lives. The only question enquiring about any effect on their lives was one that asked if they were content, or discontent with their bowel habit. Within the cohort, and identifying with Andreyev (2007) and Olopade et al (2005) that a large proportion of patients will have chronic GI symptoms, the mean number of years since completing radiotherapy treatment was 11 (4-29). It was noted that it was difficult to analyse whether there was any notable similarities between cancer types/treatments due to the improvements in surgical techniques and radiological treatments over such an extended period of time. The main finding from this study was that a large proportion of women had significant diarrhoeal symptoms post pelvic radiotherapy.

Following identification of the group of women with symptoms, they then went on to have further investigations to see if there was a treatable cause to their diarrhoea. These investigations included a SeHCAT scan (selenahomocholic acid-taurine test) to measure bile-acid malabsorption (BAM), breath testing and also small bowel biopsies for small intestinal bacterial overgrowth (SIBO), faecal testing to measure fat content, lactose testing and a range of blood tests. These tests revealed important findings, demonstrating that many of these women had treatable causes of their chronic diarrhoea. Of the 20 women, 13 had a reduced SeHCAT with 7 of these significant enough to have marked BAM. Of the 20 women, 9 showed evidence of SIBO, 7 had low level of vitamin B12 and 10 had high levels of fat in their diet, which may be contributable to pancreatic insufficiency.

Further follow-up of the women in this study with abnormal results showed that the majority responded to treatment and demonstrated an improvement in the diarrhoeal symptoms. The authors go on to recommend that healthcare professionals caring for women with diarrhoeal symptoms at any time following pelvic radiotherapy should have a high suspicion of treatable causes such as BAM and SIBO. So, although this was a useful study to highlight potential physical causes contributing to PRD, they treat the participants purely as a disease statistic, rather than considering the lives behind the symptoms.

A separate qualitative, mixed methods, Swedish study of 616 women (78% of the initial cohort) who received pelvic radiotherapy for gynaecological cancer, also identified that many of them had chronic GI symptoms, although this study only involved women who were 2-10 years post treatment (Dunberger et al 2010). Using a study-specific symptom and QoL questionnaire, which was validated through a robust interview and pilot testing process, the types and rates of GI symptoms were recorded. The data was collected in two ways, firstly with a questionnaire and then a semi-structured interview for those who further consented. The questionnaire consisted of 351 questions, including demographics, cancer type and treatment and then followed by psychological issues such as anxiety, depression, QoL and social functioning. The study reported little of the psychological findings and none of the experiences that may have been heard in the interviews; it instead tended to concentrate on the physical symptoms. They did however note an ambition of theirs regarding the women's experiences:

> *"to help improve communication between professional health care providers and patients when cancer survivors seek help and treatment options for faecal incontinence, a socially disabling and embarrassing condition"*
>
> Dunberger et al (2010) p. 614

With a similarity to studies by Andreyev (2007a and 2013), the Dunbergers et al (2010) study elicited 32 different GI symptoms. Although followed by a disclaimer that generalisation should not be made from their study, they go on to describe how 25% of the women experienced 'emptying of all stools into clothing without forewarning.' Results from the study were compared to those from Olopade et al (2005), which looked at women who had treatment for cervical cancer, as well as other pelvic cancers. It was noted that the figures for symptoms such as incontinence with both solid and liquid stools, as well as gas, were much higher in that group but Dunberger et al (2010) felt that comparison was inappropriate due to newer methods of assessing such symptoms that were utilised in their study. It was also noted that the length of time from end of treatment to study were quite different, with a mean of 27 months in Olopade et al (2005) compared to 86 months in Dunberger et al (2010) and that this time difference may play a part in both the symptoms themselves and the women's perception of them.

The Dutch based Post-Operative Radiation Therapy in Endometrial Cancer (PORTEC) trial compared impact on QoL scores following either external beam radiotherapy (EBRT) or vaginal brachytherapy (VBT), which is internal radiotherapy. This randomised multicentre trial found marked differences in patient-reported QoL at 2 years post treatment (Nout et al 2009). The assessment tool was the European Organization for Research and Treatment of Cancer C30 Questionnaire (EORTC-C30), which the paper reports, was developed for repeated QoL assessment during clinical trials and has been found to be valid in different cancer care situations. Function and global QoL was measured from 0-100, with high scores representing a better level of functioning, whereas with the symptom assessment, also from 0-100, a higher score pointed to more symptoms and decreased QoL. No clarification is given if the scoring system was explained to participants beforehand, merely that they were "handed out". This may have impacted upon participant completion if no clarification or confirmation of understanding was made.

In a major difference to Danielsson et al (1990) study, where different treatments/doses were used, in this study, every patient had undergone initial surgery and then the radiation dose for every patient receiving EBRT was the same and for patients receiving VBT, 90% had high-dose treatment and 10% low-dose. The primary endpoint of the study was comparing disease recurrence rates between the two treatment modalities and the second endpoint was to assess the impact of the different modalities on QoL. At baseline, just prior to commencement of radiotherapy, both groups scored low for global health and functioning, with a slight improvement at 6 months. Symptoms of diarrhoea and faecal leakage were significantly higher in the EBRT group compared to the VBT group, which coincided with the increased feeling that the EBRT group needed to be near a toilet with subsequent impact upon social functioning. These differences were seen throughout the 6-24 month follow-up period. Although the study used a validated QoL tool, there was little mention in the findings about the actual impact upon the women, except for comments regarding social functioning and sexual activity. It would be difficult to translate these findings into a meaningful understanding of their experiences, and what it was like to live with PRD. The study team concluded their paper with the recommendation that if, as they expected, disease control was as effective with VBT as EBRT then due to the improved QoL with VBT it should perhaps be regarded as the preferred treatment.

In contrast to the findings in the above study, that GI symptoms were more common in patients treated with radiotherapy, Bye et al (2016) found that in their cohort of 79 women, post treatment for cervical and endometrial cancer, only 5% reported side effects. They do however report that in general, the whole group of women had a higher stool frequency than the general population, and that actually, 7% had resorted to anti-diarrhoeal medication, so it could be argued that this alone is classed as a late effect. It was noted however that those women who did report substantial diarrhoea, scored their social functioning as low.

A second paper from the PORTEC-2 trial (Nout et al 2010), describes further follow-up of the original study group participants and concludes that at 65 months, the group who received EBRT continued to experience GI symptoms, compared to the VBT groups, whose HRQL were similar to an age-matched general population group. This does not necessarily mean that the VBT group are without QoL affecting symptoms, however, with sexual function, including vaginal dryness, stricturing and painful intercourse being more problematic than in the EBRT group. This later paper does not comment on the original paper's (Nout et al 2009) primary endpoint of measuring cancer recurrence, although a further literature search uncovered a separate study report (Nout 2010) which describes VBT as being as an effective a treatment as EBRT, but with fewer longer term side effects, particularly GI, and therefore should be considered as the first line treatment of choice.

Abayomi et al (2005) recognised that the figures given at the time by the National Cancer Institute (2005 web page is now unavailable and cannot therefore be confirmed) for late GI effects of radiotherapy following cervical cancer were likely to be underestimated and that many of these women were experiencing a significant reduction in their QoL. This was one of few papers that considered patient experience of PRD. Their qualitative study interviewed 10 women using an interviewer-guided approach. Each interview lasted between 30-120 minutes and used open-ended questions to cover experiences of their diagnosis and treatment, including any problems they encountered during and after their treatment, impact of their symptoms on everyday life, any attempts they made to control symptoms, and if they received or sought professional advice for their symptoms. Their use of a qualitative approach would have enabled the women to share their experiences in their own words, rather than be guided by a fixed questionnaire framework. All the women had initially had surgery followed by radiotherapy and they described how all but one had symptoms either during or after treatment, although they do not specify how many were later side effects, other than describing 'most women' as having problems. Symptoms experienced by the women included diarrhoea, faecal incontinence, abdominal pain, bloating and either weight loss or weight gain. This study also looked at reasons why the women may not have discussed their symptoms with their HCPs. Embarrassment was a major factor, with a reluctance to talk about bowel problems, something that is ‘very personal and private’ (p. 360). There was also a sense of just having to get on with things now the cancer treatment was finished. This study concluded that HCPs need to be more aware of such symptoms following pelvic radiotherapy and that they must be more proactive in offering treatment. Led by a dietetic team, the study also highlighted the importance of dietetic input as part of the multi-disciplinary team and identified that it was important to undertake further study to establish the size and impact of post-radiotherapy problems. This study provides a valuable insight into the life of women with PRD post cervical-cancer treatment. They conclude that they wished to undertake a further study, with one aim being to consider the consequences of the problems they found, which is discussed below.

Following on from the above study, three members of the original study group went on to develop a second study looking at the numbers of women who experience GI symptoms following radiotherapy plus brachytherapy or brachytherapy alone for cervical or endometrial cancer and to identify if radiation dose or stage of cancer is more likely to increase the risk of developing such problems (Abayomi et al 2009). Using an adaptation of the validated Kings Health Questionnaire to assess women with urinary incontinence, 85 women who were at least 3 months post-radiotherapy, completed the 9-domain questionnaire, enquiring about general health perception, impact of incontinence, role, physical function, social function, personal relationships, emotions, sleep/energy and severity/coping mechanisms. Results demonstrated that just under half (47%) described some form of GI symptoms and interestingly this did not have any statistical relationship when comparing if radiotherapy dose, delivery method, cancer stage or time since treatment ended, had an impact upon symptom type and/or severity. This concurs with previous papers by Andreyev et al 2007a, 2007b and 2012) who recognises that there are many varied factors that may impact upon development of late GI effects of pelvic radiotherapy. Although this study did not collect data through interviews, thus missing out on hearing the women’s voices, they conclude that it is important that HCPs are aware of the potential for symptoms following pelvic radiotherapy and that due to the difficulty in predicting who is more likely to experience problems, all patients should be screened to identify those who are affected.

Holmes (2010) concludes her study with a similar recommendation. Following a growing awareness that women who had received radiotherapy for gynaecological cancer were experiencing GI symptoms, she used a questionnaire developed by Andreyev’s team at the Royal Marsden Hospital, specifically to identify radiation-induced bowel injury symptoms. This was the one gynaecological study identified that involved patients in reviewing the suitability of the questionnaire, as recommended by Alrubaiy et al (2014). The questionnaire also enquired about bladder symptoms although these were addressed separately. 109 women were identified through the local cancer network, who had been diagnosed with a gynaecological cancer between 2006 and 2008 and who had completed their radiotherapy at least 12 months prior. Of the 109 questionnaires sent, 77 were returned. Of these, 44 had received treatment for endometrial cancer, 29 for cervical cancer and 4 for vulval cancer. Of the 77 who responded, 61 reported a change in their bowel habit. 31 respondents experienced constipation, 47 had diarrhoea, 33 had increased frequency, 20 had rectal bleeding, 39 had mucous or slimy faeces, 26 had faecal incontinence and 42 had abdominal pain/discomfort. Following completion of the questionnaires, the paper reports that several women contacted the department to enquire about the potential for further investigation and/or treatment for their symptoms. This implies that these issues had not been previously discussed or offered, yet clearly there was a need. Through the use of a comment section on the questionnaire from respondents, the study also demonstrated a need for increased awareness of the potential for GI symptoms following pelvic radiotherapy and that patients should be asked directly about the prevalence of their symptoms, rather than waiting for the women to mention it themselves. This was following several comments about the embarrassing nature of the symptoms, which was similar to those identified by Abayomi et al (2009).

Each of these studies looking at late GI effects of pelvic radiotherapy in gynaecology cancers, have all identified that approximately 50% of women will experience bowel problems after treatment. The studies have noted that awareness amongst HCPs needs to be increased and that women should be asked about potential symptoms, rather than waiting for them to mention it themselves. A common theme in these studies, as with the papers looking at PRD following prostate cancer treatment, is that they tended to concentrate on symptom identification, rather than what effect these symptoms were having on the women's lives. In the Danielsson et al study (1990) they merely enquired if the participant was 'content or discontent' with their bowel habit. This does not consider differences in the participants understanding of being 'content' with their bowels or of any allowance to ascertain what level of being ‘discontent’ they may have, or indeed what impact this has, if any, on their lives. Dunberger et al (2010) went further in enquiring about QoL issues and was one of the very few studies identified in the entire literature review to give the participants an opportunity to express their experiences using a semi-structured interview. The paper did not however, describe any of the participants’ experiences, and again concentrated on symptom reporting such as diarrhoea and abdominal pain.

Without a greater understanding of the impact of PRD on women’s lives, it may be difficult to provide holistic care, taking into account their experiences, or what other women have experienced. Although the studies reviewed demonstrate that PRD is not infrequently identified in women after gynaecological cancer treatment, very few discussed the experiences of the women who had these symptoms. This could therefore limit not only the understanding of the difficulties people with PRD experiences, but also the treatment offered to improve their QoL.

Macmillan (2014b) is leading the way in encouraging awareness amongst both patients and HCPs of late effects of pelvic radiotherapy. This document, written for HCPs, identifies that it is good practice for patients to be made aware of the potential of late effects prior to their treatment. They believe this to be vital for informed consent to be given, to ensure that the patient is fully aware of the potential consequences of their treatment. This will also make the patient aware that should they develop these symptoms post treatment, support and advice will be available to them.

PRD following treatment for colorectal cancer

Colorectal cancer is the 4th most common cancer in Wales, after prostate, female breast and lung cancers (Welsh Cancer Intelligence and Surveillance Unit 2017a). Unlike the other pelvic cancers, the radiotherapy is directly targeted at bowel tissue, and therefore radiation affecting colonic tissues is unavoidable. This section of the review will analyse literature where studies specific to late effects of treatment for colorectal cancer were undertaken. The papers will be critically analysed to identify contributions of knowledge around people's experiences of PRD following colorectal cancer as well as the prevalence and nature of PRD in this patient group.

A large, England-wide study by Downing et al (2015) identified 34,467 suitable patients from the National Cancer Registration Service who were 12-36 months post diagnosis for colorectal cancer. No mention was made of the average time post completion of treatment. Their aim was to look at QoL issues in people living with and beyond treatment for colorectal cancer. A piloted questionnaire made up of several elements, including generic health related QoL assessments, colorectal cancer specific outcomes, social difficulties, experience of care and cancer treatment, disease status and long-term conditions was offered. Of the 21,802 who participated 3,632 had received radiotherapy as part of their treatment. The participants who had colon cancer treated with surgery, chemotherapy and radiotherapy were 326 (2.4%) and 91 (0.7%) were treated with surgery and radiotherapy. For recto-sigmoid cancer, 181 (12%) had received surgery, chemotherapy and radiotherapy, and 46 (3%) had surgery and radiotherapy. 2,437 (36%) patients with rectal cancer, received surgery, chemotherapy and radiotherapy and 696 (10%) had surgery and radiotherapy. The findings showed that patients with rectal cancer were more likely than all other cancer types to report problems, with pain/discomfort being the most common. Further analysis was not designed to examine if the combination of treatment (surgery alone, surgery and chemotherapy, surgery, chemotherapy and radiotherapy or surgery and radiotherapy) had any effect on the symptoms described. The study showed that after treatment, 17.5% of patients with colon cancer reported having 'no control over their bowels' (p. 621), compared to 15.4% of patients with recto-sigmoid cancer and 13% with rectal cancer. In addition to these figures, a further 17% of patients reported having moderate bowel problems, with little or some control. Other symptoms described by patients were poor urinary and sexual function. The paper mentions that it presents only the reporting of symptoms (p.623) and so although they offer details of the prevalence of PRD, there is no discussion on how this impacts upon the patients' lives. The study data are in keeping with previously discussed studies (including Holmes 2010, Abayomi et al 2005 and Olopade et al 2005). It is impossible to extrapolate whether radiotherapy was a major contributor to their long-term symptoms, or what this means to the patient experience. Despite this, the authors highlight the Andreyev et al (2013) algorithm for patients who have received radiotherapy as part of their treatment, and recommend that cancer services must consider such services in their cancer care pathways.

A Canadian trial discussed the balance between using short-course, pre-operative radiotherapy for rectal cancers, compared to no pre-operative radiotherapy and the potential impact radiotherapy may have on the patients' QoL post-treatment (Stephens et al 2010). After noting that the QoL questionnaire used, EORTEC QLC-CR-38, generated so much data, they developed two hypotheses with which to stratify their findings on primary QoL aims:

> *What are the longer term (2-year) effects of the treatment on:*
>
> - *Sexual function?*
> - *Bowel function?*
>
> *What is the effect of treatment on physical function and general health?*
>
> *Stephens et al (2010) p. 4234*

The use of the QoL questionnaire provided data for symptoms, and although it is a validated QoL tool, symptom data alone does not provide information on what impact these symptoms have on peoples' QoL, specifically how it is affected, what the symptoms prevent them from doing, or modifications that need to made in order to function at a level considered acceptable to the patient. The findings showed that although there was evidence that pre-operative radiotherapy treatment reduced the risk of localised recurrence, there was also a significant statistical reduction in sexual function and increased bowel problems. They noted that many patients who have treatment for rectal cancer will have either a permanent or temporary stoma so figures for those experiencing bowel symptoms are likely to be under represented. 'Unintentional release of stool' (p.4236) was significantly worse in the group who had received pre-operative radiotherapy when assessed at 2 years. The study concludes with a recommendation that patients who are likely to require pre-operative radiotherapy are counselled as to the possibility of having late effects, although they anticipate that the number of patients requiring such treatments will reduce over coming years due to improved surgical techniques.

Jansen et al (2010) undertook a systematic review looking at QoL issues amongst colorectal cancer survivors of a time span greater than 5 years. Utilising a robust search approach, 10 studies were identified for review. A clear limitation of the review, which was acknowledged by the authors, was the lack of *‘gold standard’* (p. 2886) for QoL assessment, resulting in differing methods across the original studies. (See below for further discussion concerning this). Methods included face-to-face interviews (n=4), telephone interview (n-1) and postal surveys (n=5). Although the review authors summarise that radiotherapy can affect specific areas of QoL up to many years later, they presented that radiotherapy was not related to reduced QoL in rectal cancer survivors. They go on however to note that one study (Pollack et al 2006) looking at pre-operative radiotherapy versus no pre-operative radiotherapy, found that those who had received treatment recorded higher levels of diarrhoea. The findings of the low impact that diarrhoea had on QoL may be explained by the theory of a reframing/response shift, as described by Bernhard et al (1999). This is seen when cancer survivors may develop a new understanding of their QoL, partly due to relief of successful cancer treatment. Potentially therefore, this could explain the perceived discrepancy between reasonably good QoL scores but marked GI and other symptoms, where the patients develop a perceived new normality in their lives. The lack of ‘gold standard’ mentioned in this paper confirms the contention of what QoL means, and that it may mean different things to different people, including patients and clinicians. This highlights the lack of consideration given to exploring peoples’ experiences of living with PRD, how this impacts upon their lives, and if the QoL is affected. The study within this thesis will attempt to address this shortfall.

A systematic review of the literature by Panjari et al (2012) looking at sexual function, urinary and faecal incontinence and wellbeing in women after treatment for rectal cancer found that 50% of women experienced unexpected loss of flatulence (Peeters et al 2005). They described this as Anterior Resection Syndrome (ARS) (Hassan and Cima 2007), which is *'increased number of daily bowel movements, erratic defecatory patterns, urgency, tenesmus, obstructed defaecation and minor faecal leakage'* Collie (2013, p.1). There is often confusion and cross-over in clinical practice between the symptoms of PRD and ARS, but it would seem appropriate, considering the evidence seen in the literature review, to recognise the strong possibility of PRD causing bowel symptoms where pelvic radiotherapy treatment has been used. The conclusion of the review was that there was need for further study in to *'the long-term effect on these parameters'* (incontinence, sexual function and QoL) p. 2756. This declaration highlights that studies are often purely symptom focused. In contrast to papers such as this, the qualitative work in this thesis will look at participants' experiences of PRD, rather than parameters.

A later systematic review of the literature on QoL issues relating to radio-chemotherapy for anal cancer was under taken by Sodergren et al (2015). They identified that the use of chemotherapy alongside radiotherapy has been increasing, particularly following studies describing excellent response rates in 1974, despite previous thoughts that surgery was the only treatment option. One key finding from the review was that very few (4%) of the studies included had used any formal QoL assessment although they suggest this may be due to there not being a specific assessment tool for QoL issues with anal cancer, a similar finding to the lack of 'gold standard' identified by Jansen et al (2010). The studies that did assess QoL did so via tools such as the LENT-SOMA and criteria outlined by the National Cancer Institute Common Terminology Criteria for Adverse Events (CTAE). The Christie NHS Foundation Trust (2016) describes how the LENT-SOMA was initially developed in 1995 by the European Organisation for Research and Treatment of Cancer (EORTC) and the Radiation Therapy Oncology Group (ROTG), in an attempt to develop an international scoring system to measure late effects of cancer treatment. This work was further developed by the CTAE using aspects of the LENT-SOMA to assess both early and late effects of treatment. Currently used across the UK, the questionnaires have been extensively validated for various cancer specific sites, including prostate and bladder, although not currently for colorectal cancer.

A further observation made by Sodergren et al (2015) regarding low quality level of QoL detail was one paper that compared QoL following surgery or radio-chemotherapy where QoL data was extracted from medical records, rather than asking the patients. This may affect the reliability of the data, as it could depend on what the clinician asked, unless the patient voluntarily offered details of QoL issues. Indeed, the authors describe this as giving *'a very incomplete assessment'* p. 3620. It was also discussed that none of the studies in the review had utilised a qualitative approach and the authors described this as limiting the evidence of the impact of symptoms on QoL issues. This would suggest acknowledgement that using QoL data collection tools alone may miss out on identifying QoL elements that could be discovered using qualitative methods.

Overall, the Sodergren et al (2015) review ascertained that most patients QoL post treatment, of whatever source, had levels comparable to that of the general population. One reason for this was thought to be the high cure level of the disease, although it may also be due to Bernhard et al's (1999) theory of a reframing/response shift as discussed earlier. It was noted however that in a number of studies, bowel and sexual function were shown to be a significant concern and which subsequently reduced QoL scores. No mention was made of time scales post-treatment to ascertain how close to treatment these problems occurred, or potentially settled. The review concludes with a recommendation that QoL issues are considered in cancer trials and that potential treatment impact upon patients' QoL be discussed prior to treatment to enhance informed choice and consent. After noting the authors' comment on incomplete data emerging from some of the quantitative studies, this suggests that qualitative methods would provide further knowledge about the impact of PRD, and this is an objective of the research within this thesis.

A 4-year prospective German study of breast cancer and rectal cancer patients by Engel et al (2003) compared QoL issues between the two groups. They used two validated cancer care questionnaires and described differing long-term effects than demonstrated in previously discussed studies. The questionnaires used were the EORTEC QLQ-30, that use 5 functional scales (physical, emotional, cognitive, social and role functioning), global QoL measure and symptom assessment and the CR-38 which was specifically designed for rectal cancer patient questions including body image, sexual function/enjoyment, future perspective, GI & urinary problems. The GI symptoms were classed as constipation, diarrhoea or defecation problems, with 24 other non-GI related variables. Much of this study looking at rectal cancer patients concentrated on the details of differing types of surgery with or without stoma formation, although it was noted that patients who had received radiotherapy had statistically worse QoL in 16 of the variables within the year following treatment, of which 3 were those mentioned above. It was then demonstrated that following that first year, QoL began to improve in the radiotherapy only group, whereas it continued to stay poor in the stoma and low and high anterior resection groups. As the individual variables were not discussed separately, it may not be particularly clear or helpful when investigating late GI effects by stating that the radiotherapy group patients improved their QoL in the following years. Although certain aspects of life may improve in their study, it does not appear to show a significant improvement in, for example, diarrhoeal symptoms. Table 3 in their paper (p. 207) shows that the diarrhoea mean scores, on which their statement of improvement was based, were developed from just 48 responding patients, down from the original 169 participants. Although an interesting study, the reduction in participant numbers and the lack of clarity of individual variable explanations do not provide enough data to assume that GI effects of radiotherapy will improve after year one.

Another point of particular interest, is that the Engel et al (2003) notes that *'younger patients appear to be more psychologically affected by their cancer experience'* (p. 220), even though this study was designed to look at QoL rather than experience. This again highlights the confusion between what constitutes QoL, how best to understand it and whether it can be measured statistically, rather than qualitatively. Engel et al (2003) concludes, as do the majority of the other studies, that patients should be adequately informed, pre-treatment, about the potential for later problems with each individual treatment method and that QoL issues should be included in studies.

Sunesen et al (2015) also looked at problems experienced by people who had undergone treatment for anal cancer, recruiting 84 patients who had received surgery and/or radiotherapy alone or alongside chemotherapy. The median range from participating in the study from end of treatment was 33 months (5-92 months), providing some longer-term data than other studies had included so far. The authors identified that commonly used QoL assessment tools may not adequately capture long term symptoms and distress from treatment related problems, a point which had also been highlighted in the work of Sodergren et al (2015). The research team developed their own, anal-cancer specific, questionnaire. This was constructed through utilising appropriate elements from existing tools, such as the LENT-SOMA and a group of experts, although no patients appear to have been involved in the development, which may have provided useful additions and/or alterations. Distressing GI symptoms featured heavily in participant responses. 54% of patients reported incontinence of liquid stool on at least one occasion per month; this caused *'great distress'* to 76% of the participants. 56% reported faecal urgency occurring at least once a day, causing *'moderate to great distress'* to 85% in that group. Other problems expressed included urinary and sexual dysfunction. The authors go on to consider some studies which looked at whether total radiation dose increased the likelihood of developing long-term problems although the findings were unclear. The authors are vigorous in describing limitations of their study; they did not measure baseline date pre-treatment and suggest this would be valuable to measure change. They also recognise that their investigation was at just one time point and note that follow-up episodes would provide further useful data on changing symptoms over time. Finally, they comment that radiotherapy techniques are changing, improving and often vary in different counties and so individual findings may be difficult to replicate and find in other populations. They again, also conclude, as with the majority of other studies, that patient information is a vital part of the treatment pathway. Although the authors did include some measurement of distress of symptoms, using 'none', 'little', 'moderate' or 'great' as parameters, there was no discussion of the experiences or impact this had on the patients' lives. This highlights the difficulty in obtaining data regarding experiences from qualitative studies, and leaves a significant gap in knowledge.

A similar study by Das et al (2010) also showed that patients who had received radiotherapy as part of their anal cancer treatment generally had higher QoL scores compared to patients who had received surgery for colorectal cancer. They did not, however, compare them with a healthy population group, so it seems difficult to present the scores as acceptable. The study team used 2 different assessment scales. The Functional Assessment of Cancer Therapy- Colorectal (FACT-C) enquired about 4 QoL domains- physical, social/family life, emotional and functional and had an extra colorectal section. The second assessment tool, the Medical Outcomes Study (MOS) is a sexual problems scale that uses a scoring system whereby the higher the score, the worse sexual function. Higher participant age and pre-existing comorbidity, particularly of depression or anxiety, contributed to worsening of QoL scores. All patients were at least 2 years post treatment, with a median of 5 years (3-13 years). Although the paper concentrated on reporting sexual dysfunction, they also note that 31% reported problems with diarrhoea and 23% described problems with bowel control. The authors conclude that although *'a significant percentage of patients had difficulty with diarrhoea, bowel control and different aspects of sexual function'* (p.828), they still describe that overall QoL scores are acceptable. These two findings appear to contradict each other and demonstrate that QoL means different things to different people.

They also note that although newer radiotherapy technologies, such as intensity-modulated radiotherapy (IMRT), will reduce the amount of background radiation to organs others than those intended to be the focus, with anal cancer, there will likely always be an issue of radiation damage to the anal sphincter resulting in diarrhoeal and control problems.

A paper looking at a challenging situation, where, for various reasons patients being treated for rectal cancer received unconventional doses of radiation, provided a useful insight into late complications of pelvic radiotherapy. Jung et al (2001) analysed data from the event, noting that many of the patients affected took legal action due to what was seen as unacceptable consequences of the care they received. The authors defined late effects as *"symptoms which appear or persist 3 months after the first radiotherapy session or later"* (p 234). As with previous studies, the LENT-SOMA and EORTC questionnaires were used to assess the participants' symptoms. Although an extraordinarily complicated paper to extract results from, it presents a major finding that was not apparent in any other paper to date namely that the time from treatment completion to development of late effects, may not necessarily decrease. The authors calculated that the *"probability for the manifestation of late sequelae remains unchanged for many years"* (p. 244). If correct, this has significant implications for both patients and the provision of health services given the increasing number of cancer survivors, as this study implies that they may develop symptoms at any time following treatment. Andreyev (2007) and Olopade et al (2005) also noted that symptoms were reported up to 29 years post treatment. Interestingly, Jung et al's (2001) study also concludes that there may be a 'random process' by which some people develop late effects while others do not. This concurs with Andreyev et al (2007a, 2007b and 2012), yet contradicts others who believe higher radiation dose to be the causative agent (Nout et al 2010, Nout et al 2009 and Danielsson et al 1990).

A Norwegian based cross-sectional study involving 128 anal cancer survivors, with a median time since diagnosis of 66 months and who were treated with chemo-radiotherapy provided QoL information via a questionnaire (Bentzen et al 2013). A matched healthy population group were used, drawn from the National Populations Register, to provide an example of what could be considered a healthy control, thus highlighting any changes in QoL levels. This provides a direct comparison group, which was highlighted to be lacking in the Das et al (2010) study. Bentzen et al (2013) also presented that an absence of anal cancer specific health related QoL assessment tools directed them to use the EORTEC core questionnaire. The QLQ-C30 version of the 29 item questionnaire was felt to be relevant to the anal cancer patient group, including questions about bowel function and abdominal pain (Whistance et al 2009). As well as using the questionnaires, the participants also took part in structured telephone interviews where pre-defined yes/no questions were used. It would seem a missed opportunity that the telephone interviews did not have a qualitative element; indeed if the questions had answers that were simply yes/no there seems little benefit of using a telephone call to do this rather than add it to the questionnaire. Potentially rich qualitative QoL data could have been obtained. However, the quantitative data concurred with the study's hypothesis that patients treated with radiotherapy (usually chemo-radiotherapy) often experienced late side effects. Indeed, the anal cancer survivor group showed a deterioration in all aspects of the QoL assessment tool, with the largest score difference between the healthy group for GI symptoms being stool frequency, flatulence and faecal incontinence. As with the previously discussed studies, sexual function difficulties were also a major concern. The authors noted that it was unclear if the deterioration in the anal cancer survivors group was due to the disease and its impact itself and/or the treatment they received. Potentially, qualitative data may have helped clarify this matter a little further, noting when the problems began and if the symptoms progressed over time and what impact this had on the patient. The authors recommend that treatments should be specifically optimised to help reduce late effects although they note that anal cancer radiotherapy will always involve radiation of the anal sphincter and thus some level of tissue damage and impact on function is probably unavoidable.

Knowles et al (2013) recognises that the improvements in survival rates from rectal cancer is likely to see an increase in the number of people living with late and long term effects of the treatment. 381 participants responded to the offer to take part, 138 of whom had received treatment for rectal cancer and 243 having received treatment for colon cancer. Median time from surgery was 53 months (38-68 months) but a time scale from radiotherapy was not provided for the whole group, although a median time of 52 months post radiotherapy was given for the rectal cancer group. Similar questionnaires were used as the previous studies discussed, although later versions of the EORTC were utilised which involved similar elements. Of the rectal cancer group, 50 patients (36.2%) received pre-operative radiotherapy. Within this group, comparison of QoL was made with the group who did not receive radiotherapy. The treated group had significantly increased problems with defecation that then subsequently reduced their overall QoL. There was no mention of the experiences of defecation amongst these participants or how this actually impacted upon their lives. The authors go on to identify that new models of care that recognise the potential for late effects of cancer treatment are needed, yet acknowledge that at this time there are few specialist services able to support those with GI late effects (Henson et al 2011).

Each of the studies examined in prostate, gynaecological and colorectal cancer groups appear to recognise the importance of QoL after cancer treatment. There was a distinct spotlight on reporting of symptoms however, rather than the effect of the symptoms, on the participants' lives. This was acknowledged by Downing et al (2015). There seemed to be a general acknowledgement that clinicians must be aware of what symptoms may result from the treatment, in order to minimise problems in the future and increase patient awareness of the potential problems. There was an overwhelming reliance on QoL questionnaires, which will produce quantitative results, unless allowance was made for free-text. Jansen et al (2010) agreed that adequate data on QoL issues was difficult to extrapolate, despite its importance, partly due to a lack of *"gold standard"* of definition of QoL (p. 2280). This makes it difficult to understand why researchers have concentrated on quantitative methods to measure something that does not have an easily definable concept.

What is clearly lacking by using these methods then is an understanding of what QoL scores mean to patients. What, for example, is the effect of persistent diarrhoea, what does it stop them doing and how does it make them feel. In their systematic review, Sodergren et al (2015) agree that the lack of specific QoL assessment tools for certain cancers, including anal cancer, may reduce the benefit of using general QoL tools in studies looking at impact upon participants' lives. Sunesen et al (2015) conclude that patient information about the effect of symptoms on their lives forms an essential part of the treatment pathway, yet again allows their participants a limited vocabulary to describe their symptom distress, such as 'little' or 'great'. This highlights the lack of participant voice amongst the current literature. A further example of this is where Bentzen et al (2013), used mixed methods to examine participants' QoL after pelvic radiotherapy. As well as using a questionnaire they use telephone interviews. Rather than using this as an opportunity to gain rich insight into the participants' experiences, they limited it to "Yes/No" answers.

The study within this thesis is designed to listen to the participants' stories and to improve understanding of patients' experiences rather than concentrate on purely what physical symptoms they are experiencing.

Quality of life scores: a help or hindrance?

In the first few sections of this literature review, where studies were examined that looked at PRD in people with prostate, gynaecological and colorectal cancers, it was repeatedly seen that there was ambiguity between what the QoL questionnaires were designed to show. On the whole, they appeared to be data collection tools just for the s*ymptoms*, rather than focus on how the symptoms resulted in experiences which in turn *impacted* on peoples QoL. This section will look at definitions of quality of life, what scoring systems are intended to show, and subsequently what they are not designed to recognise.

The World Health Organisation (WHO) (1997) defines quality of life as:

> *" an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment ".*
>
> WHO (1997, p.1)

Within the WHO document, the authors recommend that any assessment of health state and effectiveness of healthcare should involve an assessment of QoL. They developed two QoL assessment tools, WHOQOL-100 and WHOQOL-BREF, after engagement with fifteen worldwide centres involving patients and HCPs managing a range of diseases. They believe that the main value of the tools is that they are based on the patient's perception, which may then alter the HCPs understanding of how the disease is impacting upon the individual. When considering the effect of PRD on patients' and their partners' lives, such a tool would provide an insight into how different symptoms may affect people differently. For example, some people may be able to cope with chronic diarrhoea better than others. Although the physical symptoms are the same for each, one may find it more distressing than another. The authors suggest that the tool may be useful to use alongside other disease measuring tools and that it may be beneficial to use a period of time to assess change in disease and QoL status.

Cella (1994) agrees that QoL measurement is an essential part of providing quality health care. He comments, *"no goal can be more important"* (P. 186) than ensuring that patients are experiencing wellbeing. Although the paper relates to palliative care, much of what he says is as relevant for anyone living with a chronic disease. He believes that healthcare interventions should be directed to improving QoL and treating the symptoms that are causing most distress and disruption. The article goes on to discuss the various QoL measurement tools available and suggests that there is often disagreement about which provides a more holistic view. He goes on to refer to a review (Cella 1991) that concluded the essential involvement in any tool of four main areas: physical, functional, emotional and social. Adams et al (2014) agrees about the importance of identifying the psychological impact of PRD on people's lives, and therefore added the Hospital Anxiety and Depression Scale (HADS) to their other QoL assessment tools. Developed by Zigmond and Snaith (1938), it was designed to be a quick and simple to use scoring system to identify where anxiety may be leading to depression or where it already co-exists. The use of this tool identified higher levels of depression associated with lower QoL levels, indicating that the symptoms were indeed impacting not only on people's physical well-being, but on their psychological wellbeing also. No mention was made of any free-text or interviews to ascertain what aspects the participants thought contributed most to their negative experiences.

Felce and Perry (1995) recognise that varying concepts of what defines QoL may explain why there are so many different measurement tools. They cite Liu (1976, p.52) who wrote that there were *"as many definitions of QoL as there were people".* Following a review of the available literature at the time, Felce and Perry (1995) concluded that there were 5 main QoL themes: physical, material, social and emotional wellbeing and development and activity. The last element, activity, may be because this work was developed in a mental health area and potentially is not as important in areas of chronic disease such as PRD. They conclude that the agreement of QoL assessment across all groups of people is important for data interpretation, yet they agree that this is unlikely and so differing tools should be used with caution in different disease/social groups.

The EORTC Quality of Life Group, tasked with developing validated QoL questionnaires for cancer studies and clinical practice, also noted that an over-reliance on toxicity/symptom scales may have reduced awareness of the social and psychological impact of PRD, as these issues are not included in many assessment tools (Halkett et al 2018). The group have recently produced EORTEC QLQ-PRT20, a QoL assessment tool that is specific to people with radiation proctitis, and which they describe as being *"quick and easy to complete, acceptable to patients, has good content validity and high reliability"* (p. 8). The tool encompasses five domains, one of which is emotional function/lifestyle. They propose that the tool is used alongside their previous QoL tool- EORTC QLQ-C30 for a fuller assessment of both symptoms and the effects of those symptoms on QoL. The authors note that further studies are required to not only establish the incidence of PRD but also the effect the disease has on patients' QoL. This thesis will go some way into addressing this call for further information on the impact of PRD on people's lives.

As previously discussed, gaining a greater understanding of what the patient is experiencing will help to direct treatments and resources to where the patient requires it most. The studies reviewed so far have generally adopted a quantitative approach. An alternative method of further exploring understanding is that of the 'lived experience'. In her work with people with chronic disease, Gullickson (1993) describes the benefits of using interpretive methodologies to better understand the human position. Utilizing a Heideggerian phenomenological approach, unstructured interviews were used to gain a deeper awareness of the human issues behind the lived experienced of chronic disease. It was clear from the interpretation of the interview text that each patient brought with them past experiences and past knowledge that would affect not only how they now perceived their disease but also how they might manage it in the future.

Walker et al (1999) used a narrative phenomenological approach to gain a deeper understanding of people experiences of living with chronic back pain. From analysing patients' stories they found a theme throughout; patients felt they were *"in the system*", the system/process of chronic disease; they felt things were done to them, happened to them, and that this made them feel powerless. These types of findings, explanations of why patients may feel as they do, are extremely valuable in helping HCPs understand the patient's situation and their experience. This knowledge would be unlikely to be discovered through QoL tools. Qualitative methods offer so much more information than "yes/no" questionnaires and can provide insight into expressed behaviour, such as why patients with chronic back pain may express negativity (Walker et al 1999). Kleinman (1988) summarises the benefits of hearing the patient story, of narrative, directly from the patient, rather than relying on the HCP's opinion of the problem. He says:

> *"Disease is the problem from the practitioner's perspective"*
>
> Kleinman (1998, p. 5)

This poignant statement highlights that in the case of PRD, the aim of this thesis is to hear about the issues from the participants' perspective, not what HCPs think it is, or what "yes/no" answers will tell us.

Finally, a further tool to assess patients' experiences, and one that is becoming increasingly popular, is that of patient reported outcome measurements (PROMs). NHS England (2016) describes PROMs as tools that measure a patient's health status or QoL pre and post- surgery and that are then used to assess the quality of care received. Originally limited to evaluating surgical outcomes, the use of PROMs is becoming more widespread. Muls (2014) presented how the use of a PROM, using a modified GSRS, allowed focus on GI symptoms that were affecting the patients' daily activities. This appears to benefit both symptom identification, for purposes of medical management, and also highlighting what the patient feels is important for them. Alrubaiy et al (2014) describe the current availability of over 100 PROMs directly related to gastrointestinal diseases and how they can improve health assessment as patient experiences and perceptions are included in the assessment. With a plethora of PROMs available, Alrubaiy et al (2014) recommend 5 components be considered to ensure the appropriate PROM is used/developed:

- Item selection- gained via assessment of old PROMs, patient and HCP involvement (patient involvement found to be the most valuable)
- Validity- actually measures what it is meant to
- Reliability- demonstrate consistent measures
- Responsiveness- able to change as required to the patient’s condition
- Interpretability- being easily interpreted to clinical meaningful values

This section has demonstrated conflicting ideas on how best to gather data about what the participant is experiencing. There seems to be some ambiguity over what QoL is measuring. Many of the tools described, concentrate simply on symptoms and how many people experience them. Qualitative methods and PROMS would suggest that QoL is more about how patients experience the symptoms and what impact they have on their lives. The use of PROMS is a growing area, yet is not fully embedded at this point in time in the care of people with PRD. This thesis will address the lack of qualitative data about peoples’ experiences of living with PRD, and will aim to provide a rich analysis of what this means to them and their loved ones.

Current awareness of PRD by healthcare professionals

With any chronic disease, the HCPs ability to recognise the problem is the first step in the patient receiving appropriate treatment. For more complex diseases, it may be necessary for specialised services to become involved. In this section of the review, the literature surrounding a HCPs awareness and knowledge of appropriate investigations and treatment of PRD will be examined.

A disparity between the awareness of PRD and IBD, despite a similar number of new diagnoses in both patient groups, has been highlighted by Andreyev (2005). In this paper, he raises the conflict between gastroenterologists, who say they are rarely referred this group of patients, and oncology radiologists who say that even if they do refer, often very little is achieved. Henson et al (2011) set out to scope the awareness amongst the 314 clinical oncologists that treated pelvic cancers within the UK and undertook a nationwide study. Using a questionnaire developed by a specialist working party, enquiries included whether any screening methods to identify patients with PRD were used, their estimation of patient numbers with PRD, how they manage PRD, if and how they refer for specialist input and their opinion of the current and potential future services available. 124 of those radiologists who responded said that they would attempt to treat PRD symptomatically, such as with anti-diarrhoeals. 91 oncologists refer this group of patients for specialised assessment, although 111 stated that they did not have access to a specialised service with a special interest in bowel radiation toxicity. Henson et al (2011) concluded that the services at that time were inadequate and that it was hoped that the anticipated guidelines (Andreyev et al 2014) would go some way to addressing this shortfall in service provision.

A follow-up study to scope the awareness of PRD and service availability amongst gastroenterologists was undertaken the following year by Henson et al (2012). Using a questionnaire designed by the same specialist working party, they enquired about the practice of all gastroenterologists who were on the current list of membership for the British Society of Gastroenterology (BSG). 866 gastroenterologists were approached yet only 165 (20%) responded. Admittedly, purely speculatively, this poor response rate may identify the lack of awareness/involvement of a large proportion of the speciality. Another statistic which highlights the lack of experience in this group is that just 5 gastroenterologists reported being referred more than 20 PRD patients in a year. Of all the referrals, sources included oncologists, urologists, gynaecologists, colorectal surgeons, and GPs, who had the highest referral rate. Henson et al (2012) concludes that PRD assessment and management services are sparse and that there needs to be improved communication between oncology and gastroenterology services.

Richardson et al (2011) believed that patients who had finished their cancer treatment were neglected, particularly if they were experiencing problems as a consequence of their treatment. They felt that any service improvement needed to be evidence-based, yet there was very little research focused on this aspect of cancer care. They undertook a literature review of research carried out between 1990-2009, to identify where future research could be directed. Of their top 5 topics suggested was 'methods to identify and manage the consequences of cancer and treatment' (p. 589). Andreyev et al (2016) 'The

Practical Management of the Gastrointestinal Symptoms of Pelvic Radiation Disease' went a long way to providing the answer.

Doyle (2008), a Nurse Consultant at the Royal Marsden Hospital, recognised that the term 'cancer survivorship' was a growing phenomenon. Her concept analysis concluded that with the ever-growing population of people surviving cancer, this presented the opportunity to promote healthy lifestyle advice and support, if consequences of their treatment were identified. She believed that nurses were ideally placed to take the lead in this. In contrast, only 7 years after Doyle's recommendation, Sanoff et al (2015) provided a bleak view of the lack of information and support provided to survivors of rectal cancer. Using a social media survey, with 11 fixed-responses and 1 open-ended question, they achieved 116 replies. The main themes identified were that the patients were given very little information about potential consequences of their treatment both before and after the treatment and that this needed to be improved.

Muls et al (2016) highlight however that a PRD service is neither a cheap nor easy service to provide. Their service has the capacity for 12,000 outpatient slots and receives approximately 400 new referrals each year. The authors note that NHS England do not have a cost-tariff to fund such services, even though they calculate an average cost of £1,563 per patient, including assessment and treatment, although they identify that the typical cost of the initial cancer treatment that the patients receive in the service was between £2,000 and £45,000. The authors summarise that it is essential that services treating consequences of cancer treatment, in this case GI consequences, must be adequately funded and supported if the needs of this growing patient population are to be met.

The National Cancer Survivorship Initiative (2013) set up the 'Living with and beyond cancer' initiative, which includes the aim of enabling further work to ensure effective management of the consequences of treatment (p.111). As a result of their co-operation, Macmillan have produced a number of documents that offer information about PRD for both patients, families and HCPs (Macmillan 2014a, 2014b, 2014c, 2015 and 2016)

This section of the literature review highlights that although there is a growing awareness of the consequences of cancer treatment, including PRD, there is still inadequate awareness amongst HCPs. This is likely to affect timely identification of people with PRD and difficulty in obtaining local treatment. Organisations such as the NCSI and Macmillan are working to provide education for both patients and HCPs, which in turn should improve care available for people with PRD.

The effect of Faecal incontinence

Diarrhoea and difficulty in controlling the passage of stool following pelvic radiotherapy is frequently reported yet the full incidence is unknown, in part due to inadequate measures in prospective studies of GI symptoms (Putta and Andreyev 2005). Such bowel symptoms are commonly reported in the QoL sections of previously discussed studies and it appeared to be a significant area of distress for patients. This section of the literature review will focus on the papers surrounding faecal incontinence (FI). The areas will include QoL issues and measurement of such, specifically in relation to FI and not

PRD exclusively, hence this separate section. The review will continue to look at the prevalence of stigma and depression related to FI and the impact on carers and partners.

Faecal incontinence (FI) is a description of a sign, or a symptom of a bowel problem, rather than a diagnosis (National Institute of Clinical Excellence 2007). Olsson and Berterö (2014) highlight a difference of opinion as to what actually constitutes FI, particularly whether the expulsion of flatulence should be included or not. This lack of a strict definition however, causes difficulties in interpreting data in studies (Maeda et al 2011). Another reason for lack of clarity in the prevalence of FI after radiotherapy is that patients often do not tell their oncologists about these symptoms, often because they feel there are more important things to discuss within the short clinic appointment time available (Putta and Andreyev 2005).

Quality of life

Of the 37 articles selected to review in further detail, everyone one of them referred to the effect of FI on QoL in some way. With regards to FI following treatment for cancer the knowledge of impact on QoL is limited (Knowles et al 2015). QoL is an important outcome that should be considered alongside cancer recurrence and survival rates (Murata et al (2008). Cotterill et al (2008), who summarised the issues, suggest that typical clinical QoL assessments were inadequate and unable to fully identify and appreciate the impact FI was having on people's lives. They referred to an international consultation on incontinence which identified that the clinician-administered tools typically used, were not specific enough to assess the impact of FI on QoL and there were no validated tools to do this (Donovan et al in Abrams et al 2005). Cotterill et al (2008) thus set out to look at QoL issues from the viewpoint of those affected, and to see if any existing tools were suitable for assessing impact. Through a series of sub-studies, the authors asked both clinicians and those experiencing FI, what questions/terms they felt were should be included. They then compared these with existing assessment tools and commented that 'none of the available instruments contains all of the important issues for patients' (p. 86).

Wilson (2007) also noted that existing FI assessment tools did not involve patients with FI in the tool development, people she terms as "insiders" (p. 204). Using a grounded theory approach, she interviewed 22 people. Of these, 21 commented that the unpredictability of FI resulted in "subsequent life restriction" (p. 84). She then identified five themes from the analysis, which encapsulated the experience of living with FI:

1. *Impact of FI on self*
2. *Response to FI, including adaptation/maladaptation*
3. *Interaction with partners/close relatives/friends/public*
4. *Positive/negative life direction*
5. *Interaction with health professionals*

(Wilson 2007 p. 204)

These 5 themes noted that many patients moved through a 'dynamic continuum', from overwhelming negativity about the impact of their FI, to becoming 'stoic' and 'resigned' and then on to greater acceptance. Further follow-up studies at 5 and 10 years (Wilson

2013 and 2015) showed that those participants who had remained in the study follow-up, had often developed adaptation strategies, either through practical techniques or acceptance of the limitations that FI placed upon them, and that those who reached this point often reported an improvement in QoL. Cotteril(2011) comments on this study, believing that HCPs should enable people with FI, to move along this pathway towards acceptance and to help them gain ‘mastery of symptoms’ (p.53), resulting in an improvement in their QoL.

However, not all people with FI will necessarily move along this journey to a satisfactory level of acceptance. In their study of 11 men, Peden-McAlpine et al (2012) found that ‘resignation’ was the main response to living with the effects of FI. Most felt that it was an inevitable part of aging, and therefore almost normal. They did not develop the coping strategies that the authors had found in other studies that had included women but did comment that perhaps ‘resignation is a coping strategy that protects against lower quality of life’ (p.303). In their systematic review of the literature, looking at FI in men post radiotherapy for prostate cancer, Maeda et al (2011) also found differences in the coping behaviour of men and women. They identified that women were perhaps more used to the wearing of sanitary towels for menstruation purposes, and so felt more comfortable with their use for protection against FI episodes, than men. This was also commented on during an earlier paper by Maeda et al (2008). The review also noted that the effect of FI on QoL had received little attention in research studies.

Olsson and Berterö (2014) used an interpretive phenomenological approach to identify and describe the effect FI has on everyday life. Their Swedish study involved 5 women and the interviews began with ‘tell me how it is to live with FI’. The 4 themes identified were:

1. *Self-affirmation*
2. *Guilt and shame*
3. *Limitations in life*
4. *Personal approach*

Olsson and Berterö (2014) p.145-146

These are similar to the themes identified by Wilson (2007), although Olsson and Berterö (2014) felt that ‘self-affirmation’ and ‘personal approach’ were not previously identified themes. Changes to how lives were now led were common. Participants told how they avoided going out, often making up excuses to miss events. Their homes became their ‘safe place’, where they could avoid social interaction and did not need to worry about their bodily functions. Knowledge of toilet location was important, an awareness called ‘toilet mapping’ (Ness 2012). The participants in this study were keen to tell their stories; they felt it would help to address the problem, to help others in similar situations and to encourage others to seek help. Expressions of guilt and shame were common in this study, and attempts to hide and disguise the problem were the norm. Chelvanayagam and Norton (2000) found similar feelings of devastation in their focus group of women with FI. They found the women often became tearful when they described how every aspect of their lives was affected by FI, but said they had found it helpful to talk to others about what they were experiencing. A diminishing ability to continue everyday activities was demonstrated by Lamb et al (2011), Murata et al (2008) and Horrocks et al (2004) who recognised that the restrictions were likely to be long term.

Stigma of faecal incontinence

Several authors wrote of how FI returns one to the bodily control of a small child, and of the associated shame and embarrassment associated with this (Alderman 1989, Bliss et al 2010 and Norton 2004). Lea (1999) describes the contradiction of excretion in modern society; on one hand a pleasurable and desirable event, even promoting total excretion clearance through procedures such colonic irrigation as a health and beauty treatment, yet on the other hand as something that needs to be hidden away and kept totally private. Elias (1978) cited by Lea (1999) pointed to the changes in the way society felt about bowel opening, describing how in the 16th century, books on manners and etiquette spoke freely of toileting, yet towards the end of the 18th century comments had all but disappeared. It would seem that what makes the difference between the act of excretion being normal and good, to shameful and troublesome is the matter of control (Lee 1999). Norton (2004) describes how we are taught from an early age that this lack of control is '*naughty and unacceptable*' (p. 85).

People living with FI often talk about the shame, disgust and stigma they experience (Ness 2012, Rasmussen and Ringberg 2009, Alderman 1989, Wilson 2013 and Chelvanayagam 2014). Stigma is a term used to refer to something that is 'discrediting' and therefore the humanity of a person with a stigma may be called into question (Goffman 1963, p13). People with FI may differ in the level of shame and feelings of stigma. Reynolds et al (2014) undertook a study where 80 people from a waiting list of a pelvic floor clinic were asked about how they felt about their symptoms. Their sensitivity to disgust was measured using a validated questionnaire and it was noted that symptom severity did not necessarily correlate with reduced QoL and that a greater or lesser sense of disgust towards their symptoms was heavily involved. Likewise, Perry et al (2002) noted that not every person with FI saw it as a significant problem. In their study of 10,116 participants, 1.4% reported major FI but just 0.7% reported this as having an impact on their QoL. It may be that different coping mechanisms (Somerfield et al 2000, cited in Norton 2004) as well as differing levels of disgust (Reynolds et al 2014) could explain this apparent contraindication.

Depression

Depression related to FI was also identified as an issue. One interesting letter to the Editor, (Bailey and Parés 2010) looked at the association between altered levels of neurotransmitters in patients with incontinence, noting that there was a high prevalence of depression in people with incontinence, both urinary and faecal. Biochemical changes in people with depression are thought to increase the possibility of urinary incontinence and the authors wonder whether there could be a similar mechanism with FI. They do note however, that the significant impact on QoL and the stigma attached to FI are the likely the main contributors to developing depression. They conclude that there is evidence to show that people with FI are likely to benefit from psychological support to deal with the impact it has. Parés et al (2011) studied 518 people from a general primary health centre and found the prevalence of FI to be 10.8%. Mental health issues were found in 51.8% of people with FI compared to 30.5% of those without FI. Their study recommends that all people with FI should be screened for mental health issues due to such a high detection rate in their study. The link between FI and depression was also identified by the Crowell et al (2007) study, where it was associated with impaired psychological functioning and decreasing, health-related, QoL. They also conclude that people with FI should be offered psychosocial assessment and intervention and that this may improve patients' QoL.

Impact on the carers/partners

The effects of FI can also have a significant impact on the patients' families/carers. Thomas (2008) believes we should 'consider continence essential to QoL', and recognises that the same goes for the carers' QoL. Van der Veen et al (2011) conclude that the silence and secrecy that surrounds incontinence, contributes to the difficulty in carers seeking and accessing help and support.

Information needs

With regards to FI and other gastrointestinal symptoms experienced by people after radiotherapy, Boulton et al (2015) examined the provision of information about such symptoms to people with cancer, to see if it was helpful or not. They recognise that keeping the patient informed about their cancer and its treatment is an important aspect of care, but wanted to know if the same applied to information about the late effects they might experience. 30 participants were provided with the Macmillan Cancer Support booklets- ‘Pelvic Radiotherapy in Men- possible late side effects’ and ‘Pelvic Radiotherapy in Women- possible late effects’. Responses to the benefit and timing of information were varied. Some people wanted to know about the possibility of late effects whereas some did not. Other participants wanted the information before or early on in treatment and others wanted it right at the end of treatment. It was evident that one approach did not suit all. The study concluded that it was best to tailor information given once a relationship had been established by the HCP.

Many authors concluded that by increasing awareness of the issues surrounding FI, then not only might research into its treatment increase, but that the problems and associated stigma of the effects of FI could be addressed (Norton 2004, Bliss et al 2010, Ness 2012 and Alderman 1989).

Conclusions and gaps in the knowledge

This literature review has demonstrated a growing awareness of issues surrounding PRD, including the diagnosis frequently made following investigations and the treatment of different pelvic cancers which can cause PRD. Following treatment for the main pelvic cancers, prostate, gynaecological and colorectal, it has been shown that people may experience significant GI symptoms which can affect their QoL. The use of QoL tools used in studies and clinical practice to evaluate the impact of PRD were discussed and whether these tools are appropriate for use if the HCP is to understand the *effect* on the patient’s life, rather than just the symptoms PRD causes. Faecal incontinence is a common symptom of PRD and can result in significant problems for the patient, including feelings of stigma and depression. This section will summarise the gaps in the literature and where further study is required.

Summary

The recognition of cancer as a disease is many thousands of years old, and radiotherapy has been used to treat it for the past 100 years. Due to its effectiveness in destroying cancer cells, any healthy tissue that lies in the radiotherapy beam will also be affected to some extent. Pelvic anatomy makes it likely that bowel tissues will receive some part of the radiotherapy dose when pelvic cancers are being treated. Although acute toxicity effects of radiotherapy are well recognised, knowledge about the later effects on GI tissue is an area that is still growing.

Advances in the recognition, assessment and treatment of PRD have been made in recent years. This followed findings from the ORBIT study (Andreyev 2013) and subsequent publication of an algorithmic pathway, *Guidance: The Practical Management of the Gastrointestinal Symptoms of Pelvic Radiation Disease* (Andreyev et al 2014). Due to the perceived difficulty in using symptoms assessment scores in busy clinics, further work was undertaken to improve recognition of people with PRD through the development of a quick and easy to use tool- ALERT-B (Assessment of Late Effects of RadioTherapy- Bowel) (Taylor et al 2016a). By using both the ALERT-B tool and the guidance document, the required investigations may highlight several GI diagnoses including radiation proctopathy/enteritis, bile acid malabsorption, small bowel bacterial overgrowth, carbohydrate malabsorption and pancreatic insufficiency.

The three main pelvic cancers recognised to often result in PRD following radiotherapy treatment are prostate cancer, gynaecological cancers such as cervix and endometrial and colorectal cancers. These are amongst the most prevalent cancers in the Welsh population. The studies reviewed highlighted that QoL measurement was frequently undertaken, yet actual impact of PRD upon the participants' lives was rarely considered. It was shown that the commonly used QoL tools concentrated on symptom identification, but that these tools did not allow for data gathering of the experience of living with the symptoms. If patient care is to be as holistic as possible, it is important that patient experience is included in the identification of PRD. This would then allow a greater understanding by HCPs of how PRD can cause significant problems for the patient and their families. Identification of symptoms is important, but so is an awareness that experiencing profuse diarrhoea and FI may mean the person no longer leaves home, potentially gives up work or perhaps becomes a social recluse, for example.

Knowledge of PRD amongst HCPs was noted to be poor, even amongst those who care for people who are likely to be affected (Henson et al 2011 and 2012). However, the 'Living with and beyond cancer' initiative led by The National Cancer Survivorship Initiative (2013) and supported by Macmillan, have made significant steps toward improving both patient and HCP awareness of PRD, through campaigns and production of several documents as part of their 'Consequences of Cancer Treatment' programme.

FI was noted throughout the literature to be one of the more distressing symptoms of PRD. Impact of FI upon QoL was noted in all the articles examined, and several authors identified the development of feelings of stigma and/or depression as a result. It was not only the study participants who suffered due to FI; this was also shown to affect families and friends, often with a breakdown in communication between the two parties.

The literature looking at the provision of information about the potential late effects of cancer treatment was reviewed. This was a complex area as different people want varying amounts of information whilst considering their treatment options. For some, end-survival was all that mattered, but for others, it was important that they knew all potential outcomes. Norton (2004), Bliss et al (2010), Ness (2012) and Alderman (1989) all noted that the more information and discussion there was about FI and its impact, the greater the potential reduction in the associated stigma.

The most significant gap in the literature available was a knowledge and understanding of peoples' experience of living with PRD. There was much detail about what symptoms people may experience, how PRD can be identified and even treated, but very little about what it is like to live with, apart from Wilson's (2006) study that did offer examples of peoples' experiences of living with PRD. This lack of knowledge suggests that HCPs are not fully informed of what their patients are experiencing. It would suggest that if asked by their patient 'am I the only one who can no longer leave the house?' the HCP is unable to answer with any certainty. If people with PRD are to be cared for with a fuller understanding of what types of difficulties they may be experiencing, then there needs to be further research in to peoples' experiences of living with PRD.

This thesis aims to address this gap in the knowledge currently available by enquiring specifically about the experiences of the participants, using a method and analysis that will allow the participants' experience to be clearly heard and discussed.

Chapter 3: Research paradigm focus

In this chapter, I will discuss the researcher's ontological alignments and ideas that have shaped this thesis. Denzin and Lincoln (2008) define such personal positioning behind research direction as the 'research paradigm'. This will guide the research and utilise my world view as 'interpretive-bricoleur' (p. 245), as opposed to following a set text-book process that cannot be deviated from. Using Becker's (1998), in Denzin and Lincoln (2008), description of a bricoleur as a maker of quilts, this draws a picture of the qualitative researcher using various thoughts, strategies and methods to finely weave the finished work, often resulting in unique pieces, blended together as appropriate and desired. It is important however to ensure that quality attributes of the study are visible, as suggested by Caldwell et al (2011).

In the early days of the research process, it was invaluable to keep returning to the research question as well as to my own personal philosophical stance. This helped ensure that the research journey was appropriate to the question under consideration, that the methods utilised remained appropriate and that my passion as a nurse, who cares deeply about the people she cares for, would hopefully shine through the research.

Research Paradigm

To help with clarification of how to select the research method, an examination of one's philosophical underpinnings was necessary to identify what were felt to be important philosophical aspects. This would also help to ensure that the research was in line with one's own beliefs in how truth and knowledge is learned. In the very early days of the Professional Doctorate course, the work of Durant-Law (2005) guided this thought process through the rocky journey of developing a position on philosophical foundations. Utilising his work provided the opportunity to examine the 3 questions of 'what exists?' (ontology), 'how do I know?' (epistemology) and what is valuable? (axiology)' and this would together guide the chosen methodology.

Ontological alignment

To further ascertain how best to approach the research process development, there needed to be a consideration of ideas about truth and reality and how they exist, develop and can be identified. For some, the only way to uncover a truth is to study it using scientific methods, often testing it against set criteria through modernist quantitative methods (Lincoln et al 2011). Yet post-modern, constructivist, and interpretive approaches recognise that social reality relates to culture, and often to previous experience. From my extensive nursing experience, seeing how different people, perhaps from differing cultures or social class, treat similar events, such as pain or chronic disease, it is felt that what *is* truth, and how truth is viewed through experience, can differ widely. People may cope with similar events in different ways, including bowel problems after radiotherapy. It seems evident that even those who experience the same events, such as these bowel symptoms, may identify their experiences through different realities. For example, some may cope well with FI and learn to adapt to its impact whilst others struggle to cope. Therefore, a research method was required that enabled knowledge to be gained through listening to and interpreting peoples' experiences of PRD.

Epistemological and axiological alignment

Epistemology enquires how truth and reality can be known and asks us as individuals *"how do I know the world"* (Denzin and Lincoln 2008, p. 245). It is necessary to consider this when selecting one's research method as it will influence which method will provide the answers to how you feel the knowledge can be uncovered. As Christians (2008) noted, to increase understanding of human lives there is imperative need for change from previously blanket quantitative methods of research to methods which can explore humanity and the differences we all as individuals express. When linked to my own ontology, that reality is often different for different people, then this again points further towards a qualitative approach of enquiry and one that asks different participants for their individualised view on their reality.

It was helpful to again return to the research question. This was vital in order to ground oneself in the task of identifying, initially personally for one's professional growth and then more importantly to others, what it is like for people who experience PRD. No amount of figures or statistics would get to the lived experience of what it is like for them. Yes, numerical data could explore the number of times the person had episodes of FI but it was perceived to be vitally important to grasp from the very beginning that this was not what was important to pass on to others experiencing PRD. What *was* important was to tell others about *what it is like* to experience something like FI, how that made them feel and how it affected their lives. It was therefore clear that a qualitative approach would meet this need to tell of others' experiences. Flick et al

(2004) summarises this claim of what qualitative research can achieve, and what is an objective of this thesis-

> *"to describe life-worlds 'from the inside out', from the point of view*
> *of the people who participate"*
>
> Flick et al (2004) p. 3

Within nursing practice, there are frequent encounters people with people who are experiencing similar physical problems and yet identifying and coping with it in entirely different ways. When developing the research question, consideration was given on how best to recognise their experiences given that they were often so different? How could their different realities, as individual truths, be recognised as valid experiences? This began to further guide the methodological development towards an interpretive approach where the participants' stories could be heard and an interpretation made about what the participants were saying. In this way, as a researcher and not a participant in their lives, an identification and understanding of experiences could be gained, and others told about their experiences, *in* order to increase awareness and understanding of PRD.

Methodology

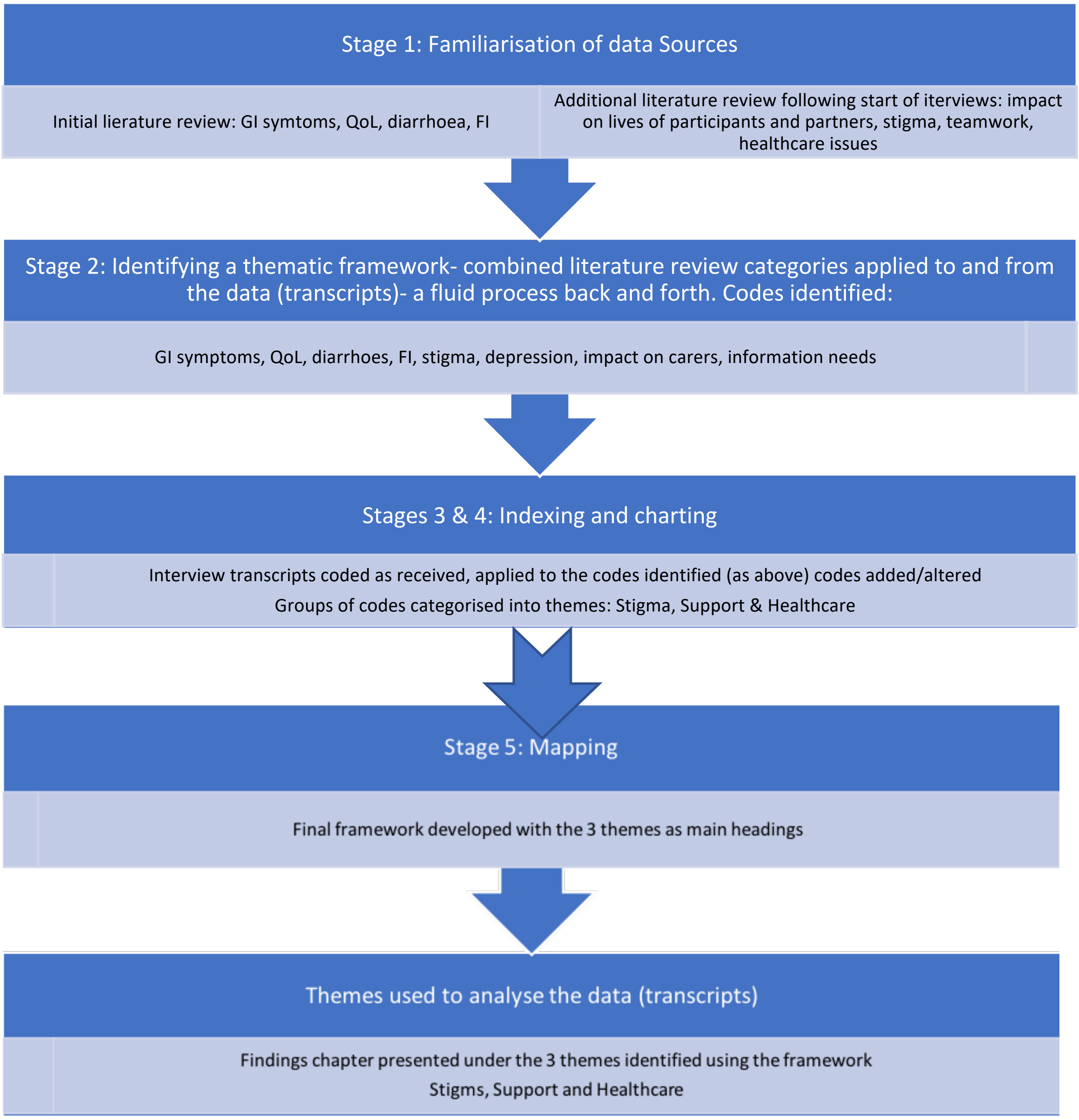
As previously discussed, it was clear that a qualitative approach would be a step towards uncovering more about peoples' experience of PRD and what living with the disease actually entails for them. Individuals' experiences of similar events or symptoms can be very different. To capture these experiences required a data collection method that allowed participant free voice to express their stories with minor guidance to keep the topic central. Therefore, a semi-structured interview was selected as the data collection tool. Another option considered was a focus group, but due to the personal nature of the anticipated stories this was not felt to be appropriate as it could have resulted in further distress to the participant. As it was a possibility that interviews could therefore identify multiple ways in which the participants recognised and dealt with their bowel symptoms, it was necessary to use a method that could help with handling the volume and complexity of data that would be collected. Using a framework analysis would support the research objective of exploring the data whilst at the same time allowing the participants' voices and stories to be heard (Ritchie and Spencer 1994).

From the beginning of the research development, it was clear that there would be elements of co-construction throughout. This would be through continual input of ideas and concepts between me as the researcher, the participants and their partners, if present, and obviously that of the research supervisors. Rather than ignore this, it was helpful instead to first recognise it, and then to use it as a positive contribution to the work. As the use of interviews becomes increasingly common, role play between the researcher and the participants is inevitable, but it needs to be recognised, and steps taken to avoid the researcher's ideas becoming more important than the story the participant has to tell (Mann 2016). As a novice researcher, it was helpful to recognise from the outset that anxiety during the first few interviews might result in the interview being overly pressurised in an earnest attempt to 'get to the truth' as quickly as possible. One way of trying to overcome this was to encourage reflexivity during the research process by using a diary, or field notes. In this way, ideas, concerns and questions could be noted in preparation for the following interviews and data analysis period, as suggested by Mann (2016).

Chapter 4: Methods

This chapter will discuss the research design of using a descriptive and exploratory qualitative approach, to undertake applied health research, and how this influenced all methodological choices , including participant selection, the data collection tool as semi-structured interviews, how the interview data was transcribed and the method of data analysis using framework analysis (FA). In order to demonstrate the scholarly value of the study, effort was made to promote quality and validity. This is one of the benefits of FA in that it encourages traceability of the management of often large amounts of data, as found in the interview transcripts. It is noted that other methods also provide this benefit. The most significant benefit of using FA, and one of the main reasons for its selection for this study, was its applied policy approach, one that provides specific information which can then be applied to policy development. Its step-wise approach also provides guidance and demonstrability of decisions made, ideas re-visited and connections made, which was ideal for a novice researcher. The following diagram shows a step-wise explanation of how FA was used to develop the analysis from the raw data.

Diagram 2: Process of framework development and application



Stage 1: Familiarisation of data Sources

Initial lierature review: GI symtoms, QoL, diarrhoea, FI

Additional literature review following start of iterviews: impact on lives of participants and partners, stigma, teamwork, healthcare issues

Stage 2: Identifying a thematic framework- combined literature review categories applied to and from the data (transcripts)- a fluid process back and forth. Codes identified:

GI symptoms, QoL, diarrhoes, FI, stigma, depression, impact on carers, information needs

Stages 3 & 4: Indexing and charting

Interview transcripts coded as received, applied to the codes identified (as above) codes added/altered

Groups of codes categorised into themes: Stigma, Support & Healthcare

Stage 5: Mapping

Final framework developed with the 3 themes as main headings

Themes used to analyse the data (transcripts)

Findings chapter presented under the 3 themes identified using the framework

Stigms, Support and Healthcare

Sampling and participant recruitment

As the requirement was to collect data about experiences of living PRD, recruitment of participants from a specialised clinic was necessary, where people were referred for investigation into bowel problems after receiving pelvic radiotherapy treatment. As usual for an out-patient clinic, there were many different characteristics of patients attending these clinics, including age, sex, original cancer type and length of time since diagnosis. Where possible it was hoped to include participants' partners, and this too would involve differences such as those who were single, married or in a partnership. Therefore, within the confines of the study, it could be difficult to ensure that each of these groups was equally represented. A return to the main aim of the study, which was to explore the participants' experiences of living with PRD, identified that a fully representative group of each cancer group, sex and age was not only unlikely to be possible within a small study, but also unnecessary. Therefore, meeting the general criteria for inclusion was the main priority for sampling (Merkens 2004).

Inclusion criteria

- People attending for their first visit to the Late GI Effects Clinic
- Ability to communicate in English

Exclusion criteria

- Comorbidities that may affect ability to participate, such as physical or language constraints
- People returning for subsequent appointments, to reduce potential conflict of interest between the patient/participant and HCP

As the participants would be recruited from the clinic that was run by the researcher, it was important to avoid any undue pressure on potential participants. Once the professional clinical relationship had developed, they may have felt under pressure or somehow obliged to participate because of the person asking them. Potential participants also needed to be aware that taking part in the study would not offer them any clinical benefit, and this was clarified in the PIS. It was recognised that undertaking the research at the same time as being the HCP involved in their medical management, could contribute to unreliable data collection; the participant may talk about what they thought was wanted to be heard, rather than perhaps be more objective with an unfamiliar researcher undertaking the interview. Therefore, the out-patient clinic nurses gave out the PIS to patients if they met the inclusion criteria and the study was not discussed at the clinic appointment unless the patient asked for more details. Attached to the PIS was a page with the contact details if they wished for further information and/or to discuss taking part.

In total nine participants were recruited, five of whom also involved their partners. Ethical permission to interview ten to fifteen participants had been granted, with partners if available, but it was clear by the eighth and ninth interview that no new themes were being identified, a process of saturation common to an inductive research approach (Cheek 2011).

Data collection

It was previously noted that using interviews as part of a qualitative approach would allow examination of the participants' experiences of living with PRD. Interviews as a data collection method are widely used in qualitative analysis as they allow the recording and analysis of the participants' perspectives (Hopf 2004). The aim of this study was to gain an insight into the participants' experiences of living with PRD and so using interviews to gain this information was appropriate. As previously discussed, due to the personal nature of the interview topic, other group interview/discussion methods, such as focus groups, were not considered to be appropriate.

As the intention was to hear about experiences associated with PRD, it was identified that a semi-structured interview would allow the focus to be kept on the subject topic, whilst allowing the participants to talk around elements of this topic that they felt had particularly affected them or if they had a story that was particularly important for them to tell. The literature had demonstrated that the patient voice was rarely heard, and that in the majority of studies their experiences were only identified through a ‘tick-box’ process. For the purposes of this study, it was recognised that by using semi-structured interviews, the participants’ experiences would be clearly heard. As the data analysis method was to be framework analysis (FA), the initial themes identified from the literature review were to be used as a basis for guiding the interview, along with open questions to give space for other areas the participants wished to explore.

Initially the plan was to begin with an open question such as ‘tell me about the time you began to notice things had changed since your radiotherapy’. The ‘things’ were not specified at that point as it was important to hear their stories, what they felt was important to talk about, hence the rather vague question to open with. As suggested by Mann (2016), a list of potential questions to consider during the interview was developed to help guide the interview in case of a blank mind due to nerves, or if perhaps the interview began to lose direction. These questions were:

- Can you tell me about the time you began to notice things had changed since your radiotherapy?
- How did you feel about that?
- Did this affect you in other ways?
- Can you tell me more about this?
- How did that affect you?
- What is it like living with these problems?
- Is there anything else you would like to add?

It was important to realise that the data would be gained through the interviews, and that it needed to be prevented from becoming a counselling interview for the participants (Mann 2016). Not only would that not necessarily provide the information required, it would have been an unethical direction and one that needed to be avoided, although a relationship with the participants to some extent was necessary to help make them feel comfortable enough to talk about difficult experiences they may have had. In line with the study design and ethical approval, each potential participant was offered the option to be interviewed in a place of their choice, including either at the hospital, or in their own homes.

Two digital recording devices were taken to the interviews, in case of failure of the first. As suggested by Mann (2016) a note book with a list of potential questions to consider during the interview, as well as space for note taking, was also used. The main issues identified in the literature were also highlighted in order to identify if these were also important themes for the participants.

The participants were offered a choice of where they wanted the interview to take place. The first participant asked to be interviewed just prior to his colonoscopy. He had travelled for thirty minutes and was still experiencing the effects of the bowel preparation. His frequent trips out of the interview room to use the toilet, anxiety about the impending procedure and the interview process itself combined with the fact that it was the first interview for the researcher, meant that it did not go well. The environment was not ideal and neither party felt relaxed enough to talk freely. This was evident in the recording and transcription, which was rather short and executed with too many questions and quick responses. The participant and his wife were not given enough time to stop and think. The silence seemed terrifying and so any pauses in the conversation were filled with my unnecessary small talk. Being so focused on obtaining information and getting through the interview with minimal inconvenience for the participants, caused it to be controlled too tightly, over-managing and strangling the free flow of natural conversation. Such was the unhappiness at the performance that the next interview appointment was postponed until the transcripts had been received to allow for reading and reflection and to learn from the mistakes.

The lack of reflexivity from this first interview was very apparent in the typed transcript pages. In an attempt to re-think one's perspectives on the research, a thinking task suggested by Etherington (2004) in Mann (2016) page 18 was undertaken. This involved a re-consideration of the influence of the researcher's background history, including presuppositions and personal positioning. This enabled a re-focusing on why the study was felt to be important and how best to gather information from the participants about their experiences. It was almost as though, through considering this prior to the subsequent interviews, there seemed to be less obvious pressure about what was needed from the interview and this allowed me to stop talking, to stop asking endless questions and confidence enough to be quiet and to only ask questions when it was really necessary. Fortunately, all of the other participants requested to be interviewed in their homes and this provided a much more suitable environment for them to relate their experiences.

Stepping back and loosening control was not easy, but it became simpler as each interview took place. I was increasingly able to allow the participant to lead the way at times and I became more adept at gently bringing the conversation back to how the symptoms were affecting them when it seemed necessary. The participants talked and their voices were heard. Noticeably, the timings of the interviews became longer, even though the transcripts were not necessarily so; there were silences, but comfortable and thoughtful ones. After the first few interviews, there were opportunities to relax and even enjoy the process although many a painful story was heard and there were often tears, both the participants' during the interview and mine in the car on the way home.

Note Keeping

A notebook was used to jot down my own thoughts both during and after the interviews. Immediately following each interview, either back in the office or mostly after moving the car around the corner from the participants' homes, further notes were written in the field note book. It was helpful to record how the interviews went, what went well and what did not go so well. Potential issues that were beginning to emerge were also noted, particularly as some had not especially been expected topics to be discussed, such as the extreme distress over episodes of FI. Attempts were made to note personal opinions, such as thoughts on the wonderfully varied homes I was so graciously welcomed into, initial thoughts on the relationships between partners when present and the perception of being treated differently as a researcher compared to a clinical nurse in uniform. These notes helped throughout the analysis period, reminding me of small nuances, like certain décor, which enabled thoughts to travel back to the interview itself. They were also used to guide subsequent interviews, with changes made, such as learning not to interject so frequently and to use long silences to promote further thoughts from the participants, rather than silences that had to be filled.

Data transcription

Before the research journey was fully begun, it was planned that transcription would be undertaken solely by the researcher. During previous study modules, there was recognition of the benefit of paying attention to the minute elements of written material and it was thought that this would encourage identification of the effect of one's personal interactions within the interview, whether co-construction of the stories was too overwhelming and the participants' voices were muffled. Other experienced researchers advised that time was to be a struggle, and so fortunately, it had already been added to the research protocol and ethical agreements that, in all likelihood, a transcriber would be used for the interview data. Although initially disappointed to be unable to undertake the whole process, it was noted that transcription of interviews can be a significant undertaking and even with the greatest attention to detail, it is merely an attempt to represent speech (Mishler 1986). He agrees that even the recording itself is only *"a partial representation of what 'actually' occurred"* (p.48). With this in mind, along with a significant increase in clinical practice work load, it was deemed necessary that in order to achieve timely paper transcripts for reflection upon in preparation for subsequent interviews, that an experienced transcriber from the University would be used.

Although there would inevitably be some loss of recall of events such as facial expressions, body language nuances and changes in voice tone, some mitigation of that loss would be made through using the field notes. There was also consolation from realising that it was the *content* of the stories that was of prime interest, and this could be more than adequately achieved through out-sourcing transcription. Cutler (2004) highlighted that one benefit of *not* performing one's own transcription is that *"erroneous assumptions"* can be avoided, where the participants' words could have been subsequently misrepresented. Some justification in this decision was felt when on a few occasions, the person who transcribed the interviews told of how she had been moved to tears during the process, and so through using independently typed interview transcripts, the data produced was as consistent and unbiased as possible.

Data Analysis

With the main aim of this study being to gain insight into participants' experiences of living with PRD, thus increasing awareness of the disease and influencing policy development so as to improve care provision, it was essential to use an analysis tool that would ultimately provide the findings to improve care. Originally developed by Ritchie and Spencer (1994), framework analysis (FA) was used to conduct qualitative research, the findings of which could have a direct impact on practice and policy implication. Its beginnings came out of a specialist unit within the Social and Community Planning Research Unit, where Government, Councils, and Universities for example could request research studies into areas requiring increased knowledge and application of findings. As Ritchie and Spencer (1994) state, *"it has a key role to play in providing insights, explanations and theories of social behaviour"* (p. 174), which fitted well with one's methodological position and the study aims of gaining insight in to the participants' experiences of living with PRD.

Although there were pre-conceived expectations about what the participants were likely to talk about, it was important to be open to hearing about their experiences, as this was the aim of the study. It was also important that the participants' voices were heard; the aim of the study was to gain insight into *their* experiences, to enable *their* stories to be told and so an analysis method was required that could keep individual stories intact. Therefore, FA was chosen as not only would it provide a basis for using interviews to study the participants' different experiences, but would also enable *their* voices to be heard, with interview extracts maintained, which could then be used to inform others using the powerful narratives obtained. With the application of a theoretical framework to the findings, it also allowed examination of the experiences of the participants through existing theories, or if indeed different concepts were presented. The fact that the authors insist it is not a *'fool-proof recipe" (*Ritchie and Spencer 1994, p. 177), but one that relies on the ability of the researcher to consider concepts and connections, became evident early on the framework development. This will become apparent later in this chapter when discussing how the themes and theories were identified.

As well as looking at the original work of Ritchie and Spencer (1994), there was also benefit in looking at how others had applied FA to their own work. Gale et al (2013) used a similar method to examine paediatric homecare and gave a useful description of not only how to apply the method but listed potential pitfalls which were useful to consider prior to starting. In their study, they also adapted some of the terms originally used by Ritchie and Spencer (1994), making the definition between codes, categories, sub-themes and themes a little clearer to understand and define. Ward et al (2013) also found FA a useful approach when managing interview data and recommend it as a beneficial tool for nursing research due to its transparency, rigour, and guided process.

Other methods were considered including narrative analysis but further enquiry into this method suggested that in-depth linguistic analysis would have been necessary for a richer analysis and the lack of information available about *how* to undertake narrative analysis made this a difficult option for a novice researcher. Denzin and Lincoln (2011) describe qualitative research as an activity that “*locates the observer in the world”* (p. 3), however a full immersion in the field, such as an ethnographic approach described by Hammersley and Atkinson (2007) would not offer recommendations for policy/practice change. Interpretive phenomenological analysis (IPA) would have also offered the opportunity to look at the participants’ experiences. This method is particularly beneficial if the study is looking at *how* the participants are trying to make sense of what has happened to them. For this study however, the main aim is to hear of the participants’ experiences, what happened to them and how this made them feel, rather than how they understand the process of what has happened to them.

Upon receiving the first transcript, it was evident that even early on there were certain themes that were standing out, and further exploration was required. Therefore, it was clear that the choice of FA as an analysis method, with themes at its core, would be appropriate. Whereas it was recognised that other qualitative methods would have enabled some of the benefits outlined above, framework analysis has a specific design and history to encourage an impact on and change of practice, the ultimate objective of this research project. Other suggestions of the potential benefits of my using FA provided by Ritchie and Spencer (1994), included the ability to provide a greater understanding of the issues, such as those experienced by people with PRD whist employing structure and transparency to the work if further examination of the process, or indeed further study in the future, was required. In summary, to identify participant experience, and to be able to use this knowledge to improve care, FA was selected as most suitable to meet these requirements.

Stage 1: Familiarization

Prior to starting any data analysis, it is important to become familiar with the wide body of knowledge that already exists around the subject under study (Ritchie and Spencer 1994). The literature review formed the basis of current opinion on the recognition and management of PRD, and to some extent, the symptoms people with PRD describe. The literature search and the writing of the review, was an important stage of my familiarization with this existing knowledge; what studies had been done, their findings and what impact this was starting to have, if any, on patient care. At this stage, the framework began to develop. It was clear from the literature that people with PRD were experiencing troublesome symptoms, particularly FI. Hospitals and various healthcare establishments seemed to play a big role in the form that investigations and treatments were taking, although it was noted that awareness of PRD amongst HCPs was not considered to be acceptable or consistent.

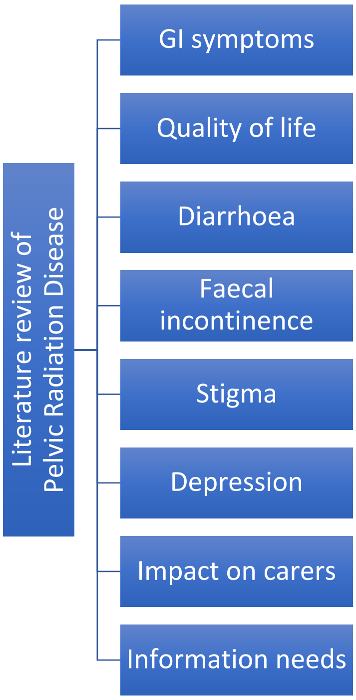
The process of familiarisation with the interview data began as soon as the first transcript was received. The transcript was edited to create line numbers, which would help with categorising, re-checking and general data handling. As well as repeatedly re-reading the transcript, the recording was listened to several times, to check both the accuracy of the typed work and to be reminded of elements that took place during the interview, such as a partner moving to sit by their loved one, an episode of depressed body language or tears spilt. In conjunction with the field notes, there was a development of a sense of immersion in the participant story. This was repeated for each subsequent interview.

Stage 2: Identifying a thematic framework

The development of a framework is performed by considering ideas that are starting to emerge, initially from the literature review, and then applied to and added to from the data collected through the interview transcripts. Ritchie and Spencer (1994) describe this as "*beginning the process of abstraction and conceptualisation*" (p. 179). This may occur differently in different studies depending on the size and time available. For some, all the data is reviewed, whilst for others, only a sample is used to form the initial review of the data issues. For this study, the literature review was considered in its entirety. The ideas highlighted from the literature review began to form the basis of the framework.

As discussed, during the familiarisation stage, recurrent issues were becoming evident from the literature. The literature review had identified that PRD was relatively common in people following treatment for prostate, gynaecological and colorectal cancers and so the first key issue was 'GI symptoms'. Many of the papers discussed that QoL was often affected and that frequent diarrhoea was one of the major factors. Therefore, 'QoL' and 'diarrhoea' were also noted to be key themes. Due to the issues of 'diarrhoea' and 'FI' being noted as major concerns for people with PRD, these issues were further explored within the literature and again identified as key codes, along with 'stigma', 'depression', 'impact on carers' and 'information needs'. The initial framework was developed from the literature, resulting in the first eight codes. This basic framework was then applied to the first interview, to help understand if these were major issues for the participants, or if indeed different issues were raised.

Diagram 3 - Initial framework formed through the literature



One of the main processes of FA is to develop and refine the framework through frequently re-visiting the data, in this case the literature initially, and then through application to the interview transcripts. The next stage, indexing, played a significant role in the further development of the framework.

Stage 3 & 4: Indexing and charting

Although Ritchie and Spencer (1994) have these as separate stages, for this study it seemed natural to undertake these steps as one process as the steps occurred concurrently and steps were frequently re-visited. Others have also altered the stages slightly to suit the progress of their analysis. Gale et al (2013) and Ward et al (2013) use similar terms but in a different order and it was useful to use their stages as an accompaniment whilst following Ritchie and Spencer's (1994) method, noting suggestions to enable provision of a clear, demonstrable pathway.

Indexing is the process whereby the initial framework is applied to the data, developing the framework further. It is a fluid process that involves constant return to previously indexed transcripts, and throughout this, judgements are made on meaning, and potentially alterations made to the framework, until consistency has been achieved. This process must be visible to others, a particular requirement if multiple researchers are working on a larger study, to ensure each researcher is using similar thought processes, but also to allow traceability and justification of decisions made for every study.

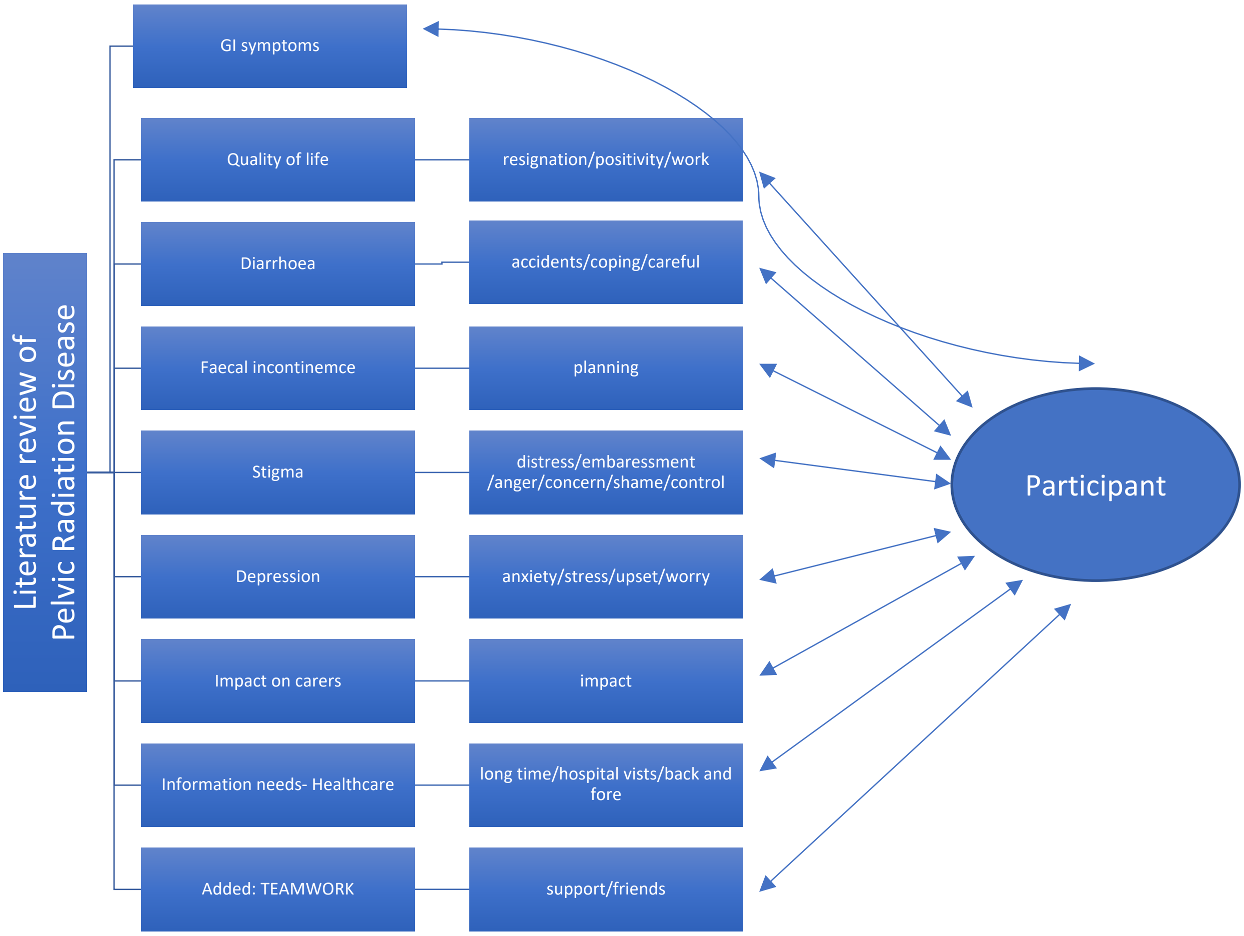
Each of the interview transcripts were coded as they were received. This not only enabled the framework to develop in a measurable way, through annotations in the margins, but also allowed subsequent interviews to be guided. With the use of coloured felt pens, many hours were spent poring over the transcripts, noting issues and marking similar elements. Because this was done as each new transcript was received, recurrent ideas were recognised and considered if there were connections or diversities across the interviews.

Small stories and sometimes just phrases or sentences, were identified from each of the transcripts using the initial code identified. Groups of codes were beginning to emerge at this point, particularly as I was noting that some of the codes were often inseparable from others. Gale et al (2013) suggests beginning to group the identified codes into categories, then subsequently into themes (p. 4). To help guide this process I used the diagrammatic process seen in Table 5 as a guide.

Through the use of coding, recurrent topics, many of which had not been particularly expected, clearly began to emerge, particularly after the first two or three interviews were analysed. Although there are computer packages to assist with coding, this process was undertaken by hand, and indeed was found to be a necessary and natural step in getting to know the data. At its simplest, coding is an aid to begin categorizing and sorting (Charmaz 2006), although the process itself provides much more than just a 'filing system'; it is another important step in the analysis process that can lead to expansion and transformation of data (Coffey and Atkinson 1996). Even at this early stage, I used my own judgement to consider the relevance of individual narratives, phrases and use of words and to decide which code to apply. Ritchie and Spencer (1994) describe this as requiring "*both logical and initiative thinking*" (p. 180) and Gale et al (2013) highlight the need for "*reflexivity and rigour*" (p. 2). An example of how coding was undertaken, is shown in Appendix 3.

The coding process further developed the framework and Table 5 below shows how each of the original codes either developed into, or was added to, during the coding process.

Diagram 4 - Code development



During the first few interviews, although the initial eight codes were at the forefront of thought for purposes of identification, the main aim was to identify what the participants were telling me, rather than, at that point, purposefully look for what was expected, and so an inductive approach was used. Induction takes place when patterns are identified from observation (Snape and Spencer 2003). Talk around GI symptoms such as diarrhoea, abdominal pain and faecal incontinence was expected, yet these words were rarely used, as is shown in the above diagram where ‘GI symptoms’ is not followed by further coding. It became apparent that many of the participants were talking of their shame and embarrassment, rather than the symptoms themselves and so further reading of literature about the psychological impact of living with chronic diarrhoea/FI was necessary.

The work of Goffman (1963) appeared regularly in the literature about the effects of FI. As I read more of his work on stigma, elements were noted that had not appeared so clearly to me initially and I identified that his existing theory was beginning to fashion my thinking and helping me to understand the participants' experiences through that lens. Other authors also considered how an excretory event that defers from the 'norm' is considered antisocial, illicit and unacceptable. From that point onwards, deductive coding was also used, keeping a clear mind for isolated and repeated experiences, yet also focusing on areas around stigma, as Goffman's', Inglis's (2000) and Douglas's (1966) work had provided evidence to support the conclusion that stigma was a major factor in people's experiences. Coding in this way encouraged a greater recognition of the feelings and experiences with which the participants identified.

As refinement of the framework developed through coding and development of the thought process, the codes began to emerge into categories which in effect, were groups of codes. The table below gives examples of extracts that were coded initially and how they further developed into the categories. Both the reference of interview and the line number have been kept intact for purposes of traceability as they were throughout the original work saved in the note pad. This was particularly helpful when reflecting and conducting further analysis, looking at patterns, similarities and differences across the data.

Table 4 - Development from code to categories

Codes and examples quote	**Categories**
Distress: "*It was a nightmare*" Int 2, line 31	How this made them feel
Embarrassment: ***"****I wished there was a big hole and I just could have been swallowed up in in"* Int 3, line 208	
Anger: *"Why didn't they look after me?"* Int 4, line 531	
Upset: *"well I'm thinking this is not living, it's just existing"* Int 6, line 230	
Anxiety: *"I'm frightened of being on 2 trains to get to town"* Int 9, line 23	
Stigma: *"that's how he is, he thinks it's a stigma, it's terrible"* Int 3, line 533	
Shame: *"He's such a private person he do say this is the worst thing that could ever have happened to me"* Int 3 line 494	
Impact: *"my daughter gets upset because he won't even go over to her house for a cup of coffee"* Int 6, line 166	Effect on their lives
Worry: *"you're keyed up all the time…I wouldn't want to stain the seat of a blooming taxi"* Int, 6, line 267	The need to avoid
Concern: *"Still in my mind isn't it. You know, what damage has been done because it can cause cancer can't it?"* Int 4, line 317	

Accidents: *“I have had accidents and the pad hasn’t been sufficient”* Int 8, line 102	Difficult experiences
Control: *You know I don’t really want people staying here either because they might be in the bathroom when I want to use it”* Int 8, line 130	
Planning: *“I’ve got to know where we’re going….and I’ll think to myself where are the toilets in town?”* Int 9 line 104	The need to plan
Careful: *“So I always make sure I know where the toilets are, I will not make the mistake again if I have food out”* Int 9, line 124	The need to avoid
Resignation: *“I just try and get on with things”* Int 8, line 249	Support of family
Family: *“I definitely wouldn’t give up” “Wouldn’t let her” (husband) “Oh definitely, I would have got through it otherwise”* Int 7, line 177	Support of friends
Friends: *“I’ve got another friend, she’s been brilliant, absolutely”* Int 8, line 225	
Colleagues: “*they all know in work, my condition, and they’re very good about it, I say you can’t go in the loo I’m off, you know, they know about my wind, because everywhere I go I’ve got sprays and they all laugh you know, good as gold in work”* Int 9, line 82	Teamwork
Teamwork: *“I’m going to make sure he gets through this”* Int 1, line 161	

Positivity: *"I try to see it positive because they've cured one thing but given me another"* Int 5, 104	
Work: *"(husband) was lucky enough where he worked, they gave him the full six weeks off"* Int 7, line 186	Problems with healthcare services
Coping: *"I think it's the way I've got to cope with it"* Int 4, line 377	
NHS: *"They don't cater for people with my type of cancer. -the chair, I couldn't even sit down. Some days I was in so much pain with my skin and everything and they expect you to sit on those hard plastic chairs. I think there was one comfortable chair in the whole department because you just can't sit on them"* Int 7, line 196	Lack of awareness, understanding
GP's: *"I had a bit of a performance with my GP over that, to get back to see the Consultant. He wasn't very helpful"* Int 3, line 161	
Charities: *"There's a charity, Tenovus, I went to one of the mobile clinics in the car park and I spoke to the clinical nurse and they gave me his card and he said straight away I think you've got prostatitis"* Int 1, line 108	Difficulty in accessing the right services
Back & fore: *"Even when I was going back and fore to the hospital every three months and every six months, I mentioned it but no one said anything"* Int 9, line 30	
Long-time: *"Every time I went back like three months, they'd obviously ask you oh how's your bowel, and I'd say well I can't control them, oh try this or try that or, and they were giving me different medications to try and help thing like that. But I mean*	

this is like eighteen months down the line from when my treatment finished" Int 7, line 206 **Hospital visits:** *"Well I'm just taking it one day at a time really, trying to get well, dealing with physiotherapy and more scans and visits to the hospital and yeah, that's all it looks like at the minute is just hospital visits and see what they can do for this or that"* Int 7, line 160	

As suggested by Ritchie and Spencer (1994), the framework was developing from codes identified in first the literature, then the interview transcripts. The codes were then focused into categories, which were then further developed into themes. The table below demonstrates how the framework was developed using this process:

Diagram 5 - Development from categories to themes- format

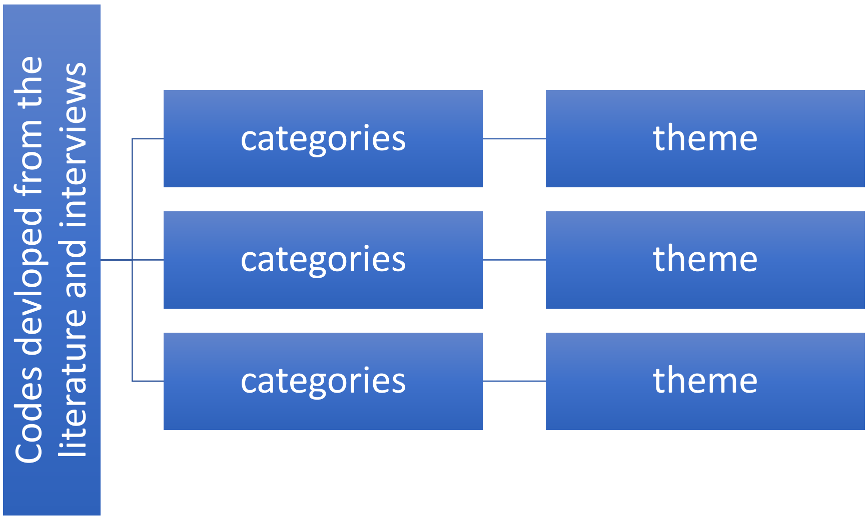


Table 5 - Development from categories to themes- in practice

Categories	Themes
How this made them feel Effect on their lives The need to avoid Difficult experiences The need to plan The need to avoid	Stigma
Support of family Support of friends Teamwork	Support
Problems with healthcare services Lack of awareness, understanding Difficulty in accessing the right services	Healthcare

The volume of data was increasing. As a personal preference I like to work from pieces of paper rather than a computer package, a large art pad was purchased that allowed actual cutting and pasting of individual stories from each category and for them to be stuck into the pad, enabling the different categories to be clearly visible for further analysis. Blue tack was used rather than glue, so the coded sections could easily be moved the around themes if appropriate. The individual stories and phrases were placed on pages using the three main themes identified: stigma, support and healthcare. Data volume alone clearly demonstrated that experiences around stigma issues were the major theme in the study; this took up 6 large pages in the art pad, compared to two for 'support' and three for 'healthcare issues'.

Various authors have noted slightly differing methods of charting their data (Ritchie and Spencer 1994, Gale et al 2013 and Ward et al 2013), however it was important that a suitable method was chosen that would work well with the data. It was noted that the original developers of framework analysis (Ritchie and Spencer 1994) were somewhat critical of a *"cut and paste"* process (P. 184), and used more extensive headings and sections, believing this helped with synthesis. However, using the art pad during the charting process, helped to develop a fluid process, supporting the aim to identify individual experiences and one that would support the further analysis journey.

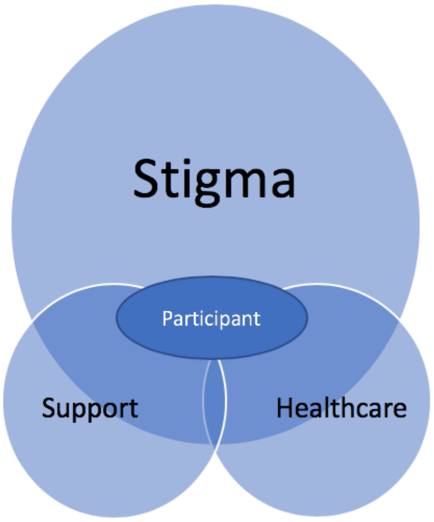
Stage 5: Mapping

Initial FA studies grouped mapping and interpretation together (Ritchie and Spencer 1994) but to help a clearly defined research process, the mapping and interpretation will be discussed separately. The process of mapping informed the method of data handling and this is discussed below. It was identified that data interpretation was a fluid process that inevitably began with the literature review and then followed throughout the interviews and framework development, as this is where ideas and thoughts began to be constructed. It was decided however to present the interpretation process separately, which is discussed in the following chapter- "Findings".

Although the later stages of the framework development had identified the three categories of stigma, support and healthcare, it was vital to again return to my research question to examine how these categories would be used to begin to provide answers to the question. Associations, patterns, differences and a structure to further work were needed. There are various approaches with which to do this, and the more visual method of the traditional ‘mind map’ was used and initially undertaken in pencil in the art pad. This became a fluid process, looking back at the charts, the original transcripts and the field notes. This process validated the earlier decision to use blue tack, pencil and a rubber as thoughts developed. The questions were developed through a joint utilisation of the developed framework and personal thoughts. For example, with ‘stigma’, an exploration was needed to define what constituted stigma for some, such as feelings of upset or embarrassment, and to discover if they applicable throughout the data set.

Below is a simple diagram of the final stages of development of the FA. It is shown how the three categories of stigma, healthcare and support could be construed as quite separate yet are also closely linked throughout, with the participant at the centre of the three main themes, of which stigma is by far the most prominent.

Diagram 6 - The final framework for analysis



The framework was the applied to the data set and the process begun of identifying the findings from the participants' interviews. This is discussed in the following chapter.

Ethical considerations

Ethical permissions

Ethical approval was sought and gained initially from The Research Ethics Committee at Cardiff University (Appendix 4). Approval was then gained from The Research Ethics Service at Health and Care Research Wales following attendance at the ethics committee meeting with minor amendments being made (Appendix 5). Health Board Research and Development permission was also sought from, and granted by, the Health Board where the research was undertaken. Up to date attendance and certification of Good Clinical Practice (GCP) training was ensured

Informed Consent

Those who met the inclusion criteria were provided with the study Participant Information Sheets (PIS) (appendix 6 & 7) In order to minimise any risk of perceived coercion, the PIS were distributed by out-patient nurses, and not discussed with the potential participant unless they themselves requested more information. Stamped, addressed envelopes were provided with each PIS with contact details if they wanted to find out more about the study or arrange an interview. Prior to each step of the interview process, including date arrangement, Consent Form completion (Appendix 8), commencement and completion of the interview, the participants were reminded that their involvement was voluntary and their permission could be withdrawn at any time without affecting their medical treatment in any way.

Data Management

As outlined within the ethical and research applications, all data was managed in accordance with the requirements of both the Health Board and University and Health and Care Research Wales. This is equally in line with the GCP principals. Any files were stored on Health Board password protected computers until anonymised. The consent forms were stored in a locked filing cabinet in a locked department in the Health Board. The participants were also provided with a copy of their completed consent form.

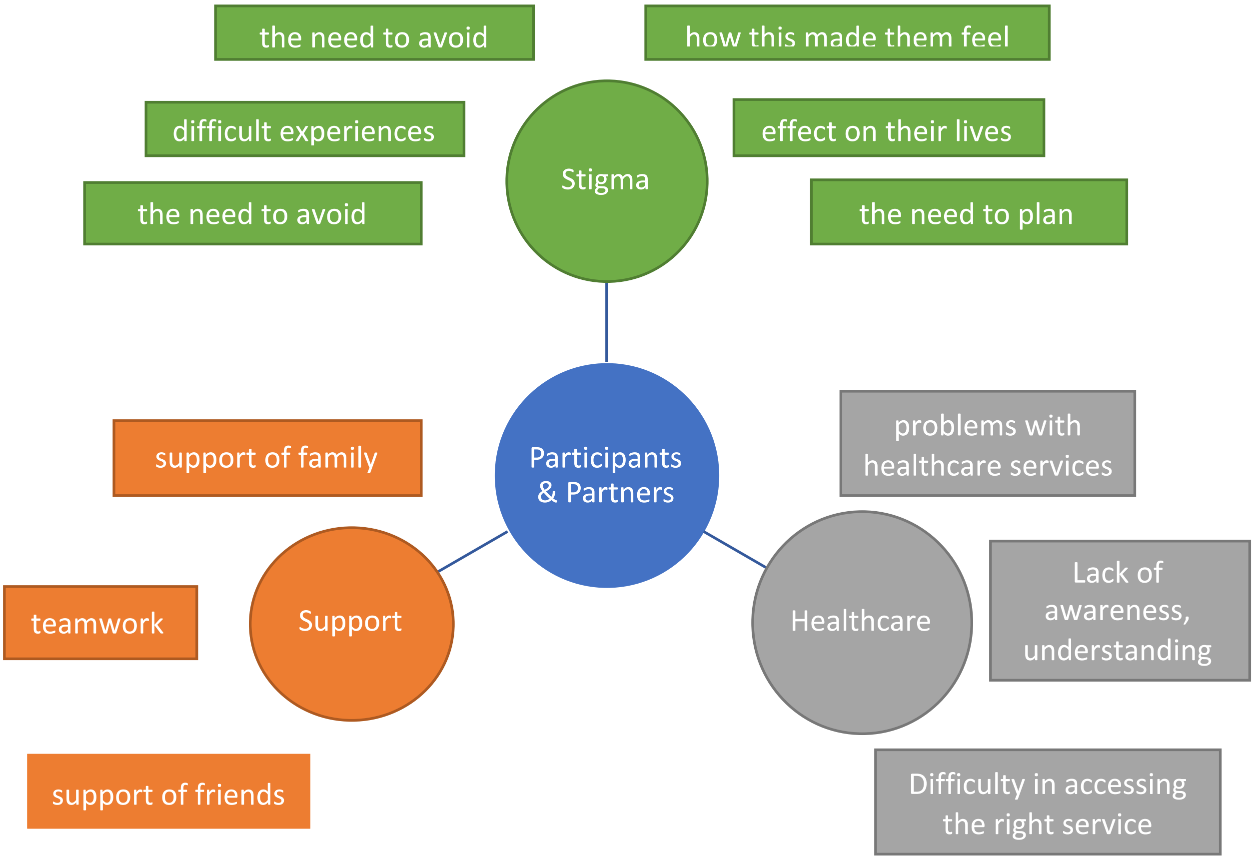
Confidentiality

Participant confidentiality was maintained at all times, as is mandatory for the above mentioned organisations and also the Nursing and Midwifery Council (NMC) Code of Conduct (2015). Following completion of the consent process, each interview was assigned a study number, from 1-9. At the outset of each interview it was explained that I would avoid using their names when asking questions, to protect confidentiality. As soon as I received each transcript, any remaining names were replaced to ensure anonymity.

Chapter 5: Findings

Three key themes, stigma, healthcare and support, were identified. Table 9 demonstrates how these themes are inter-related, and that the participants' experiences are at the core. The diagram below offers a visual presentation of how the categories were linked to one of the three main themes, and how the participants' and their partners' experiences, remain at the core of the analysis.

Diagram 7: Categories to themes to findings



For the purpose of clearly describing and interpreting the findings, each of the main themes will be discussed independently, and at the end there will be a summary of how the three themes are often all linked and can impact on each other, which then affected the participant experience. The themes were developed from the framework analysis process, where the findings were identified to be related to overarching themes of stigma, healthcare and support. The main theme of stigma was seen throughout the participants' experiences. Although the word 'stigma' was vocalised on only a couple of occasions, synonyms such as "upset", *"devastated" and "embarrassed"* were noted thorough out. Stories of the participants' experiences of healthcare services also played a big role in their journey. This included struggles to have their new symptoms taken seriously with subsequent referrals for further investigation and treatment delayed. Each of the participants spoke of their support network of either close friends and/or family. Generally, these were positive experiences, but there were also stories that described a drop-off of support once the actual cancer treatment was finished. This meant that there was often a lack of understanding about the impact PRD was now having on the participants' lives. These will now be explored in more detail.

Key theme 1- Stigma

From the Greek, the word 'stigma' related to something physical about a person that signified something different and bad about the person (Goffman 1963). Originally thought of to be evident as an actual bodily mark, inflicted to define, or mark the person as a slave or prisoner, the concept was developed over time to reflect something distasteful about that person, a difference that is considered unacceptable within their social position. Another term used to describe those as different, in a negative way is ‘deviant’ (Falk 2001). Although each of these sociologists has written of different ways that unpleasant attributes are developed and regarded in society, for the purpose of this thesis they shall be regarded as holding a distinct characteristic; in general, the person is unlikely to find it a comfortable and highly regarded title.

Whilst considering the theme of stigma and how it was present in the data, the following areas were explored:

- What did the participants consider as being stigmatising?
- How did this make them feel?
- Did anything in particular contribute to causing the stigma, and was this the same or different for all of the participants?
- Was there anything in particular that helped to reduce the feeling of stigma?

Within my interviews the actual word ‘stigma’ was not spoken until the third interview- *“that’s how he is, he thinks it’s a stigma, it’s terrible”* (Int 3, line 533). There were elements of stigma within the preceding two interviews that were only noted upon returning to them again during the framework development. In the first interview, David had talked about being “*disturbed”* that he had soiled his clothes, and then later that he was embarrassed. Tony, in the second interview, had mentioned that it was “*a nightmare”* having to use the enemas. In both cases, the relevance of what the participants were saying was unclear until the framework was applied, and the concerns of stigma became clearer. As the theme of stigma became clearer, it was evident that it was also a major theme for the other participants' experiences.

As demonstrated in the codes concerning stigma (table 6) there were several elements of unpleasant experiences identified, such as embarrassment and worry. The majority of these codes were identified within stories of loss of bowel control. The participants identified with the understanding that adults should not soil themselves and so when this does occur, it was deeply distressing. In the very first interview, David describes how this made him feel:

> *David: "We'd go for a walk each day and it involves a hill which is quite steep and I used to find that I'd get feelings in the back passage that I needed to go quite urgently. Sometimes I would have an accident. Being quite a clean person it's quite disturbing really to soil your clothing…. the embarrassment of it all…"*

David had mentioned that he lived on a hill leading down to a beautiful park where he and his wife often walked. He spoke as though despite the fact he knew he might have an episode of FI, he would still go out, although he "needed to be quite careful". Being "quite careful" describes a particular plan of action used to avoid something, in his case either actually experiencing FI in public, or being *seen,* or *witnessed* having FI. David spoke of *'we'*, meaning him and his wife. So this was a joint walk, a joint trip out and one that for whatever reason he still continued the pattern of, despite the possibility of soiling himself, which he commented was very embarrassing.

Several of the participants related stories of times when they had had an '*accident'*. Jenny recalled one incident when she had been out with her daughters and granddaughter, and was unable to get to the toilet in time. This resulted in an episode of faecal incontinence, where not only her clothes but also the toilet floor was soiled:

> *Jenny: "We went to a zoo somewhere, just my two daughters and myself, out for the day, I took all the necessary stuff I thought with me, we went out and this was not long after I stopped the treatment and I had, they only did healthy eating, so I had a sandwich with brown bread, oh that was, I was really embarrassed that day. I had that, fine we walked down and I thought oh my god and it literally was rolling down my legs so I walked back up and I managed to clean myself in the toilet, I came out and it started again. Well my daughter was there, she had to go into the toilet next door, she had to take off her knickers for me to put a pair, but literally pouring off me and it was all over the floor in the, luckily I managed to get into the disabled toilet but it was all over the floor, then I felt awful, I really felt awful. I cleaned it all up but I felt awful"*

Jenny had made an effort to leave the house with her family despite the fact that she knew she may experience FI issues. She commented that the café only sold *"healthy eating*" which suggests this is in contrast to what she normally ate. People often become aware that high fibre foods may cause further upset for bowels and so try to avoid them. In this case Jenny suggested that she could not avoid *"healthy eating*" and so hints that this may have been the cause of this episode, even though she spoke of other episodes where *“healthy eating*” was probably avoided, but the FI still occurred. Jenny goes on to describe a situation where diarrhoea is running down her legs. She cleans herself up but it happens again. Her daughter comes to the rescue and takes off her own underwear to give to her mother, ensuring that her mother’s modesty is returned, perhaps at her own expense.

Many of the participants spoke about their attempts to hide from others what was happening to them. This included family, friends and even complete strangers. When going out was necessary, planning was required to ensure bowel accidents or trips to the toilet were minimised. Some avoided going out altogether. John and Barbara explained how he rarely went out socially anymore because as soon as he was invited he wondered how quickly he would be able to get home if necessary:

> *Barbara: “and you know if we want to plan to go anywhere or if we’re invited to different places and I say shall we and he will hesitate straightaway and know it’s because what’s going on in his mind, will I be able to get back If anything happens or... and it do spoil your social life really, it does affect your social life”*
>
> *John: “You’re afraid to go anywhere you know”*

Even when John did leave the house, it generally was only for a short period of time. He found being away from his own toilet facilities too distressing, and admitted that he was struggling emotionally because of this:

> *John: "it's embarrassing to me but I don't like using the toilet anywhere because it's a real, with this mucus it's a horrible smell. It's not like normal toilet use, there's a real strong horrible smell to it as well. So I'm embarrassed even to use the toilet out and I won't, you know. I never use the toilet; I come home, if possible. It do affect me terribly on times and I do, she don't even know this until now, it do, I do suffer with a little bit of depression over it as well but I keep it away from her and from the kids, I don't want to worry them any more than I've already worried them, you know. But I do, it do pull me down like you know, it do"*

At this point, as recorded in the field notes, Barbara moved from where she was sitting to hold John's hand. His eyes were beginning to fill with tears but he composed himself with his wife's support. It seemed that this was the first time John had admitted to anyone just how much of an impact the FI was having on his life. Up to now he appeared to have been hiding it well, as he mentioned that his wife had not known this *"until now"*.

John was not alone in avoiding going out. Ken described that although he used to enjoy going to the pub with his friends, the only time he went anywhere now was shopping with his wife. He spoke as though he was looking at his diary, seemingly quite concerned about days and length of time out of the house. This indicated that his life was structured around when he felt comfortable enough to leave the house, or when he realised this was impossible for him.

> *Ken: "Well I used to go out then, I don't go out any more, you know it's sort of the only time I go out now is if I go out with my wife shopping. Because when I get the urgency now to go to the toilet, if I don't get back and I have an accident or if I just make it, I'm home but if I was out and it happened, I'd be too embarrassed because I can't walk that far so if I do go out socially which has been like three times in the last year, it's only been local and it's been just over an hour and I can't sort of plan to say right I will next Thursday, I've got to wait until next Thursday comes to see if I'm up to going out or if I'm not up to going out. But from like the November, it might have been October, when I was, the hospital put it down to prostatitis but then I find that as I say I've got no control over my bowels at all, the urgency was there and it sort of haven't gone from that. I try to control it with people like yourself and the waterworks is under control with urology who I'm seeing as well but it's not enough for me to go out. You know I was in the supermarket the other day and we had to stop shopping because I needed to go to the toilet and because we were around the corner I said it's quicker to get home than me trying to get there and have an accident or make a mess in the supermarket. So I wouldn't go out socially, I don't go to the pub to see my mates or nothing like that"*

Although this meant for some of the participants that they rarely went out, others made significant efforts to ensure they carried on normally as much as possible. Bev still tried to see her friends when she felt up to it, however did comment that she did not want them to know that she was struggling. Bev used self-developed techniques to hide what was happening to her, perhaps as a protective mechanism for herself, or perhaps for the sake of her friends and family. This however, also made it difficult to see her family at times:

> *Bev: "I haven't really told them about the accidents. I'd rather not talk about it to them really because…." Did her family know? "No, not really, not about the accidents, they know that, you know, when I've stayed up there it's. They always ask me if they can have a bath because the toilet is in the bathroom, you know do you know do you want to go and use the loo because I'm going to have a bath and there have been times when I've stayed and one of them is in there and I'm like oh just hurry up, hurry up. You know I don't really want people staying here either because they might be in the bathroom when I want to use it"*

Instead of staying home, Bev planned her days around how she felt and how to reduce the chance of accidents. She described how mornings were particularly difficult and so ensured that any shopping or social activities were restricted to the afternoons. Planning did not always result in a good outcome however. Bev spoke of a time she went out with friends and had to ask the driver to stop repeatedly so she could use the toilet. As she had not told them about her problem, they were not particularly helpful and she found this difficult. So even though Bev made significant efforts to continue as normal, this was not always possible and she found this upsetting:

> *Bev: "When I'm home, yes I have had accidents and the pad hasn't been sufficient but you know if I know I'm having one of those days and I feel awful, I so say oh sorry I'm not coming out tonight and I feel as if I'm, I think sometimes as much as they try to understand what, they haven't really got a clue and it's not something that, you know oh sorry I don't want to come out because I've got an upset stomach and you know I might have an accident and it's horrible, absolutely horrible"*

Bev was not alone in her meticulous planning in an attempt to carry on with her life, despite having bowel problems, and this will be further discussed in the following chapter. Jenny explained how she was obsessive about using perfumed sprays to mask any smells she might emit. She also used an element of humour and said that her co-workers laughed with her about her use of perfume. Although she laughed when she told me this, she also described how she clearly found it no laughing matter:

> *Jenny: "They all laugh you know, good as gold in work. No one has ever said anything to me and I'm always conscious you know, I'm always spraying myself, cleaning myself, changing, but you're always conscious. I find myself always conscious. Where some people are conscious about their deodorant, I'm not, it's not that that worries me, it's always down below that worries me in case there's a smell"*

I asked Jenny if this was something that was always on her mind-

> *Jenny: "Always, always, like today I was in the shop today and I had to alter all the shop around so I'm up and down off ladders and I think oh I hope I'm not up here now and something happens and someone passes. How embarrassing would that be. So as soon as I feel a little inkling I go, I get off and I go upstairs and then when I feel alright then I'll come back down but all the time, all the time, behind the till sometimes and I'll think is that me, you know and I say to my kids am I smelling and they say no mam, but I'm thinking about it, you know. I'd hate to think of my customers coming in the shop and thinking oh my god she smells because that would crack me up, that would crack me up. But it's always there, always there".*

Knowing where the toilets were if venturing away from home was important for all the participants. Known as 'toilet mapping', for some this made going out possible:

> *David: "That's right because if we'd go say to town for instance we'd plan out basically where the toilets…."*

Gary limited his time out of the house depending on how long he felt he had between needing to use the toilet. His wife Marie spoke for him, so clearly, she knew at least some of the struggles he was facing and at one point acknowledged how he had become fearful of experiencing FI when out:

> *Marie: "You always had to make sure that you went to the loo before you went out because then you could go three or four times. You'd walk through the door and then you'd have to rush back again and it would, you know you could delay going out for an hour or two. You were scared to go anywhere. I know it doesn't sound very much but you then got quite fearful about it didn't you because you thought you were going to have an accident"*

Jenny not only knew where the toilets were but also ensured that she had a bag of clean clothes with her in case she had an accident. Although she recognised the possibility of having a problem when out, she decided that, for whatever her reason, she would make plans to minimise the risk of being FI in public:

> *Jenny: "She'll say (her sister) come on we'll go out and I'll say yes but where are we going? I've got to know where we're going because like she'll say we'll go to town and I think to myself right where's the toilets in town, ah there's a couple of cafés I can run in and I'll say to her buy a coffee and I'll run into the loo. But all the time I'm thinking where's the toilets, the nearest toilets, you know, can I make them if I do have an accident and my bag is always full of everything, everything in case and the same with the car, if we go out for the day I've got a little bag in the car with everything in case I have an accident. But it's all the time, all the time.*

John and Barbara talked about a deeply distressing event that happened at an airport. Their story was interlaced with times when John put his head in his hands when describing his shame and laughter between them both looking back on it. They had decided to book a holiday to try to relax and recover from recent events but John had recently been prescribed medicated enemas to try and relive his symptoms.

> *Barbara:* ***"****With the enemas we nearly got arrested at the airport- they had to take them away because when he was prescribed them we booked a holiday to Benidorm so he had to take them because of course he couldn't stop taking them and they're liquid as well so I said well we'll have to pack them so I said we'll put them all in a clear bag and he said well put the box in, I said no don't put the box in because your name and everything is on it that they'll know your name or your medical numbers so I took them out of the box. Well of course in the airport they didn't know what they were did they because there was no prescription so, well they tested them with this, they tested them with that, oh my god"*
>
> *John: "In the airport, in the security and everybody is there and they're all going and I had to explain what they were for and what I done with them"*
>
> *Barbara: "Oh he was mortified"*

Interviewer: *"So you're laughing now but….."*

> *Barbara: "Oh he was terrible" John: "At the time I wished there was a big hole and I just could have been swallowed up in it"*
>
> *Barbara: "And I felt terrible then because it was my fault really because I took the box"*
>
> *John: "I said you never ripped the label off, saying it was mine and who prescribed them and what have you and she said oh there's no need for that and I wanted to strangle her"*

Despite them telling such a difficult story, when John felt his wife's actions had contributed to his embarrassment, the closeness between them was evident; they glanced and smiled at each other throughout, and when John became visibly distressed, Barbara moved seats to hold his hand. It was an obvious display of affection, of teamwork in difficult circumstances.

In contrast to John and Barbara going away on holiday, Ken had a very different story to tell. He had other chronic health problems which he had said caused him some difficulties but I had asked him if his bowel problems had affected his family as well as him. He particularly identified his concern about travelling through the airports, just as John had.

> *Ken: "We always had holidays; I haven't gone on holiday now since, well since the stroke really. 2013 was the last time we went, I went on holiday"*

Interviewer: *"Okay, with your bowel situation, would that prevent you going away*"?

> *Ken: "Well yes, because how could you go through airports or anything like that, you know?"*

Interviewer*: "What does your wife think about all this"?*

> *Ken: "Well it's hard because we don't have a holiday together, she goes on holiday, she goes with my daughter but then that's the only time I do see people, they'll call or they'll ring and my sister or whatever will ring to check I'm okay because while they're away for the week or my friends will ring, my neighbour will knock, just to check that I'm okay and is everything alright do I need to go to the doctors or I might need any medication which is normally in hand but like I say I haven't had a, the last time we went on holiday it was October 2013 and we went on a cruise and that was a disaster because even then I couldn't do things. I was learning to do what I could do, this was before I was diagnosed with the cancer and even then it was limited"*

Interviewer*: "So it was limited before and this has just made things that much worse"?*

> *Ken: "Yes, it's made it worse"*

Whereas John and Barbara went on holiday as a team, despite them knowing their time away might be difficult with him needing to use enemas, they had not let it stop them from going. For Ken this was different. He and his wife no longer went away together. Their last holiday on the cruise ship had proved too difficult to try and repeat. Ken did not say whose choice it was that he wouldn't go with his wife from then on, and he seemed to accept it without any obvious bitterness, at least during the interview.

Harry had also decided that it was best not to leave his house unless absolutely necessary. I asked him if he went anywhere:

> *Harry: 'Only to bed"*

When asked why, what was his main problem, he replied:

> *Harry: "Well I mean it's embarrassing, and when that wind starts you're emptying your bowel then you know. It's the staining and…."*
>
> *Gwen: "That's the worst thing that you've found, it's this wind problem isn't it"*
>
> *Harry: "Oh yes well that's embarrassing enough and the problem with the fact that you know, I could be anywhere and suddenly this comes on and you know, quite honestly when I go down the hospital, I'm right there aren't I, I get there about half an hour before, you go to the toilet, and then check my, I take a spare pad, and then if it's stained at all well I put it in whatever it is and I put*

> *another one, you know I'm thinking ahead all the time to try and think well I don't want to get in there in an embarrassing situation"*

Whereas Ken had lived for a good few years with other chronic health problems affecting his ability to carry on as normal, Harry had always been in good health. He and Gwen wondered if this was why he was struggling so much, but both Ken and Harry seemed to struggle with their change of circumstances with the same amount of difficulty:

> *Harry: "I mean I've been a lucky man all my life"*
>
> *Gwen: "I think that's, in a way made it worse for him because touch wood, he's been so lucky with his health over the years, he's had flu, he's had shingles, he had a sebaceous cyst removed from his back and I think in his 86/7 years that's about it so he has been extremely lucky and I think sometimes that can be harder then, when something does go wrong you know, to cope with. If you've had niggly things going on and on and on, I think you think oh here's another thing but I think it's hit him hard because he's been so lucky you know"*

Although some of the participants used various ways of coping, trying to continue their lives as normally as possible, they all have experienced significantly difficult changes. From avoiding any situation that might leave them vulnerable to having faecal accidents, to trying to manage their lives around their bowel problems, each of the participants spoke of the difficulties. This stigma, as some referred to it as, impacted on all aspects of their lives, from interacting with family and friends, to trying to cope with work. Some like Jenny and Bev appeared to cope better than others like John and David. However, when hearing all their stories, it was evident that they all struggled to some extent. It was difficult to identify why some tried to carry on as normal while others almost gave up. This could be due to factors such as age, where the younger people found it important to have a life outside of their homes, while this may not be as vital to the older participants, although Jenny was a similar age to many of the participants who avoided going out. Therefore, perhaps this difference is more down to personality, that some just cope better than others. Jenny and Bev certainly came across as highly social people, often mentioning family and friends, although both ladies were single. This could mean that they wanted to have more social contact than those who had a partner at home and this could also identify that having a partner does not necessarily equate to a better coping and managing outcome. This would be an interesting area to examine in future research.

The participants and their partners became adept at managing and hiding their difficult experiences. Their days were often spent planning how they could continue going about their everyday business, working out where toilet facilities were available and how to minimise the risk of having faecal accidents when away from home. Despite meticulous planning, occasionally their worst scenarios actually occurred. When they experienced faecal soiling in public places their humiliation was clear and in some, but not all cases, this then reduced even further where they felt able to go.

In conclusion, when considering Goffman's (1963) description of the original use of the term 'stigma', physical differences of people experiencing GI late effects of radiotherapy are not obviously on show but remain as a stigma for them. This is contributed to by the presence of issues that may or may not be obvious to others around them, such as flatulence, smell and the behaviour felt necessary to hide what is happening. This concept of stigma was noted throughout the interviews and was seen to impact on the participants' everyday activities and experiences.

Key theme 2- Healthcare

The second theme developed from the FA was healthcare. This included contacts with primary care, secondary care, private and charitable sectors. The participants frequently spoke about their medical care, both in positive and negative ways. This was a group of people who had been through significant health issues, yet were now 'the other side' of their cancer treatment. Exploration of how interactions with healthcare services had impacted their experiences of living with PRD was an area of particular interest for this study. The ideas considered were:

- What experiences did the participants have with healthcare services when symptoms were beginning to develop? Where these good or bad experiences?
- Did their experiences identify aspects of healthcare that could be improved?

There was a wide variation in the acknowledgement by healthcare professionals of the need for further assessment of symptoms with which the participants presented. The speed of referral for some was immediate, for others, it was a long frustrating journey with multiple re-presentations at the GP's. For Tony, the experience was quite positive:

> *Tony: "I was happy with the speed all the way along the line in the sense that after seeing the GP, referral was very, very quick. In the same way that referral back this time, when I saw this, was very quick"*

For most of the other participants however, the story was very different. John had begun to experience rectal bleeding. I asked him if he had thought his cancer might be back?

> *John: "Yes definite, I thought there's no doubt so I made arrangements then to go and I had a bit of a performance with my GP over that, to get back to see the consultant"*
>
> *Barbara: "Oh the GP is not very good"*
>
> *John: "He wasn't very helpful. I went and explained this to him and he wrote, he said here you are, he said there's the surgeon's secretary's phone number, ring her and she'll sort you out and I thought I haven't seen her for like nearly a twelve month, she's not going to do it like so I rung the secretary and she said oh (name) have you been with us in the last four months, I said no, she said I can't do nothing for you you're going to have to go back through your GP so I had to wait another fortnight then to see the GP because that's how it is, you've got to wait a fortnight isn't it and eventually I said look she won't do anything*

> *and he said oh right, I'll write to her and so he wrote so eventually I got back to see her and then straightaway she gave me a colonoscopy you know, an appointment for a colonoscopy and that took about two weeks or so and then when they was looking and they said we don't think it's the cancer, this inflammation and ulceration in your bowels like you know"*

Even though John's GP acknowledged that they may be a problem, the suggestion for John himself to contact the Consultants secretary was incorrect and resulted in a significant delay.

Ruth experienced similar indifference from both her GP and the oncology clinic:

Interviewer: "*Did it take you a long time to get some help for your bowel problems now, were people listening to you"?*

> *Ruth: "I would say no at first. Well at first they wouldn't even listen that there was a problem, if I didn't keep on going back to my GP saying look I know that there's something there, I can feel it"*

Interviewer*: "But after the treatment, once you'd had your treatment, and things weren't settling down, was anyone interested?*

> *Ruth: "Every time I went back like three months, they'd obviously ask you oh how's your bowel, and I'd say well I can't control them, oh try this or try that or and they were giving me different medications to try and help and things like that"*
>
> *Jason: "Nothing specific"*
>
> *Ruth: "It was like, that was more like for diarrhoea and I said I haven't got diarrhoea, so it's pointless like bulking everything up because obviously it'll be more painful to pass, because my skin is always sore and things down there anyway"*

Interviewer*: "So you felt perhaps they weren't really listening or not understanding"?*

> *Ruth: "I don't think they were, probably a little bit of both, they seem to think oh well take this but it was more like diarrhoea related, like with the control, I said to them it doesn't matter what the bowel movement is, I can't control it. I've got no muscle there at all to hold anything in, we went to Tesco's this morning didn't we and I said I've got to go to the toilet, and I've got to go, I can't wait and say oh I'll just pay for my shopping first and then go, because I won't make it"*

Interviewer*: "And how long then did it take for them to think about getting you some specialist referral"?*

> *Ruth: "Probably the last time I saw Mr (name), wasn't it"?*
>
> *Jason: "Two months ago"*
>
> *Ruth: "because I know I'm due to, yes a couple of months ago. But I mean this is like eighteen months down the line from when my treatment finished"*

Interviewer*: "So ideally this all should have happened earlier for you"?*

> *Ruth: "yes, yes"*

Not all participants had problems with their GP, or accessing healthcare after their cancer treatment. Bev commented on how helpful her surgery had been since her cancer diagnosis:

> *Bev: "If I've got any problems but I also know that if I have got a problem and I'm worried I've only got to phone (oncologist) and they'll bring my appointment forward. So that's really reassuring for me. My GP has been really good in the sense when I have contacted them for an appointment they've always managed to fit me in that day. I don't know whether that's because of what's happened but I don't feel that they really understand the side effects of what's you know"*

Interviewer: *"Do you feel that, particularly perhaps with (cancer hospital) and your GP that they have listened to your worries about your bowels or have you had to fight at all"?*

> *Bev: “Well I think initially with (cancer hospital) it was sort of at the 12 months, just after the 12 month mark so you know when I sort of said about, that’s when they said they’d refer me. So yeah, I think up until then they were most probably hoping it would settle back down, it’s what they sort of said and that”*

Bev said that the cancer hospital had referred her at about 12 months when she had raised the issue- *“when I sort of said..”* even though it sounded like they did know she was having problems but were “*hoping it would settle back down”*. It was unclear whether this was due to lack of awareness of problems such as PRD by the HCPs, or due to a clinical set-up where the patients simply were not asked about such things, nor had a plan in place when such patients should be referred for specialist help.

Jenny also mentioned her telling the oncology team at her cancer hospital that she was struggling with symptoms, but that nothing was done about it for some time:

> *Jenny: “I just thought it was through the treatment, but no one ever said anything. I kept seeing different people. Even though when I was going back and fore to the hospital every three months and every six months. I mentioned it but no one said anything”*

There was very little mention about involvement with the cancer charities. Only one participant, David, mentioned anything at all regarding them. Following completion of his radiotherapy, David was experiencing pain when passing urine. One morning, whilst out with his wife, he noticed a Tenovus mobile clinic in a supermarket car park. The Clinical Nurse Specialist on board recognised his symptoms straight away and sent him to see his GP with a note that he was probably experiencing prostatitis. Several patient information booklets have been produced by groups such as Macmillan about late effects of cancer treatment including PRD, as discussed in the literature review. These are suitable to be on display in hospital and GP waiting rooms as well as to be given to patients at various points of their cancer treatment journey and so it is noteworthy that none of the participants mention them.

There appeared a difference in the expectations of the participants in the giving of information by HCPs, about the possibility of developing problems after the cancer treatment. Tony seemed quite accepting of the risk of effects of treatment saying:

> *Tony: You accept that apart from anything else you've got to sign up to the risk…"*

Gary noted that even though he was given information about the potential side effects of the radiotherapy treatment, he had not really taken it all in:

> *Gary: "I think you can give somebody a leaflet and you can read it but you're not actually absorbing that"*

Ruth also commented on the lack of information she received about the possibility of experiencing problems such as PRD, prior to her cancer treatment:

> *Ruth: "I think they should go into the side effects and the long-term side effects in a bit more depth than what they do, I mean they just say oh it could bring on the menopause, you might have aching joints or but I don't think they go into it enough"*

Likewise, Bev noted that she was not really aware of the potential of late effects of the treatment. She commented that she had just been told that she had cancer and so was focused on doing whatever was necessary to survive. However, Bev also noted that maybe if she had been told about all the potential side effects that it would probably have been too much information to take in at that point:

> *Bev: "Well you know before the treatment, you sign a consent form you know, there could be short, long term side, I can't even, you know and at the time if they were listed on there I signed the consent form because I've just been diagnosed with cancer so it's all too much info sort of to take in but it was very vague anyway, whatever I signed, I can't remember you know but. But there again, do you want to know all of that, you've got so much to take in and I am one of these people I wanted to know what stage it was, you know, you know what the out, the likelihood of curing it and things and yeah maybe the long term side effects in great detail would have been too much info at that stage"*

Unlike the others mentioned, Jenny was quite certain that she had not been told about the possibility of late effects of treatment, either verbally or by a leaflet:

> *Jenny: "But no, no one ever mentioned there could have been problems, I've got to say that, no one did mention"*

A few of the participants spoke about what they had found helpful and suggested ways in which the various healthcare services could be improved. Tony talked about the benefits of Specialist Nurses. When he was telling a friend that he was going to be seen in the hospital, his friend commented:

> *Tony: "well with any luck you'll see the Specialist Nurse…they usually have more time to spend with the patient than the Consultant or Registrar"*

Ruth spoke about the practical problems of sitting on the hard-plastic chairs at the hospital following radiotherapy for rectal cancer.

> *Ruth: "I couldn't even sit down, some days I was in so much pain with my skin and everything and they expect you to sit on these hard-plastic chairs. I think there was one comfortable chair in the whole department because you just can't sit on them"*
>
> *Jason: "You had to fight to get that chair"*

Although this sounds almost humorous now in a written form, when they told this story, neither Ruth nor Jason even smiled. They looked at each other and shook their heads. Ruth had been amongst a group of patients who had received radiotherapy directly to sensitive areas of skin, which would obviously suffer the weight and friction of sitting down, yet this did not appear to have been taken in to account. As Jason had commented that Ruth had to *'fight'* to get the one comfortable chair, this implies that all of the other patients in that room were experiencing the same problem.

There was a consensus amongst many of the participants that healthcare staff should be more aware of the potential of bowel problems after radiotherapy and to ask patients if they are experiencing symptoms. Harry's wife Gwen commented that it was up to healthcare staff to ask about symptoms, rather than wait to be told. Jenny talked about how she had told them about her symptoms, but they did not offer any help. Bev recalled signing a consent form prior to the radiotherapy and that she thought it mentioned the risk of short and long term side effects, but at the time she just wanted the cancer to go away. She said that even if she had been aware of the subsequent problems she still would have gone ahead with the treatment, as it offered a chance to be cured from the cancer.

In conclusion, for some participants, the journey from the end of their cancer treatment to the point where action was taken regarding the late effects of their treatment was not straightforward. The term "*back and fore"* was frequently used and describes a difficult and long process. Most spoke of difficulties they had experienced in getting healthcare professionals to listen to their problems. Even when those healthcare professionals were based in the cancer hospital, the very place where it could be expected that they would be aware of the potential late effects of the cancer treatment, it was not uncommon for the correct knowledge and support to be unavailable. Either the professionals did not ask the participants about late effects, or, when they were made aware, did nothing with that information. Even when timely and appropriate care was available, there was still room for improvement. The issue with the hard, uncomfortable chairs was an area that was relatively easy to resolve. Most participants also spoke highly of their healthcare teams. The fact that they were still alive to tell of their stories was noted by many. There were elements of exceptional care, such as Tony's and Bev's prompt treatment through their GP, although overall, several areas where improvement could be made, were highlighted.

Key theme 3- Support

The third of the major themes identified within the FA was 'support'. Each of the participants spoke of involvement of the significant others in their lives, including family and friends. I was keen to understand what impact this support had on their experiences. Ideas to consider included:

- What types of support were there and what form did this take?
- Did the support help? Did it not?
- Were there any obvious gaps in the level of support?

For those participants whom I interviewed along with their partner present, I was struck by the atmosphere of teamwork between them. This was evident through both the language used and more subtle expressions of support; glances between them and physical contact, particularly when one of them became upset. All of the couples spoke in terms of "*we* decided", "*we* did this..." and "*we* went to the GP". It was also clear from the interviews with the couples, where the man was the patient it was their wives that took on the caring role:

> *David: "That's right, they told me to drink plenty and (wife), she's always chasing me get on with the next drink"*

Interviewer: *"Yes, has it meant a lot for you to have the support of your wife, because obviously not everybody has got that. You seem like a good team"*

> *David: "Yes that's right, we are, in fairness to Megan she's very good to look after me really and because I sometimes forget to take my drinks and within half an hour after she's saying have you had your drink?*

Interviewer: *"Has it caused you as his wife much concern to see him going through all this?*

> *Megan: "Yes it has because we've been very close, we've been married 46 years and we've always done everything together. We're a small family aren't we? And I was sixteen, he was seventeen when we met so we've more or less been together always. So to not, how can I put it, to have your partner that's not*

> *100% it does worry you and you're very concerned that they are going to come out, you've got to think positive and you've also got to think well I'm going to make sure that he gets through this"*

Ruth and Jason were the one couple interviewed where the wife had been the patient. He showed his support in different ways:

> *Jason: "Well just, be there for her basically, anything she wants, even just a lie in"*
>
> *Ruth: "He was lucky enough where he worked, they gave him like the full six weeks off"*
>
> *Jason: "I'd have took you anyway, simple as"*

Those not in a relationship spoke of others as being their main givers of support. Tony spoke of how his friends offered practical help by driving him to his hospital appointments. Bev told a story about when her toilet flush broke she went to stay with a friend, whose husband then mended the toilet. Jenny was particularly close to her daughters, one of whom still lived with her. Her family made sure she could go out and enjoy times with her grandchildren, and then offered practical support, such as swapping underwear when she'd soiled her own, as previously mentioned. As discussed, those couples interviewed together described a close, supportive relationship. Ken was interviewed alone, while his wife was out. Although he had mentioned that she now went on holiday without him, he described how his wife still showed that she was sensitive to his needs, although it also suggested that she now planned her life to go on without him by her side, recognising that he was no longer able to play much of a part in it:

> *Ken: "There are days I just, my wife will come home and say you've been crying again and there's, I just say it's getting me down and I say perhaps I'll ring up so and so and go out for an hour and then she'll say well you're not really well enough to go"*

The support from families and friends is not always harmonious however. Although I sensed a great love between most of the couples I interviewed there was also a palpable air of frustration at times, which was often only noticeable in the vocal tone of what was said, and eyes cast upwards when looking at me. As these were not captured on the voice recorder I made notes where possible in my field notes. I asked Harry's wife, Gwen if she struggled at times with the difficulties inherent in them going out together:

> *Gwen: "You feel impotent because you can't do anything, if I say anything he gets his knickers in a twist you know and I mean I don't understand…. well maybe I don't"*
>
> *Harry: "Gwen laughs at me, even when we've been to the hospital and I say now let's have a bag, and a little cushion for me to sit on because if you go in the taxi and something happens…"*

> *Gwen: "yes but you've got a pad on, you're not going to soil anything, you're not going to soil anything when you've got a pad and underpants and trousers"*
>
> *Harry: "I don't know" Gwen: "well of course you do"*
>
> *Harry: "look Gwen, better be safe than sorry"*
>
> *Gwen: "mmm…."*

Gary's wife Marie spoke about how she had told one of her friends what was happening, because she later said it helped her to talk to others about it, but he was not happy:

> *Marie: "Initially when all this happened, when we came back from France I think I might have told one of my friends, somebody you know, and you were really angry about it because you didn't want anybody to know"*
>
> *Gary: "I don't share it with my friends or family. I find it difficult to talk about anything really you know. I can talk about other people but I can't talk about myself that much"*
>
> *Marie: "I mean I know that it's a problem bothering him but Gary is like a closed door but you ask too many questions you get angry about it don't you"*

The drop-off of support once the cancer treatment was finished was noticed starkly by Bev. Her friends played an important part in trying to keep her life as normal as possible, despite her bowel problems. She explained that she often replied at short notice to say she could not go out with them, but she would not tell them it was because her bowel problems were particularly troublesome that day. She sensed they were becoming less patient with her:

> *Bev: "Some of my friends say oh I'm not even asking you to come out again, because I've changed my mind sort of at the last minute, it's sort of half-heartedly, but you know, I'm like, are you moaning again? Are you not well again?"*

Bev went on to explain that she feels her friends think she should just get back to how things were before now:

> *Bev: I've got to the stage now here I think oh just don't say anything about how I'm feeling because yeah, it's like, they just don't understand that, they think you've had cancer, you've had the treatment, and that's it, you know I should be back you know, I should be my normal self now"*

In conclusion, each of the participants spoke of how someone had supported them through the difficulties and practicalities of living with late effects of the radiotherapy. For some this was provided by family members, and for others, it came via close friends. It was evident however that the type and level of support differed, often depending on the understanding and tolerance of the support giver. Whereas at times it may have appeared that family and friends were less than supportive, it was clear that this was often because the participants, including Gary and Bev, had chosen to not fully disclose the difficulties they were experiencing to protect themselves from what they perceived to be the stigma of bowel problems. Even in the close supportive partnerships of some of the couples, there lay a hidden frustration between them, as displayed by Harry and Gwen. Although outwardly Gwen was fully supportive of Harry's struggles, it was evident on a couple of occasions that she was becoming frustrated by his apparent lack of coping with his problems and that this this was now impacting upon both of their lives. It would seem that whilst the partner can offer support to the one experiencing the late GI effects, there is no support for the partner themselves.

Stigma, Healthcare and Support; the experience of living with PRD

There are elements of each of the main themes of the experience of stigma, healthcare and support seen with all the participants. There were some clear descriptions of where one element clearly impacted upon the other. For example, healthcare interventions occasionally contributed to feeling of stigma. A prime example of this is when John and Barbara were caught up at the airport when suspicion was aroused as to the nature of the enemas he was taking with him:

> *John: "In the airport, in the security and everybody is there and they're all going and I had to explain what they were for and what I done with them"*
>
> *Barbara: "oh he was mortified oh he was terrible"*

> *John: “at the time I wished there was a big hole and I just could have been swallowed up in it”*
>
> *Barbara: “and I felt terrible then because it was my fault really because I took the box”*
>
> *John: “….and I wanted to strangle her”*

John was following instructions from the hospital to use the enemas. It would suggest that John had not discussed the holiday with his HCP, else the practicalities of taking them would ideally have been discussed. Either John had not mentioned he was hoping to go away, or the HCP had not enquired if any holidays or journey were planned. For whatever reason, John felt he needed to take the enemas away with him, rather than leave them at home. This resulted in a deeply embarrassing situation for him at the airport.

Both Gary and Bev explained that they did not want their friends knowing about their health problems as they felt it was a private matter. This however may have affected their friends’ perceived lack of support at times:

> *Gary: “I’m a bit of a private guy, I told you that I don’t share it with my friends or family”*

> *Bev: “as much as they try to understand they haven’t really got a clue”*

Other participants made a big effort to avoid their friends due to the perceived stigma and the need to hide their problems. This often left them feeling isolated and missing the support they may otherwise have received:

> *Gwen: "I mean two of his friends, well people we know, called over the last day didn't they"*
>
> *Harry: "Well, that's another thing, if somebody comes here and I think oh God"*
>
> *Gwen: "he's on pins"*
>
> *Harry: "family, I'm not being unkind but I wish they weren't here because I'm all on edge you know, oh God, now I've got to go or something"*

The data presented shows that aspects of stigma, healthcare and support are interwoven in the participants' experiences. Some of these experiences are good and demonstrate love and support between the participants and their family and friends. Others tell of how the perceived stigma has driven wedges between those who they care about and who cared about them. Many healthcare encounters left a lot to be desired. It was a common theme that the participants had to battle to get the help they needed. Even those healthcare professionals who cared for people with and after cancer did often know what was happening. The most obvious feature of all the interviews is that these experiences had a significant impact on the participants' and their partners' lives. The next chapter will discuss these findings in further depth and consider what this may mean for people experiencing PRD in the future.

Chapter 6: Discussion

The aim of this study was to gain an insight into the participants' experiences of living with PRD. To achieve this, the objectives of the research study were to provide an insight into the experiences of living with PRD. This included the physical, psychological and social impact, examining what this means for the person with the disease as well as their friends and families.

The literature review focused on PRD and the effects of FI. The framework was initially developed through the literature and then refined by applying it to the first few interview transcripts. Using this FA approach, the three key themes identified were stigma, healthcare and support. The theme of stigma was undoubtedly the most prevalent amongst the participants. Each of them made some reference to elements linked with stigma, either directly using the word, or describing times when they were distressed, embarrassed or humiliated. By re-visiting the framework shown in Table 9, the branches from each of the three themes focused the further reading of other study findings and theories to help develop discussion around the findings from this work.

This chapter will explore issues raised in the findings, considering each of the three main themes. Where appropriate, other literature will be discussed alongside the study findings.

Following the section about stigma, there is a further section about QoL. This was not considered to be a fourth theme for the framework for a specific reason. Although the inclusion of quality of life scores was noted time and time again in the literature of studies about PRD, as will now be discussed, this seems to be quite removed from the actual experience of the participants, and so it will be argued, QoL scores may not be as helpful in gaining insight into the experiences of people with PRD as they might, at first, appear to be.

Stigma

The concept of stigma was not initially prevalent in the review of the literature but negative experiences were often hinted at through the description of poor QoL scores. Further investigation into the topic revealed that stigma, or ideas around stigma, was not uncommon with people with bowel problems, particularly FI. Throughout the initial reading of the transcripts, and then during the subsequent interviews, the theme of 'stigma' began to become even clearer. The participants used different words to describe experiences that were clearly difficult including accidents, distress, embarrassment, upset and worry.

The distress of the participants was particularly noted when relating their stories of faecal accidents. The impact of this upon their lives was distressing both for them to tell and to listen to. Tears were often shed, or at least silences as they tried to compose themselves when they talked about how such incidents made them feel. It was difficult to hear such distressing stories and following some of the interviews, I often cried in the privacy of my car, before then making additional field notes while the experiences were still raw and real. As with my clinical work as a nurse, it is important to be able to show the patients, or in this case the participants, that I am empathetic with them, yet to also have the professional ability not to let one's own distress to further impact upon them.

As the framework was applied to the findings in the interviews, the work of Goffman was given particular attention, as he was referenced in many papers looking at the distress of symptoms and how the perceived stigma can impact on every area of life.

Goffman (1963) believed that society generally categorises people, often based on their first appearance. For example, if someone looks and behaves as one would expect, then they possess a *'virtual social identity'* (p.29). What the person is actually like, considering any nuances, problems and hidden disabilities, is what Goffman calls their *'actual social identity'(p. 29).* When these two categories reveal someone with a difference, something that at that time is thought of as unpleasant, or unnatural, they are seen to have a stigma. The term 'stigma' refers to something that is deeply discrediting, and therefore someone with a stigma is seen as being 'discredited' (p.13), and can often be ostracised, either by society, or even choosing to isolate themselves in an attempt to hide what is happening to them. Goffman describes those without stigma as *'normals' (p.15)* which then equates that those with a stigma are abnormal, *"are not quite human"* (p.15). It was these expressions of stigma that were identified throughout the interviews.

The role society plays in ostracising people who are different has been also recognised by other writers, including Durkheim (1895), Falk (2001) and Douglas (1996). Durkheim (1895) was one of the first sociologists to identify the power of stigma to not only discredit people, but then to empower the dis-creditors, holding the society together with their shared values and beliefs. Determined to develop sociology as a science, he recognised that the individual's behaviour was directly impacted on how society at large viewed the phenomenon under study. For example, by creating a group labelled as 'different' people, boundaries are drawn, and solidarity amongst those considered 'normal' is protected. Falk (2001) also noted the benefits of having certain groups with a stigma label, in that it creates a feeling of solidarity amongst everyone else. The theory of socially structured rules created by stigma was also developed by Douglas (1996) who noted the dominance of symbols, through which society functions. Societies are guided by symbols, both good and bad, which construct the rules of that society. She identifies that dirt, including faeces, holds different symbolic meaning in different cultures and/or time periods.

Previously some anthropologists have described the use of faeces in magic (p. 146) although Douglas argues that rather than seeing faeces as a positive element, which, she feels, was developed through informant and observer bias, faeces was actually used as a negative magical force. Freud famously noted that prior to having their culture ingrained in to their everyday belief and culture system, children focus on bodily excretion, particularly faeces, in a positive way (Inglis 2002). Freud, and then later Douglas (1966) claimed that this pleasurable element was forced aside through toilet training, where faeces was from there on to be seen as dirty and only to be expelled in private. Bourdieu (1992) describes the development of defecation from an unhidden event to the private act it is today through the birth of the bourgeois, those who were deemed more civilised through their city dwelling. Within the modernising society of the

11th century, it became ideal to act as someone who did not defecate, but that if they had the need to do so, then certain rules should be adhered to; these rules included the use of privacy, to minimise faecal odours and for any language used to describe the bodily output to be wisely chosen, preferably using a "euphuism" (p.54). Through further development of society, many of these 'rules' became necessary to help prevent the spread of disease but this also saw the rise of derogatory faecal-related terms used to describe others in a negative sense. Inglis (2002) noted that although faecal terms had been used in a negative sense towards enemies since medieval times, the development of class-related toileting improvements provided the opportunity to enhance the insulting of others by highlighting their superior methods of hiding and disposing of faeces. This is why, according to Freud, faeces is now considered "morally dirty" (Inglis 2000, p. 122).

The majority of the participants expressed feelings of experiencing a stigma of some sort, related to their bowel problems. Some used the word 'stigma' directly, such as Barbara, John's wife: '*he thinks it's a stigma"*, whilst others used terms that described its effect upon them, such as distress and embarrassment. The events they described and the concerns about potential loss of bowel control were very upsetting for them. This was evident through their words, their body language and their facial expressions. In an attempt to reduce the impact of their perceived stigma, participants and their partners went to great lengths to try to avoid situations where they may encounter a problem, or where others may discover what was happening to them. This avoidance often took the place of intensive planning on where and when it might be 'safe' to venture, where there would be toilet facilities or from where they may be safely and quickly able to return home. For others, avoidance meant just that; they avoided going out, just in case they had an episode of FI. The impact of the perceived stigma was different amongst participants, or at least presented by them as being different. Many of the interviews involved tears and descriptions of lives on hold, or even that happiness with their lives had now ended. Others made great efforts to try to continue as normal, although behind the outward display of coping, there were often hidden feelings of shame and hurt from the impact they were experiencing.

Some of the participants, including David and Harry, had commented on how distressing it was to soil their clothing, with Harry describing it as *"staining"*. Norton (2004) discusses how we are taught as we grow up that passing stool anywhere but in a toilet, is "*naughty and socially unacceptable"* (p. 85). Using the criteria of social acceptability then, faecal incontinence identifies with Goffman's (1963) attribute of a 'stigma'. In this major work, Goffman defined early on what he means by stigma- *"an attribute that is deeply distressing"* (p. 13). This certainly concurs with the stories of my study participants, where terms describing "accidents'", "embarrassment", "distress" and being "mortified" were frequently expressed. Olsson and Berterö (2014) found similar levels of distress and shame in their study. Some of their participants spoke of their fears: *"I feel ashamed"* (p. 145). This was also seen in John's distress at the airport when the security person held his enema aloft- "a*t the time I wished there was a big hole and I just could have been swallowed up in it".* If faecal incontinence is therefore considered to be a social stigma, then those who experience it may have little choice but to either accept it as a stigma or to learn to hide it from others and cope as best they can.

Earnshaw et al (2011) examined the experiences of people living with various chronic illnesses. They found that where the illness was considered to be related to a stigma, such as bowel problems, epilepsy and other neurological conditions, the participant was likely to experience a lower quality of life than those with a condition that was considered by society as less stigmatising, such as heart or lung conditions. They found that even just the knowledge that their condition involved areas of stigma was enough to affect how they perceived the impact of stigma on their own lives, whether or not they actually experienced the stigmatising symptoms. John seemed to particularly struggle with this perceived stigma, and the shame of it:

> *John: "I do think then, sitting by here and I think to myself why can't I just feel normal, not feel…"*
>
> *Barbara: "And he do always say, this is the worst thing that could have ever of happened to me"*

So John believes FI was the worst thing that could have ever happened to him. The transcript goes on to show that this is qualified further on, that the cancer he could deal with, but the shame of the late effects, including FI was overwhelming for him. If as Earnshaw et al (2011) suggests, this 'anticipated stigma' develops through reaction by healthcare staff, as well as family and friends, as Earnshaw et al (2011) hypothesised, then this may be one way of addressing the root cause of the perception of stigma, thus increasing quality of life of those experiencing it. Goffman (1963) suggests that one method of reducing stigma, both the experience of it and the public recognition of it, can be through the development of groups for people with similar conditions. He noted that stigmatised individuals may become "*speakers*" to groups of stigmatised and *"normals",* raising awareness that even though they may have these problems they *"can be a good person"* (p. 37). This perception is seen daily in gastroenterology clinical work. One clear example of this is the "Get Your Belly Out" campaign for ostomists, supported by Crohn's and Colitis UK (CCUK 2018), an organisation that supports people living with inflammatory bowel disease (IBD). As well as providing group support around the UK they also have several celebrity ambassadors, showing the public that even though they have IBD, they still have valuable and productive lives. The Pelvic Radiations Disease Association is a support group for people with PRD, but it is a very small group with limited members and finance to make a significant impact at this point in time.

Another potential reason for reduced quality of life amongst those with a chronic illness may be that those with stigmatised conditions often conceal their problems and so receive less support. This may be due to a simple desire for privacy or even a coping mechanism described "protective buffering" (Langer 2009). In a perceived attempt by the person with illness to protect their loved ones from the consequences of the disease, they hide what is happening. They may also try to protect themselves from their own distress, as though to pretend it is not really happening, and also to buffer themselves from the distress caused by the loved one adding to their problems. The authors found however that this coping strategy rarely had a good outcome; the family and friends they were trying to protect, can be very hurt and upset at the deceit. The study recommends that clinicians identify such behaviour and address it with open dialogue and counselling.

Most of the study participants spoke of how their family and friends often did not know the full extent of their health problems. Gary, in particular, did not want anyone to know. When his wife had inadvertently told her friend, Gary had become angry with her for discussing his private business. He had previously mentioned that he had received treatment for a heart condition, and when asked if he had ever mentioned that to his friends, he gave a wry smile and replied *"Yes you've got me there, yes, I'll talk about that".* Gary's acknowledgement that not all conditions have the same level of stigma attached to them is an interesting point. It is helpful to revisit Goffman's (1963) original concept of what constitutes a stigmatising condition. He uses the term "*normals"* to describe those without differences, which in turn implies that those with differences are not 'normal' and "*not quite human"* (p. 15). Goffman goes on to discuss how some individuals will attempt to correct what they see as their problem, but this is not always possible, as is often the case of chronic illness. When correction of the 'abnormality' is not possible then one may then develop strategies to cope, to hide, or to manage the condition which, as will be discussed, was seen in the actions of many of the participants.

By hiding bowel problems there is an element of control maintained, perhaps in an attempt to self-manage. Avoidance of a difficult situation is a form of coping, and one that many participants utilised to some extent in both my own and Olsson and Berterö's (2014) study. The lives of both participants and their partners revolved around strategies to maintain some form of normal existence. For some like John this involved attempting to open his bowel before going out, often going back and forth- Barbara: *"(he) will go about fifty times before we leave the house just making sure".* Although "*fifty"* is almost certainly an exaggeration, it gives an idea that not only does John go back to the toilet many times before going out, but that also Barbara notices this and feels it is excessive and abnormal.

Toilet mapping, as described by Ness (2012), was a common theme throughout the interviews, including Bev, Jenny and Harry, as described in the findings chapter. This occurs when people plan their days around where there are toilets. In clinic, patients often say that the first thing they do when they arrive at a new location is find out where the toilets are, if they have not already planned this out in advance. There are several smart phone Apps available for this purpose. Sometimes however, even meticulous planning was not enough, and what they saw as humiliating faecal incontinence was experienced, such as what happened to Jenny at the zoo.

If the person is able to hide it, to act as though there is no problem, then they have regained an element of control over their lives. For some participants though, the anxiety created by the stress of social interactions means that it is easier to avoid social contact whenever possible. Returning to John's distress at the airport- *"at the time I wished there was a big hole and I just could have been swallowed up in it",* it strikes a similar chord to a man quoted in Goffman's work (1963); *"it seems to me…that everybody is pointing at me with his finger"* (p. 28). These men express the same feeling of being exposed, being outed as being different, with their stigma displayed to all. John's experience, as well as all of my study participants, matches those described by Goffman (1963), as the additional problems of experiencing the onset of a new stigma later in life. He goes on to describe how this group of people may have particular problems in accepting their differences, as they often have a long-life experience of previously being ‘normal’. Goffman believes that in such scenarios it is a specific role of healthcare professionals to *“inform the infirm who he is going to have to be”* (p. 49). Although this belief suggests that it is the role of healthcare professionals to be involved in supporting people with chronic health conditions, Goffman’s comment seems to dismiss the significant work that should come before this statement; the work to ensure that any potential improvements are made, and that the ‘infirm’ are as confident as possible that all that can be done has been done. Of course, this opinion of Goffman’s decree may be a little unfair; however in this study it appears to be an important element in the care and reassurance of the participants.

The participants in the study each presented stories and examples describing how they experienced stigma because of their bowel condition. This was a common finding amongst the literature, where faecal incontinence was frequently linked with feelings of disgust and distress. Participants in this study were in a different group than most of those previously presented in the literature. These participants were experiencing bowel problems as a consequence of cancer treatment, rather than a stand-alone condition. They were asked about their experiences of this, not just what symptoms they were dealing with. As demonstrated in the literature review, there is a growing body of evidence looking at the prevalence of PRD. Most of the studies used quantitative methods to identify what physical problems were experienced and when they occurred. Disease and QoL scores were used in abundance however very few used a face to face qualitative interview approach to ask people about their experiences.

The study by McSorley et al (2013) used both quantitative and qualitative approaches to enquire about coping strategies in men following prostate cancer. They found that that although some used avoidance techniques, the men generally coped well, and accepted any permanent alterations they needed to make to their everyday routines. When considering the differences between their findings and the findings within this study, of the great difficulties amongst the participants, it was noted that the participants in this study were people who had already been referred for help due to experiencing particularly bothersome symptoms, compared to the cohort in the McSorley et al (2013) study who were recruited from a general prostate cancer clinic. One of the other few qualitative studies to look at late effects of cancer treatment was the dietetic-led study by Abayomi et al (2005). They too presented their findings under the headings of long term side effects such as diarrhoea, weight gain and abdominal pain, as opposed to the themes of participant experience, such as those encased within stigma, healthcare and support. Their interviews however, of women post treatment for cervical cancers, found a high occurrence of bowel symptoms that affected their quality of life. Although there was no mention of stigma related issues, there was a comment that there were some cases of *"social withdrawal"* (p. 360), although no further explanation of what was meant by this was given. When examining the participants' experiences of the study presented in this thesis, this withdrawal found by Abayomi et al (2005) could have been similar, attempting to either not go out at all or to limit any outside socialising to times where any episodes of FI could be prevented or managed privately.

Quality of life

As mentioned in the introduction of this chapter, although QoL was a major issue running through the literature review looking at the different late effects of pelvic cancer, it was not noted to be a main theme in the framework. The reason for this is simple; the participants rarely mentioned QoL in the way the term was expressed in the studies, especially the specific ways described in the various papers looking at QoL measurement tools. They did, of course, throughout their interviews, mention distressing events that were impacting on their QoL, but this was often expressed in narratives of difficult experiences, and these were identified within the framework under the three main topics. Returning again to the definition of QoL shown previously, it is noted that it describes perceptions and concerns, the impact of their environment and so on, rather than just a list of physical symptoms:

> *"an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment"*

The World Health Organisation (1997, p.1)

Whereas it is appreciated that measurement tools can be useful for brief interventions to identify if the person is experiencing difficulty, it is also noted that often an individual's problems may not fit neatly into a tick box method, where discrete issues are concerned and needs could be missed.

It is helpful to consider the work of Koller et al (1996). They noted the rise in use of QoL questionnaires in clinical studies and care planning, but that also unexpected results from the use of such questionnaires often arose. The authors suggested that there are variables not normally connected, or at least not in 1996 when their paper was published, to health related QoL scoring systems, hence some questionnaires may not be fully addressing issues which can impact upon QoL. Their study aimed to examine what other elements could be affecting QoL but were not currently at the heart of existing questionnaires. The results of the study, of which they used three different analytic measures to improve validity, showed that what mainly impacted upon cancer patients' QoL were not necessarily their health problems, but their emotional and social distress. This was based around the participants' experiences of stigma. The discussion around whether QoL measurement tools are able to fully capture the extent of distress is an area where further research would be helpful.

Another example again taken from the literature review, of how QoL measurement tools may not be truly capturing the true patient experience, comes from a narrative researcher who was particularly interested in people's stories-

“Disease is the problem from the practitioner’s perspective”

Kleinman (1998, p. 5)

This would suggest that if you are looking for a diagnosis of a disease, then QoL scores may help. If you are looking for an understanding of the *impact* of the disease, or of symptoms, then something else is required to gain the information that QoL scoring systems alone, cannot. This is seen in those studies examining PRD however, having been found lacking in stories of patient experience, whether they experience stigma similar to people with other bowel conditions that result in continence issues, and also how their physical symptoms impact on their everyday lives. The literature surrounding studies of faecal incontinence and chronic illness make a direct or indirect link with issues of stigma and these are comparable with the experiences found with this study’s participants.

Healthcare

Discussion around the various roles of healthcare interventions was frequently noted during the literature and throughout the interviews and was highlighted as the second major theme in the framework. Most participants described difficulties in accessing the required healthcare services. There has been increasing awareness of the consequences of cancer in recent years, but clearly there is still much work to do (Andreyev 2014 and Henson 2011). As both John and Jason described in the findings section, they were both *“going back and fore”* to their GP to try to get them to address their problems. Even when cancer healthcare professionals were still involved, often the problem continued to go unrecognised, as previously described by Bev.

There are several policy documents that mention the ongoing needs of people following their cancer treatment. The Wales Cancer Network Cancer Delivery for 2016-2020 (Wales Cancer Network 2016) highlights key points as:

> *35. The consistent application across Wales of elements of the 'recovery package' as appropriate*
>
> *38. To offer timely, high quality and accessible information… including…complications of treatment*
>
> *39. To establish routine liaison mechanisms between primary and specialist care to meet people's ongoing and post-treatment care needs*

Cancer Delivery Plan for Wales 2016-2020 (p. 13-14)

Although this document appears to note potential issues with late effects of cancer treatment, the wording is rather vague and could be interpreted as giving very little acknowledgement to the need. The Recovery package mentioned includes a holistic needs assessment and an individualised care plan, both of which, if used appropriately could be used to identify late consequences of treatment. In contrast, under the umbrella of the National Cancer Survivorship Initiative (2013), the Department of Health, Macmillan and NHS Improvement jointly developed a document looking to direct cancer survivorship work development in England- “Living with & Beyond Cancer: Taking Action to Improve Outcomes” with an entire chapter devoted to consequences of cancer treatment. Their key messages are much more strongly worded in improving care for people with late effects of cancer treatment, including PRD:

> *To design and commission pathways and services that minimise consequences and address need*
>
> *Begin the assessment and monitoring of patients for consequences of treatment during the active treatment phase, and continue for as long as necessary*
>
> *Empower patients and primary/community care professionals to manage the consequences of treatment*
>
> National Cancer Survivorship Initiative (2013)

Many of the papers examined referred to the above document in their introduction, demonstrating that in England at least, healthcare teams are recognising the need to address the area of consequences of treatment. The NHS England (2015) Cancer Strategy also recognises the need to identify research priorities for late effects of cancer treatment, and then to make sure the research is undertaken. The NHS Wales logo and endorsement did not feature in the document, despite it being led by the *National* Cancer Survivorship Initiative, suggesting that perhaps Wales will follow the Cancer

Delivery Plan for Wales 2016-2020, with the limited mention of late consequences of treatment as shown above.

Despite the Government documents declaring that cancer care does not finish at the time the treatment ends, the literature continues to show a general lack of awareness among healthcare professionals. An online survey of GP's attitudes towards cancer survivorship care was undertaken by Walter et al (2015). Only 29% of the 500 respondents felt very confident in managing treatment related side effects, of all cancer treatments not just pelvic radiotherapy. Despite the recommendation of undertaking Cancer Care Reviews, as recommended by the National Cancer Survivorship initiative document (2013), only just over half felt they were useful, although those GPs who used a pre-set template to undertake the review were more likely to find the whole process beneficial. They did however feel that further education in this area would be beneficial. The participants in my study did not comment on whether they had a Cancer Care Review. Jason commented that his GP would not listen to him despite being sure there was a problem and attending the surgery repeatedly. Others, including Tony and Bev, had better experiences. They both mentioned that their doctors had acted quickly when ongoing problems were discussed. It was evident that the participants' stories and journeys very much depended on the way their GP dealt with them when they began to have problems.

It is not only primary care however where awareness of late effects is poor. Henson et al (2011) conducted a study to examine awareness of late GI effects among clinical oncologists who undertook pelvic radiotherapy. Although the Oncologists recognised that a significant proportion of their patients went on to experience late GI effects, they generally did not know how best to manage them. Indeed, 55% said that they would manage rectal bleeding symptoms with steroids, a practice which is now known to be ineffective (Stacey and Green 2013). The ability to refer such patients on to specialised gastrointestinal services was inadequate. Over half of the respondents did not have access to anyone with a specialist interest in late effects. 90 % of the oncologists who took part felt this was a vital service provision requirement. In my study, Jenny had also found a lack of awareness amongst the oncology follow-up team. She commented how she saw different people each time she went and even though she mentioned her bowel problems to them nothing was acted upon.

In a follow up study, Henson et al (2012), gastroenterologists were asked about their confidence in treating people with late GI effects. Just 47% said they were "*confident treating basic cases"* (p.2131). It was also noted that any cases they encountered were few and far between, meaning that they did not feel able to develop any form of expertise in the area. The study concluded that there needed to be improved development of and access to such specialist services.

It is evident from the above discussion that there is non-uniformity of healthcare provision regarding where people are most likely to have their concerns of late GI effects identified and directed to the appropriate care. A qualitative study by Brown et al (2016) examined patients' knowledge about late effects of treatment for colorectal cancer. Using framework analysis, they identified three main themes; merit of self-empowerment, the importance of a teachable moment at the end of treatment and the value of MDT working. They identified that with the support of the MDT, patients could be educated and supported towards the end of their treatment and empowered to know how to look after themselves and identify when they needed to seek expert care. However, they found that most participants felt they had been insufficiently warned about late effects of their treatment and that often they had received what they called "*false reassurance"* (p. 196) from clinicians, that any such problems would settle eventually without treatment. The authors concurred with Harrison et al (2012) and one's personal observations from the above discussion that if clinicians themselves did not fully understand the consequences of treatment, then they could not be expected to adequately inform patients of the possibility of such problems. Although a valuable paper on the issues surrounding identification of late effects, no mention is made of the need to identify specialist referral centres for those requiring further investigation, but merely expounds the value of self-care.

Taylor et al (2012) also examined follow-up for people after colorectal cancer care, specifically looking at the role of the health needs assessment, and the role it could play in identifying late effects of treatment. They suggested that a "Post Treatment Clinic" was the ideal place to identify any on-going issues. It was noted that people who had recently completed their treatment had more problems than those who had finished a while ago. The authors also found that a benefit of using the HNA was that more in-depth discussions could take place around areas most concerning the patients, be that physical, social or psychological. Two main issues are raised regarding using the HNA at an early clinic. Firstly, the HNA needs to specifically enquire about late GI effects. In the development of my own clinical role, the expression "don't ask, don't tell" has been heard numerous times, specifically when clinicians were discussing what to do if patients mentioned problems that, at that time, had no direct referral route. Patients will often not talk about things they find embarrassing unless specifically asked. Harry's wife Gwen had commented in their interview that she felt healthcare staff should ask about symptoms rather than waiting to be asked, although Harry himself answered saying *"well unless you tell them I suppose… you know…".* It seems that even a close married couple are unable to agree whose duty it is to make sure the problem is aired. Studies of late effects of cancer treatments involving other organs identified similar problems; sexual problems following gynaecological and prostate cancers were often not openly discussed by patients and it was deemed necessary to include specific questions to address potentially sensitive issues (White 2015, Sekse et al 2010, Fernandes et al 2015 and Jakobsson et al 2000).

Secondly, it has been shown that late GI effects of cancer treatment can occur up to 29 years after completion of treatment (Dunberger et al 2010, Andreyev 2007 and Olopade et al 2005). Therefore, if the HNA is only conducted as early on as within the first six weeks of treatment completion, as suggested by Taylor et al (2013), then it can be concluded that many patients will not have begun to experience late-onset symptoms and so could be missed.

The best time to discuss the issues of late consequences of treatment is unclear, even before treatment is given. Bev recalled being given a consent form to sign before her treatment and recalled that it may have mentioned side effects, but felt that her only priority at that time was to give whatever consent was required to try to survive her cancer diagnosis. Doyle and Kelly (2005) believed that by developing a treatment and aftercare plan early after the initial diagnosis, then discussing issues such as potential consequences of the intended treatment could be a more formal process. By treating a cancer diagnosis as a chronic disease, rather than just the acute episode, then long-term health needs can be better anticipated and catered for (Phillips and Currow 2010). Taylor et al (2013) also identified that managing patients' expectations regarding their long-term symptoms should be a priority before the onset, ideally well before treatment commences. They believed that educating patients about normal bowel function and how this can be interrupted by the cancer treatment can be a helpful intervention. Husson et al (2011) and Nikoletti et al (2008) recognised that addressing the issues early on may reduce uncertainty, improve coping with bowel changes and prompt more timely access to treatment of late effects when necessary.

To facilitate identification of people experiencing late GI effects, a study group was set up to create a tool, quick and simple enough to be used at any healthcare episode. This was discussed in detail in the literature review. The ALERT-B Tool (Assessment of Late Effects of Radiotherapy- Bowel) (Taylor et al 2016) (See table 10) has provided a validated screening tool that can be used in clinical practice to trigger a referral to a gastroenterologist for investigation into late GI effects of pelvic radiotherapy. Four simple questions identify individuals for whom further investigation may be beneficial. If the person responds "yes" to any question then further conversation can be had regarding the potential for specialist referral.

Diagram 8 - Alert B Tool

Following your pelvic radiotherapy:

1. Do you have difficulty in controlling your bowels?
2. Do you have bleeding from your bottom?
3. Have you had to adapt your lifestyle because of your bowel or tummy problems?
4. Do your bowel or tummy problems affect your mood, social functioning or relationships?

Taylor et al (2016)
See Appendix 10 for the complete tool

Another reason why simple tools such as the ALERT-B may be so useful is the current failure to identify accurately which patients may go on to develop significant late effects. A systematic review of prediction models examined fourteen studies where statistical methods predicted the risk of developing late effects (Salz et al 2015). These were not restricted to GI effects but included all known late effects of cancer treatment. The reviewers noted that only two of the studies used validated prediction tools, and that these were rarely accurate in predicting who would experience severe late effects. Therefore, a quick and easy tool could help to ensure that a vast group of patients could be screened to identify late GI Effects. In the local area, all GPs now have access to the ALERT-B tool, with many choosing to display it in the patient waiting rooms so in effect, people have the opportunity to 'self-screen'.

Finally, ongoing attempts are being made to reduce the direct radiotherapy damage by refining the target dose. Nicholas et al (2017) discusses how adaptations to radiotherapy techniques are showing dose reductions to healthy tissue, and it is anticipated that newer radiotherapy techniques will minimise normal tissue exposure to radiotherapy, so reducing late effects (Macmillan 2016). Andreyev et al (2012) believes however, that more targeted treatment will only alter the time and severity of effects in the GI tract. A recent study by White et al (2018) appears to confirm Andreyev's concern. The study examined the use of new technology volumetric modulated arc therapy that reduces the radiation dose to the organ itself, although results in a larger full body dose. It was anticipated that the reduced radiotherapy dose for gynaecology cancers would therefore reduce the number of late GI effects. Unfortunately, there was no reduction seen in the level of GI toxicity compared to conventional radiotherapy techniques and this is an ongoing area for research.

In conclusion, the literature has shown that there remains inconsistency as to awareness of the consequences of cancer treatment amongst healthcare professionals. In addition, there does not seem just one single method of ensuring the patients' experience of late effects is heard unless they are specifically asked. People like Harry may feel uncomfortable raising the subject and so it is important that healthcare professionals ask the patients themselves, either verbally, using a prepared tool, such as the ALERT-B or Macmillan's HNA, or a combination of methods. Increasing patient awareness may also empower them to recognise when they are experiencing late effects and to seek advice form the healthcare provider at the time.

Support

The participants in this study had a variety of support structures in their lives. Some, like Harry and Gwen were married whilst Bev was divorced but spoke warmly of her son and close friendships. As discussed, the element of ‘teamwork’ was clear amongst the couples interviewed. There were however a few notable, yet barely visible, demonstrations of frustration between the couples, where there seemed a mismatch of expectations.

There were relatively few articles looking at issues of on-going family and friends’ support of long term cancer survivors, although there was work on the need for some form of support in one form or another. The family/friends support for participants in this study was demonstrated in the term frequently used- *“we”* (did this, went there.. etc.), indicating a joint approach. This was demonstrated by both the couples and those interviewed alone. Mellon et al (2006) found that those cancer survivors who had a greater element of social support described a higher quality of life than those who were less supported. In their study of 123 cancer survivors with an average of three years post-diagnosis, they found that those participants who were married identified higher QoL than those who were not. The authors suggest that marriage may offer some protection from the stresses of cancer. It would be wrong to even try to identify a similar theory from my own study, due to small numbers and study design. From this study it was noted that each participant commented on the benefit of support they received and it was not noted to be particularly relevant whether this support came from a spouse, other close family or friends.

From the same study as that discussed above, Mellon (2002) found that although the person no longer has cancer, the effects of having had the cancer were long lasting. This was often due to late effects such as fatigue but also due to changes in the dynamics of relationships. These changes were positive and negative; positive because of a chance of a new future ahead but also negative due to ongoing concerns having had cancer. This potential change in relationship appeared evident with Harry and Gwen. Although they physically demonstrated to me a loving relationship, with hand holding, facial expressions and stories of concern, it was also evident that Gwen was struggling with the change in Harry-

> *Gwen: "Yes, frustration as much as anything you know because you feel impotent because you can't do anything, if I say anything he gets his knickers in a twist you know… This is why I haven't clocked you one before….I mean my daughter gets upset because he won't even go over to her house for a cup of coffee or whatever.."*

Gwen appeared to find the impact of Harry's problems difficult to cope with and clearly, they had previously had words about this. Maybe it was affecting her own activities, and certainly she noted that it also was upsetting her daughter. Perhaps Mellon's (2002) observation that the ability to carry on as normal was important, explains why Harry's inability to do so was causing some conflict between him and Gwen.

Jefford et al (2008) utilised a focus group to look at the perceived needs of twenty-two cancer survivors and twenty participants from various groups of healthcare professionals. It was noted that there was a perception of loss of support from the hospital staff once cancer treatment was over and that participants felt they were being told, by the healthcare professionals to “*go back to your life”* (p. 23). This was noted to be difficult to do, particularly if they had ongoing effects of the cancer treatment such as fatigue, anxiety of cancer recurrence or late effects from the radio/chemotherapy. Bev noted that this expectation to ‘get on with things’ was part of her experience, and was causing difficulties. Having previously been a very sociable person, Bev was now struggling keeping up the persona she once had. She had commented a few times that her friends felt that now the cancer treatment had finished that she should get on with her life and that “*I should be my normal self now”* (line 220). In a study looking at issues of cancer survivors returning to work, Nachreiner et al (2007) found that Bev’s experience was typical. Friends and work colleagues tended to judge one’s ability to carry on with their life depending on how they physically looked. Two examples of this are the comments- *“like, you’re fine now, aren’t you?’* and “*I heard tons of ‘you look wonderful’, ‘you look fantastic’ and ‘I can’t understand why you’re so tired’”* (p. 293). The fact that people like Bev also felt the need to hide was they felt were stigmatising symptoms, meant that friends and colleagues were even less likely to know that something was wrong; Bev was hiding how she felt, so people thought she should be back to normal.

Whilst looking at the literature about support after cancer treatment, one element found, that was not identified in this study, was the role that support networks can have. Taking place whilst being physically present in a room or through on-line groups, this seems to be a place where many found others in similar situations to their own. Ussher et al (2006) examined the role of peer support groups, although participants were either still undergoing or had recently completed cancer treatment. The authors examined multi-cultural studies regarding such support mechanisms which identified consistent findings; people found it helpful to identify with others going through similar experiences. In their own study, participants commented that they could say things to others in the group which they could not say to their own family and friends;

> *'Oh, I've gone to meet someone and they make excuses to get away from you because they don't want to hear what you're going through, whereas here, everybody listens and everybody talks"*

Ussher et al (2006) p. 2569

There may be several reasons why the participants in the study did not mention such support groups. Firstly, they were not actually asked if they had used such groups. There is only one group for people with late effects of radiotherapy that currently exists, and this is generally publicised and managed via the internet. Most participants were at least in their mid-seventies and so may not be computer savvy. Also, it maybe that the timing of study participation was not suitable for attending this type of group; the participants were asked to share their experiences soon after referral to the late-effects clinic and so it may have been too soon for them to be thinking about alternative support and perhaps they were busy concentrating on coping with their physical symptoms. Whatever the reason, the benefits highlighted in Ussher et al (2006) show an element of support that may be useful to consider in the future for supporting people with late GI effects of radiotherapy.

Findings conclusion

When considering the participants' experiences and referring back to the FA utilised for this study, the link that holds them all together is the participant and their partner, if present. Each of the three main themes, stigma, healthcare and support, impacts on the other and ultimately, the participant. Each of the participants spoke about the stigma of experiencing late GI effects of radiotherapy. As Goffman's' (1963) work showed, bowel function in particular is highly stigmatising. People with such symptoms after cancer treatment find this problem extremely difficult to cope with, both physically, socially and psychologically. For those whose cancer was not involving their bowels, it was likely that they did not have bowel symptoms prior to their treatment. As Ken said, *"they've cured one thing but given me another."* (line 104).

The participants' experience of healthcare during the initial stages of recognising late effects of the cancer treatment was often not a positive one. They often had to return time and time again to access the help they needed. Their GP and even the oncology teams often did not recognise there was a problem. This issue was identified in the literature, and further adds to the distress of the patient. The apparent lack of awareness amongst HCPs of PRD further adds to the perceived stigma. The participants often found it difficult to talk about the symptoms, particularly if they felt they were not being acknowledged. By having to talk frankly about the distress and impact of their bowel problems, seeking the help they knew they needed, may have made the embarrassment even more acute. Practical considerations by HCPs were sometimes not seen. Ruth's experience of feeling intense pain when sitting on hard chairs at the cancer hospital could have, and should have, been identified prior to her interview. It was not clear why this was allowed to happen, but it has since been rectified as a direct result of this study.

The third element of support equally impacts upon the issues of healthcare and stigma. The main origin of support available to the participant was family and friends. Yet, due to the stigmatising nature of the symptoms, the participants often tried to hide their problems, particularly from those from whom it was possible to hide: their friends and family who did not live with them. This meant that they sometimes felt isolated, which worsened feelings of shame and depression. If HCPs are unaware of the potential of late GI effects, then the ability to support this group of people will be limited. Other forms of support such as peer groups have not been widely available for this group of people and this is an area that warrants further exploration.

The FA encouraged identification of the participants’ experiences of PRD around three main themes noted in the literature and the interviews as being of greatest significance-stigma, healthcare and support. Each of the participants had stories to tell of how these issues had affected them, their family and friends. The symptoms of PRD caused significant distress resulting in many different expressions of impact on their everyday lives. Their contacts with healthcare services had not always been positive, mainly due to delays in identification of PRD, lack of knowledge by the HCPs they met and lack of information about potential problems on completion of radiotherapy. Family and friends were a great source of comfort to the participants but there were often times of frustration on all sides, mainly due to the ongoing nature of the symptoms when everyone was hoping the cancer journey had been completed. PRD was found to be a difficult condition to identify, to ensure the appropriate investigations and treatment was provided and that resulted in a significant impact on the participants' lives.

Chapter 7: Conclusions

As this thesis draws to a conclusion, the aims of this study, the findings and the discussion of the issues around findings will be examined. The limitations of the study will be discussed, and also the contributions to better understanding, demonstrated. Recommendations for practice will then be made, and the thesis completed by outlining the benefits already obtained through the development of the thesis on both a personal and clinical level. The aim of the study was to gain an insight into the participants' experiences of living with PRD and to achieve this, the objectives were:

- to consider the current literature surrounding PRD and to identify gaps in knowledge

- to provide an insight into the experiences of living with PRD. This included the physical, psychological and social impact, examining what this means for the person and their friends and families

- to develop recommendations that encourage the identification of people with PRD, through the use of existing guidelines and assessment tools. This included promoting access to HCPs with specialist knowledge of PRD, so enabling appropriate assessment and treatment, as well as further support for those people affected

The literature review looked at PRD, including how the disease came to be recognised, what the symptoms are and how they were ideally investigated using an algorithmic approach to enable diagnoses of individual conditions. PRD following the three main pelvic cancers, prostate, gynaecological and colorectal, was found to be not uncommon. Various QoL scoring tools were used although very few allowed the patients to talk about their experiences. Despite growing numbers of studies concerning late effects of cancer treatment, there was a significant lack of awareness of PRD amongst HCPs. This included oncologists and gastroenterologists. Faecal incontinence was frequently found to be a major problem for people with PRD often resulting in difficult experiences which caused feelings of distress and shame.

The framework identified three main issues: stigma, healthcare and support. Stigma was found to be a major issue for each of the participants. This impacted on their lives in different ways. Some like Bev tried to hide it and attempted to carry on as normal, whereas others like Harry and Ken experienced such major changes in their lives that they felt unable to continue as they were and instead carved out a new way of existing. Both coping mechanisms had positive and negative elements. Bev still had a generally active social life although this was often based around where the toilets were and she had little support as she chose to hide her problems from her friends. Harry on the other end of the spectrum decided to not go out. In this way he avoided embarrassing toilet accidents but also upset his wife and daughter as he withdrew from family occasions. Bev, Harry and the other participants each developed coping mechanisms to continue their lives, although with varying levels of satisfaction as to how they now perceived their existence. When asked how he saw his future, Harry replied *"none"* (line 185) whereas Jenny was trying to live as normal life a possible- *"I love working… the thought of staying home."* (line 132).

Awareness of late GI effects of radiotherapy amongst healthcare professionals was poor. More and more people are now surviving cancer and so the issues of consequences of the cancer treatment will also grow. The participants had differing experiences of seeking help when they began to have symptoms. For some like Tony, the acknowledgement of the need for referral to specialist services was relatively quick, whilst for others including Garry, Ken and Harry, the experience was very different, with each commenting on the need to go back and forth several times before they were listened to. Some participants were asked about possible late effects at follow-up appointments, whilst others were not. There was disagreement whether it was up to healthcare professionals to ask, or if was up to patients themselves to bring it up. There was also disagreement regarding how much information about the potential of late effects should have been provided; Gary and Bev's comments on this provide explanations as to why there is not a 'one size fits all' solution to this issue:

> *Gary: "You can give some a leaflet and they can read it but you're not actually absorbing that"*

> *Bev: Before the treatment, you sign a consent form. There could be short, long term effects. I can't even, you know….. I signed the consent form because I've*

> *just been diagnosed with cancer so it's all too much info sort of to take in, but it was very vague anyway, whatever I signed, I can't remember"*

Listening to the participants' experiences highlighted a relatively simple to solve problem within the healthcare setting; Ruth's comment about the hard chairs has since resulted in all patients attending for treatment/follow-up of anal cancer, and other cancers involving the perineum, being offered an appointment with the Occupational Therapists to be measured and advised on obtaining an inflatable cushion. The patients' can then bring with them to hospital appointments and also use elsewhere when helpful.

The support from family and friends was clearly important for all the participants. This was demonstrated in different ways, from enabling a lie-in some mornings, car lifts to appointments, ensuring a good diet and fun nights out. There were several examples of how these support mechanisms were sometimes problematic. The effects of stigma resulted in the participants hiding their problems from loved ones, resulting in reduced awareness and subsequent lack of support. The perceived need to avoid any potential embarrassing situations sometimes caused relationship difficulties, where family events were affected and spoiled. The participants noted that now they no longer had cancer, people were less understanding. They acknowledged that this was because they often hid their bowel problems and so others thought they should get back to their normal lives. There was a noticeable lack of alternative forms of support, such as peer groups. This therefore resulted in only those closest to the participants being aware of the struggles they were facing, thus reducing the possibility of being able to talk freely about their problems and concerns, resulting in further isolation.

Study limitations

Qualitative research is not immune to the criticism of being weak in its method of knowledge production (Silverman 2000) and it can be difficult to define criteria of what qualitative research is, and therefore how to demonstrate reliability (Hammersley 2013). There are however, accepted criteria to demonstrate quality in qualitative research including credibility, transferability and reliability (Steinke 2004). FA utilises these criteria and helps to ensure that the methods and steps taken are documented to allow explanation of how the research was performed, such as the identification of codes and themes, encouraging clarity, openness and validity of findings.

The decision on which was the most appropriate time point to select and then interview the participants was important in order to hear of their experiences prior to any further investigations and treatment. The potential group of participants were those attending PRD for their first appointment. Prior to this, they were unknown to the clinical team. One option would have been to send study information out to potential referrers, to allow a wider audience to have the chance to participate. As a single researcher however, this would have complicated the process and was therefore not chosen. It was recognised though that by only offering the study to those who were being seen for the first time may have put some pressure on the clinic patients to participate, even though this was addressed in the PIS that they were not under any obligation to participate, and that by not responding, their clinical care would be unaffected. The small sample size allowed the study to be more manageable by reducing the amount of data collected. This meant that the participants will not have been a full representation of the types of people/cancer types affected by PRD. A larger sample size that included a wider range of age, cancer types and length of time of experiencing PRD symptoms, may have provided more varied narratives, but it was recognised that this was not achievable within the confines of this study. The principles of purposive sampling were therefore adhered to, allowing a representation of people with the phenomena under examination, in this case people who have PRD (Silverman 2000).

The interview process required careful consideration of how best to reduce participants' potential perception that they should provide answers that they felt were expected of them. The ethical considerations of ensuring that the participant felt safe in the knowledge of confidentiality, that the interviewer's 'power' was not misused and that co-construction was appropriately used, were important. At the beginning of each interview, the PIS and consent forms were again discussed before signing. They were reminded of the confidentiality statements and use of their data, as well as reassuring them that they could withdraw at any time without it affecting their clinical care. Smart but relaxed clothing was worn by the researcher, rather than uniform, to help draw a distinction between the study and the clinical contact. This was vital as the researcher would have by then already seen the participant in a clinic consultation and there was a need to reduce any feeling of obligation of the participant to take part, or reduce any parts of what they were talking about, especially if it was criticism of care they had received. A potential way of reducing this further would have been for a second researcher to perform both the recruitment and interviews, but this was not feasible within the confines of this study. Edwards and Holland (2013) spoke of the power held by the interviewer in qualitative research. This was necessary up to a point to help guide the interview towards the development of required data, but must not be misused and the well-being of the participants must be maintained. The recording devices were kept out of line of sight as much as possible following the first interview. It was identified when reading the first transcript that the devices were checked several times during the interview to check they were working, mostly as an anxiety-driven concern. Not only did this interrupt the flow but kept drawing attention to the fact it was being recorded, which could then influence how the participant responded.

Co-construction of the interview process can be improved through recognition that the interview process is an event between at least two people. Reflection during, and following each interview, helps to consider the impact the interviewer's behaviour may have, in both positive and negative ways. Notes taken throughout each interview, as well as those written in the office/car immediately afterwards, supported this process. One note in particular stood out after both the first and second interview- STOP TALKING!!! It was recognised that in an anxiety-driven attempt to get the information required, too many questions were asked, silences were immediately filled and the interviews were perhaps cut too short to enable it to be finished. The notes also helped to reduce bias in subsequent interviews; leading questions were replaced with ones that were more open. An example of this was changing "tell me about your symptoms" to "tell me about what it was like for you…". Some researchers choose to re-visit the participants for a second interview. This can provide more detail in areas noted after listening to the recordings, or reading the transcripts where particular areas of interest are noted. For this study, it was decided that this could further compromise the research/clinical relationship. Soon after the initial interview, the participants would have undergone investigations and would have had further telephone/face to face appointments, and this could have undone the work around reducing any perceptions of coercion to take part by the participant.

Transcription of the recordings was done by a typist linked to the university. This was to reduce time from interview to transcript readiness, to promote recollection of non-spoken occurrences, such as participant and partner hand holding, glances and smiles and so on. Undertaking one's own transcription however, may have helped to develop analysis earlier on and allowed more linguistic transcription to be made, noting voice tones, laughter and sighs to be placed within the transcription. Applying language study to the analysis would have increased the work load enormously, and this was not time that was available, although may have provided an additional useful viewpoint.

FA provided the structure with which to examine the data. Gale et al (2013) highlights a number of limitations to using this method. The framework approach may encourage novice researchers to apply quantifiable measurements to their findings, such as "50 % of the participants said….". Even though the step-by step approach directs the process, it may also encourage an over-reliance on 'rules' rather than encouraging a freedom to interpret the data. The perception of it being an easy method, due to the step-wise guidance, could also result in new researchers misapplying the steps if adequate training is not provided. The research education received in the first two years of the

Professional Doctorate went some way to addressing this, as did the support of the two supervisors throughout the study. The approach can be time heavy, as with all qualitative data. By using the services of the professional transcriber, this helped to limit the length of time to transcript production.

Involving a second or more researchers in the coding process is a common feature in larger studies and helps to harmonise perceptions of what each code means. Saldaña (2016) identifies that as *"inter-coder agreement or interpretive convergence"* (p. 37) and encourages consistency and reliability. Galman (2007) in Saldaña (2016) however, recognises the benefit of the lone researcher- being *"intimately involved with her data"* (p. 36). During the development of the FA, the large art pad that was used to present the data in a visual way was discussed at supervision meetings and an explanation of codes and FA process development agreed. Interpretation of both the codes, development of the framework and analysis were explored jointly throughout the process.

Original Contribution to knowledge

This research has provided an original contribution to the knowledge of the experiences of people with PRD that has not been previously demonstrated. The literature review recognised that whilst the symptoms of PRD have been extensively explored, there was very little awareness of what it is like to live with this disease. While QoL scores are included in many of the research papers, the progression from symptom identification to patient experiences has not been determined. The FA was developed from the literature, applied to and refined through the first few interviews and then applied to the interview transcripts. The study found that the participants experienced significant problems with various issues around stigma, healthcare and support, and these issues had not been particularly recognised and/or discussed in previous studies looking at PRD.

- People with PRD experience a significant impact on their everyday lives. This includes various distressing feelings of stigma, which results in depression and social avoidance. Current QoL scores are useful in identifying symptoms but often do not offer the opportunity to learn of the impact these symptoms have on the patients' lives, thus resulting in an unmet need.

- Getting timely access to appropriate healthcare services for identification, investigation and treatment for PRD is often a slow, difficult and frustrating process. Although there has been improvement in HCPs knowledge of PRD over recent years, the general level of awareness remains poor. This inevitably impacts upon the patients' ability to receive timely assessment, investigations and treatment for PRD.

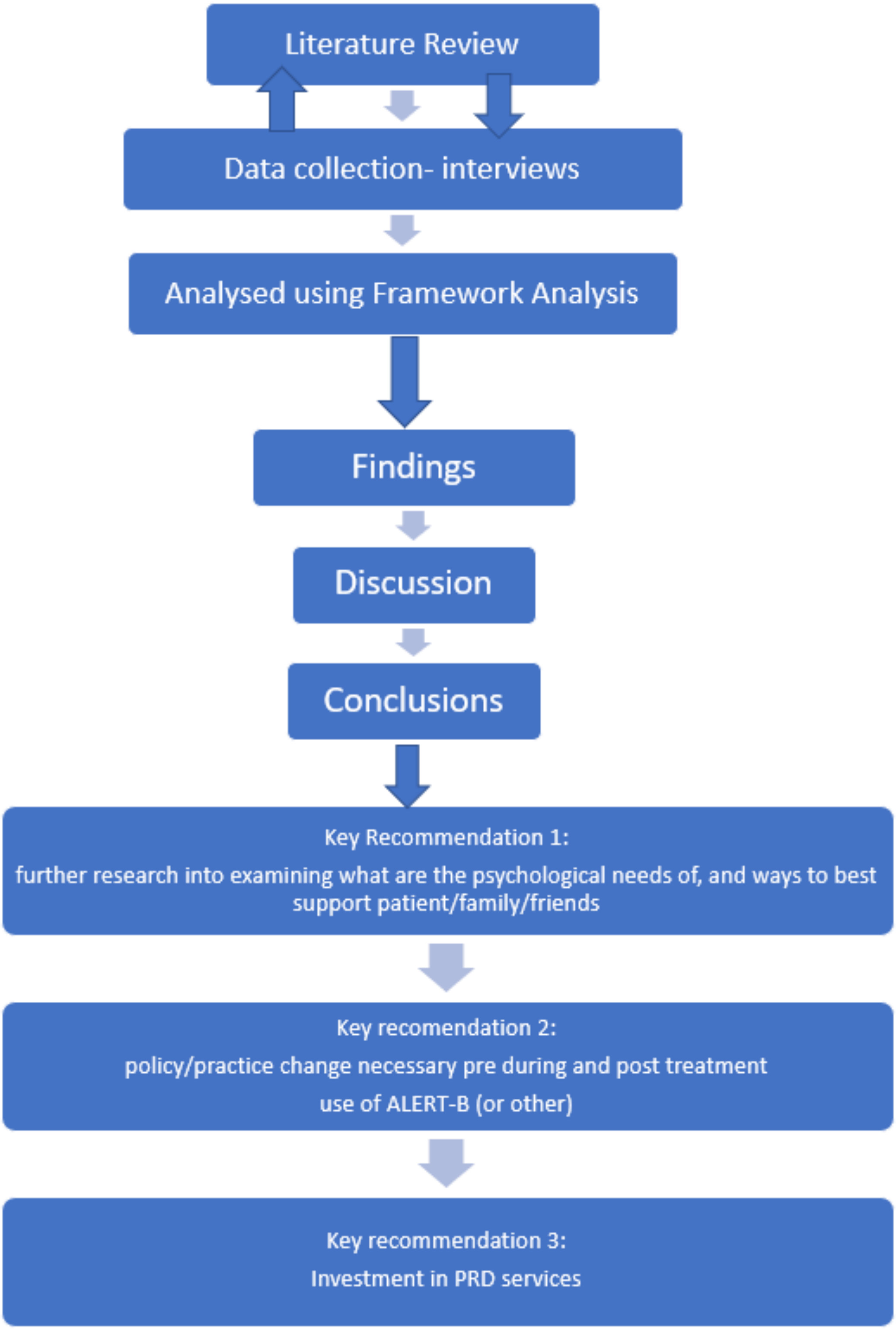
- A sense of teamwork provides a great deal of support for people with PRD, from their family and friends. These relationships however can be strained due to the on-going nature of PRD following completion of cancer treatment and patients may notice a drop off in their support systems over time. Cancer charities such as Macmillan have made significant developments in the support of people with late effects of cancer treatment, however it appears that patient awareness of this information and support services, may be poor.

Recommendations for future research

Further research into the barriers of HCP awareness of PRD would be useful. This could then be used to design an educational programme to improve the identification of those people who may be at risk of developing PRD, to improve recognition of those with PRD and to then have the knowledge of where to refer onwards for appropriate care. Further understanding into the complex psychological needs of people with PRD would also be a useful area for further research. These are a group of people who have already undergone the trauma of a cancer diagnosis and subsequent treatment. Just as they anticipate that their lives are about to return to some sense of normality, they then experience distressing symptoms which often go unacknowledged and untreated. Support from family and friends is important throughout this time and yet, due to all the support given during the cancer treatment, there may be a reduced level of support available. Understanding the best way to offer support, such as one to one counselling, group therapy or perhaps on-line sessions, would go some way to helping these people through a difficult period in their lives.

The following diagram outlines the steps of the whole study, ending with a summary of the key recommendations that are addressed in more detail in the subsequent section.

Diagram 9 - Study Outline



Key recommendation 1:

Further research is required to examine what are the psychological needs of patients, family and friends and what is the best way to support them. It is clear that this is a group of people who have difficulties that are unlike people with other bowel conditions. There needs to be a continuous drive to promote the needs of people with PRD. This includes identification of research needs and the ability to take these forward to develop robust studies. The publication of articles and studies around PRD will encourage the growth of awareness amongst HCPs and so ultimately, an improvement of services.

Organisations such as Macmillan, Prostate Cancer UK and Cancer Research UK play a tremendous role in providing information, support and research funding for cancer. It would be helpful for them to consider a national campaign to raise awareness of PRD and other late effects of cancer treatment, particularly considering the significant number of people surviving their cancer diagnosis as presented at the beginning of this thesis.

Key recommendation 2:

There is a need to change policy and practice in managing patients pre and post treatment, using evidenced based research. This study has identified several areas where policy and practice could be improved:

Pre-radiotherapy

Some of the participants had mentioned the lack of information about the potential of late effects of the radiotherapy treatment. They did however recognise that often the information that was given to them may not have been fully absorbed because at that time their main priority was treating the cancer with the sole aim of survival. To meet the differing and changing information needs of people throughout their diagnosis, treatment and follow-up care, it may be helpful to ensure that a wide range of information is available, perhaps through a list of topics/titles given to them, a display of leaflets/booklets at clinics and to ensure the patient has a point of contact to discuss any concerns over the weeks, months and years of their cancer journey.

Oncology follow-up

As well as the Holistic Needs Analysis being undertaken, other screening tools such as ALERT-B should be used to identify people with PRD. All tools, but particularly general QoL tools, should be only used as a basis for further discussion about the impact of symptoms, rather than simply a disease status gathering exercise.

Education and awareness must be improved for primary and secondary care health organisations, including GPs, Practice Nurses, Oncology HCPs, radiographers, CNSs, and endoscopists. This could be done by presentations at training days and meetings, newsletters for professional groups, such as GP clusters and posters for staff rooms and patient waiting rooms. This then links into the final recommendation that investment is necessary to achieve these changes

Key recommendation 3:

In order to improve services for patients with PRD and their families, there is a level of investment necessary. As well as services such as the clinics mentioned above, there is a need to consider the diverse nature of this group of patients, as well as others with late effects of any cancer treatment. This must take into consideration specific needs such as difficulty in leaving the house to attend appointments and so perhaps telephone or Skype could be utilised, at least for the initial assessment.

The third sector also has a strategic role to improve networking for HCPs with an interest in PRD. Macmillan has produced several PRD information booklets aimed at both HCPs and patients. Raising awareness and providing information in the monthly HCP newsletters has already gone some way to achieving this.

Secondary care/Gastroenterology Services

There should be named gastroenterologists in each Health Board/Health Trust with a special interest/knowledge in PRD, and involvement made with the specialist multidisciplinary group “Macmillan on-line MDT”. These groups should meet perhaps yearly to discuss any new advances in diagnosis and treatments, potential areas for research and case discussions.

Tick-box forms should be used with care. Although useful to identify specific symptoms and to steer the clinical assessment, ensure they are used only as an *additional* tool and not purely for information gathering.

As people with PRD often have a complex medical history and may be experiencing significant physical and psychological distress, as highlighted by this study, it would be helpful to ensure ‘new patient’ time slots are of longer length to provide the time required for this group of patients.

Ensuring the patient with PRD is seen by the correct HCP requires planning. The referral letters should be carefully vetted and the appointment made in a clinic where specialist interest and knowledge is available. For example, have a dedicated PRD clinic code, to prevent the appointment being made in a junior Registrar’s clinic. These clinic codes can then be used to generate the longer ‘new patient’ slots as suggested above. This will also help to ensure these patients are seen promptly, and by the appropriate clinician, rather than simply being added to the general waiting lists.
Links should be developed and maintained with specialist services that will be able to provide additional assessment and support to people with PTD. This includes physiotherapists, dieticians, psychology services and colorectal/pelvic floor services.

A personal reflection

The development of this thesis has provided rich experiences and learning opportunities unlike that which have been achieved throughout my career until now. As well as the benefits personally afforded, small changes and improvements have already begun to emerge that will, I hope, ultimately go some way to improving the experiences for those with PRD. This section will discuss these changes, and it will be explained how I believe this thesis has already demonstrated a benefit, at least to me as a passionate clinical and now academic nurse.

Personal achievements

Having undertaken several degree level courses over recent years I was comfortable studying and writing to the required standards. Working towards the Professional Doctorate has however taken this to a whole new level. I think I may have declared several times to my husband that if or when I attend the graduation ceremony, I will be receiving an award for persistence and resilience. My mantra has become “this is a marathon, not a sprint”, words that have been repeated at most fellow student group get-togethers. I have developed my study skills, learning that ‘little but often” has been the way forward. Ideas and direction have often come to me whilst in the strangest of places, often when I am most relaxed. This has resulted in me carrying either my journal or a note pad with me wherever I go, although I must admit that many of my night-time written notes have become illegible by the morning. This may sound to some that the process has been unpleasant, but although difficult at times, it has been both a pleasure and an honour. To be given permission and reason to study a fascinating topic so in-depth and one that is trying to achieve improvement for others, has been a remarkable opportunity for which I am extremely grateful. Having to do all the studying in my evenings, weekends and holidays has been a struggle, but one I believe that has been worthwhile.

My now grown-up children and I have studied together; both have completed or almost completed degrees during my own time at University. We have all studied together, procrastinated together and achieved together, taking it in turns to ‘give up’ and then to pull each other through. What a wonderful experience this has been. Moving forwards, I would say that I have definitely caught the ‘research bug’ and as a clinician, my next challenge will be to find a way of combining my new passion for research with my life’s passion of nursing.

During my time working towards this award, my clinical career has progressed rapidly. I have become the clinical lead for IBD, not also for my Health Board (HB), but also as the lead nurse on an all-Wales IBD Development project. My endoscopy skills have also improved significantly; I am the first nurse in my HB to move from flexible sigmoidoscopy to colonoscopy. Throughout this I have also developed my work within the world of PRD, being the only nurse in Wales, and one of only a handful in the UK, within this specialism.

Having little allocated time with which to do this has been difficult, but using the knowledge I have gained from developing my other clinical roles has taught me to be political and savvy to ensure the service can withstand an on-going difficult period in the NHS.

Patient care achievements

From the very first interview for this study, my interaction with my patients has changed. I thought I knew nearly everything there was to know about bowel problems, given my long GI nursing career but as a result of this study, I now have a greater understanding of what it might mean to live with bowel problems, and the effect this can have on people’s lives. Usually working within a busy clinic, many consultations begin with the patient completing a symptoms assessment tool. This is a tick-box form, enquiring how troublesome various symptoms are, such as diarrhoea, incontinence and urgency. On the back is a small Likert-scale question- asking “how much does this affect you”? Prior to the study interviews, I would concentrate on the symptoms, as after all, I felt the patients were there for me to resolve their symptoms, to find out what was wrong and to correct it. Since interview 1, I have changed my viewpoint and the way I conduct the clinic consultations. I now believe that an important part of the patients’ first attendance at clinic is to have their symptoms, and the impact of these on their lives, acknowledged. I am frequently asked *“am I the only one like this”*, and now I believe that I can address their concerns in an entirely different way.

With some shame, I now acknowledge that before interview 1, I wrongly assumed that the bowel symptoms only occasionally affected their lives causing minimal disruption. After all, having incontinence would affect anyone’s life to some extent. Having now gained a deeper insight into my participants’ experiences, having heard their stories, been a witness to the distress and shame this has caused, I feel that I can support my patients in a different, more insightful way. Although the tick-box form is still used as it supports application of the guidelines algorithm, I now use it as a platform to guide the consultation. The way I ask the questions has changed; previously I would enquire how often they have FI; I now ask, “What affect does having FI have on your everyday life?” The detail of their answers has now changed from a numerical total of FI incidents, to a deeper explanation, and therefore understanding, of the effect of their FI; does it stop them going out? Does it mean they have had to give up work?

Over the last year or two, I have noticed a change in the way my patients respond at this first clinic appointment. Tears of relief that finally someone is really listening to them are frequent. I have been told that I am the first person they have spoken to that understands. What an honour that is. I have been able to share stories of others' experiences, of the bad times, but also the good. The hope that this can bring is priceless. I have learnt that tick-box forms have a place, but listening, really listening and asking about impact and experience is what makes the difference.

The findings chapter revealed that Ruth talked about the hard-plastic chairs in the follow-up radiotherapy and oncology clinics. Ruth and her husband had joked about having to fight for the one soft chair in the department. Following that interview, I contacted the team in charge of the department to discuss this experience. A small group including myself and departmental nurses, radiotherapists and occupational therapists (OT), collectively discussed how to improve this situation. From then on, each person attending their first appointment for radiotherapy that was likely to include the perianal area was assessed by the OT. Soft, inflatable cushions are now provided, or suggested for purchase, which the patient can keep for hospital and home use. Unless I had specifically asked Ruth to tell me of her experiences, it is likely that this issue would not have been raised or addressed. If my research provides just that one benefit alone, then I believe I have made a difference, however small this may seem.

Having published an article in a peer-reviewed journal (Ludlow 2016), I have been asked to present my work on several occasions. As discussed in this thesis, the consequences of cancer treatment are a growing area of interest amongst relevant clinicians. I have been invited to present my clinical work and research findings at two conferences where they hope to develop similar services. The objective of my presentations is not only to discuss the practical aspects of setting up such a service, such as the tick-box forms, but to impress upon the audience that, from the very outset they *need* to enquire about and include the patients' experiences in the consultations. As busy clinicians, it is often too easy to see the patient in front of you as just another set of symptoms, a puzzle to solve, but they are human beings with stories to tell.

Due to my PRD nursing role and this research project, I was invited to take part in the final research priority workshop for the "What is Living with and Beyond Cancer Priority Setting Partnership". Supported by the James Lind Institute, this project was led by the National Cancer Institute and was as a direct result of the NHS England (2015) Cancer Strategy that includes the need to identify research priorities for late effects of cancer. Using the knowledge gained in this thesis on the significant impact of PRD on my participants' lives, I could ensure that the need for further research that would support this group was high up in the list of research priorities. This included improving the understanding of why late effects happen, to support improvement in treatment delivery and so reduce the risks of late effects happening, as well as improving the lives of those affected. I have also been involved in updating the Macmillan Late Effects booklets, ensuring that the suggestion to inform their HCPs about symptoms that affect their everyday lives was included.

Lastly, one insight I have gained from studying the experiences of my participants is that they have different stories to tell than people with other bowel conditions, such as IBD.

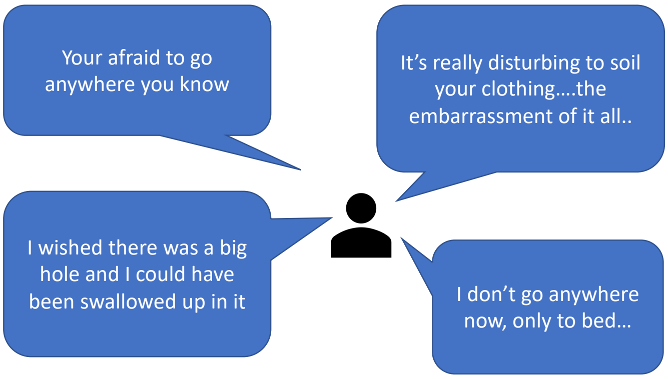
Patients attending the PRD clinic frequently tell me that their bowels were fine before the cancer treatment, and indeed this is an important question so ask when trying to assess when their symptoms developed. I recognise this group as people who had no or few bowel problems prior to their cancer treatment. The very treatment they received for their cancer has now left them with often devastating bowel problems. Jon's story has stuck with me in particular. As described in the findings chapter, the tale of humiliation at the airport sums up the devastation of the effects of PRD:

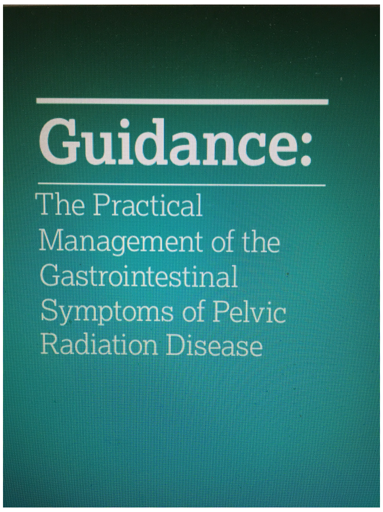
> *John: "At the time I wished there was a big hole and I just could have been swallowed up in it"*

It is for people like John that I have a strong sense of professional responsibility to play my part in improving the care and support available to people with PRD.

Executive Summary

The number of people being diagnosed with cancer is increasing year on year. With 19,088 new cancer diagnoses in Wales in 2015, this was a 10% increase from the previous ten years (Welsh Cancer Intelligence and Surveillance Unit 2017a). Cancer survival in Wales also continues to grow, with an average increase of approximately 3% for both one and five year survival (Welsh Cancer Intelligence and Surveillance Unit 2017b). As well as radiotherapy treating the cancer itself, there will inevitably be collateral damage to nearby tissues. When this affects the pelvis it is known as pelvic radiation disease (PRD) . This has a significant impact on the lives of people who experience it.




Guidance:
The Practical Management of the Gastrointestinal Symptoms of Pelvic Radiation Disease

The document above- Guidance: The Practical Management of the Gastrointestinal Symptoms of Pelvic Radiation Disease (Andreyev et al 2014) gives a step by step approach to the assessment, investigation and treatment of PRD. In findings from the EAGLE study (Taylor et al 2016b), where men developed PRD following prostate cancer, a Specialist Nurse-led clinic was found to be an effective care delivery model, with costings of £117 per clinic visit with a total cost of £2390 for investigation and management of these patients. Considering the impact on the patient and their family as shown above, this cost could be considered minimal if it allows people to get back to their pre-cancer lives.

Recommendations

There is a requirement for investment into PRD Services. This includes:

- A dedicated PRD clinic in every Welsh Health Board, with ability to use innovative services such as telemedicine/skype
- Improved education and awareness of PRD for Healthcare Professionals both in Primary and Secondary care
- Support for research into preventing, identifying and managing late effects of cancer treatment
- Improved support services for people affected by PRD and other cancer treatments

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Appendices

Appendix 1: Literature of QoL Tools Review Table

	Brief Title	**How QoL Assessed/Tools etc.**	**Comments**
Das (2010)	Long-term QoL after radiotherapy for treatment of anal cancer	Questionnaire mailed Functional Assessment of Cancer Therapy- colorectal (FACT-C) Medical Outcomes Study (MOS) Sexual Problems Scale	FACT-C : is self-administered, 34 items- 4 domains of QoL: physical, social/family, emotional and functional & colorectal sub-scale MOS: 4 item Q max score 100, higher score=worse sexual function
Sunesen (2015)	Long-term anorectal, urinary & sexual dysfunction…Danish multi-centre	Questionnaire mailed	Developed own anal-cancer specific questionnaire, using existing grading resources. Parts of LENT_SOMA used (for subjective symptoms & management/medical intervention) Part based on the St Marks score for faecal incontinence Symptoms distressed used a 4-category verbal scale (no, little, moderate or great distress)
Engel (2003)	QoL in rectal cancer patient's- a 4 year prospective study	Says Q "administered"- to detail of how/where Patient invited/consented at primary treatment then posted questionnaires European Organization of Research and Treatment of	EORTEC QLQ-30: 30 questions, 5 functional scales (physical, emotional, cognitive, social and role functioning), global QoL measure, symptom assessment

		Cancer (EORTEC) generic and rectal & specific Q's-	EORTEC CR38- designed for rectal cancer patient's questions including body image, sexual function/enjoyment, future perspective, GI & urinary problems
Stephens (2010)	Impact of short-course pre-op radiotherapy for rectal cancer on patient's QoL (Canada)	Medical Outcome Study Short-Form 36 item EORTC QLQ-CT38	IMOS- SF-36 (general health Q, 8 subscales (physical function, role-physical, bodily pain, general health, vitality, social function, role-emotional and mental health EORTEC CR38- designed for rectal cancer patient's 938 questions including body image, sexual function/enjoyment, future perspective, GI & urinary problems
Bentzen (2013)	Impaired health related QoL after chemoradiotherapy: late effects	Q's sent and telephone interview EORTEC (QLC-C30) EORTEC (QLQ-CR29)	EORTEC (QLC-CR29)- 4 scales assessing urinary frequency, faecal seepage, stool consistence, body image and also urinary incontinence, dysuria, abdo pain, buttock pain, bloating, anxiety, flatulence, faecal incontinence, sexual interest, impotence and dyspareunia Telephone interview- structured, pre-defined questions, yes/no not at all/very much
Knowles (2013)	Long term effect of surgery and radiotherapy for colorectal cancer on defecatory function and QoL	Postal questionnaires Memorial-Sloan-Kettering Cancer Centre (MSKCC) Bowel Function Instrument EORTC-C30 EORTC QLQ-CR38	MSKCC- 18 items, 3 subscales- frequency, urgency/soilage/dietary
Cameron (2012)	A descriptive study of functions, symptoms and perceived health state after radiotherapy	Pre-treatment surveys Post-treatment questionnaire via telephone European QoL scale- EuroQoL: EQ-5D- 5	Identical content in pre and post treatment surveys European QoL scale (EuroQoL: EQ-5D- 5 domains of patient function (mobility, self-care, usual activities, pain/discomfort and anxiety/depression and

		Expanded Prostate Cancer Index Composite (EPIC)	a rating of global health state EPIC- 50 item health-related QoL specific to prostate cancer patients
Crook (1996)	Effect of pelvic radiotherapy for prostate cancer…the patients perspective	3 page 20 point questionnaire posted	Questionnaire based on questions from an earlier study (Fowler et al 1993) where post prostatectomy patients were asked about symptoms via mail/telephone/personal interview
Pinkawa (2010)	Consequential late effects after radiotherapy for prostate cancer- a prospective longitudinal study	EPIC questionnaire was used, given at clinic appointments	EPIC- see before
Nguyen, (1998)	Late effects after radiotherapy for prostate cancer in a randomized dose-response study……..	Posted questionnaires	Questionnaires adapted from those used by Crook et al (1996), Jonler et al 91994) and Fowler et al (1993)
Nout (2011)	5 year QoL of endometrial cancer patients treated in the PORTEC-2 trial	Questionnaires give out at 1st clinic appointment EORTC (QLQ-C30)	EORTC- see before
Nout (2009)	QoL after pelvic radiotherapy or vaginal brachytherapy for endometrial cancer- PORTEC-2 trial	Questionnaires give out at 1st clinic appointment EORTC (QLQ-C30)	EORTC- see before
Abayomi (2009)	The prevalence of chronic radiation enteritis following radiotherapy for cervical or endometrial cancer and its impact on QoL	Questionnaire based on a previous study (Bug et al (2001)	Questionnaire was adapted from the King's Health Questionnaire (a condition-specific health-related QoL questionnaire to assess women with urinary incontinence. It was then tested for acceptability, reliability and validity by postal survey.
Abayomi (2005) **qualitative**	A study to investigate women's experiences of radiation enteritis following radiotherapy for cervical cancer	One to one interviews at home/hospital	Interviews lasted 30-120+ mins. 'Interviewer guided approach', open questions. Covered: experiences of diagnosis/treatment, problems during/after treatment, impact of symptoms of everyday life, attempts to control symptoms, professional help sought/received regarding symptoms
Holmes (2010)	Identifying side effects of pelvic radiotherapy	Posted questionnaire developed on the Royal Marsden Hospital for radiation-induced bowel injury	2 patients reviewed the questionnaire and amendments were made (not said what/why). Note made that the questionnaire was to confirm level of bowel/bladder function but did not measure QoL or

		Comment box on questionnaire	other late effects. After some people received the questionnaire they rang to see if they could have more help for their symptoms Free-text comment box provided useful data
Atherton (2013)	Assessment of patient-reported measures of bowel function before and after pelvic radiotherapy….	At 4 weeks, 12 & 24 months: Bowel Function questionnaire Uniscale QoL measure Content validity questionnaire (CVQ)	BFQ- created by Mayo Clinic to assess bowel function after resected rectal cancer yes/no answers 0-10 scale (0=as bad as it can be, 10= as good as it can be) CVQ- determines importance score patient rates each BFQ symptom on a 5 point scale (0= not v important to 5= v important)
Gami (2003)	How patients manage GI symptoms after pelvic radiotherapy	Face to face interview,	30 structured questions. Questions developed from a previous audit. If patients reported a symptom they were asked if it affected their quality of life
Gillespie (2007)	The clinical needs to patients with chronic GI symptoms after pelvic radiotherapy	Posted a questionnaire	24 structured questions, with option of giving free text answers. No in-depth explanation of questionnaire, but seems to ask about impact of symptoms on QoL-)no effect, very much…)
Henson (2013)	Structured GI intervention and improved outcome for patients with chronic GI symptoms following pelvic radiotherapy	Inflammatory bowel disease questionnaire (IBDQ) Vaizey incontinence questionnaire (VIQ)	IBDQ previously used for PRD- 32 questions on symptoms and effect on social functioning and QoL VIQ- to detect faecal incontinence, 7 questions, used before with PRD 0-24 (0= prefect continence 24= severe

		Common terminology criteria for adverse events (CTCAE) Hospital anxiety and depression score (HAD) EQ-5D All at baseline, 3 & 6 months	CTAE- to detect side effects of pelvic cancer treatments with bowel, bladder and sexual domains. Separate male/female questionnaires. Extensive validation. 0-4 4= more severe symptoms HAD- 14 items, 2 subscales of anxiety (HADS-A) and depression (HADS-D). Extensively validated. EQ-5D- 5 item patient reported questionnaire plus a visual analogue scale 0-100 for general health state.
Brown (2013)	Assessment of long-term rectal function in patients who received pelvic radiotherapy….	Bowel function questionnaire Uniscale QoL	BFQ- created by Mayo Clinic to assess bowel function after resected rectal cancer yes/no answers 0-10 scale (0=as bad as it can be, 10= as good as it can be)
Adams (2014)	The effects of pelvic radiotherapy on cancer survivors: symptom profile, psychological morbidity and QoL	A department al developed questionnaire which incorporated: Late effect of normal tissues- subjective, objective, management and analytical measure- LENT-SOMA EORTC QLQ- C30 HAD score	LENT-SOMA- a framework for assessment and grading of late effects due to radiotherapy. Male & female versions See before See before
Jung (2001)	Quantification of late complications after radiation therapy	Questionnaires: Modification of EORTEC and LENT-SOMA	See before
Olopade (2005)	A modified Inflammatory Bowel Disease questionnaire and the Vaizey incontinence questionnaire are simple ways…..	Questionnaires: IBDQ Vaizey LENT-SOMA	See before

Bye (2009)	Health related QoL and occurrence of intestinal side effects after pelvic radiotherapy…	Questionnaires: EORTEC QLQ-C36	See before
NHS England (2015) **Qualitative**	Quality of life after colorectal cancer survivors in England	Postal questionnaire Patient recorded outcome measures (PROM's) Euroqol 5 level (EQ-5D) Functional Assessment of cancer therapy (FACT) Social difficulties inventory (SDI) Free text comments	76 questions Eq-5D: Generic health related QoL measure FACT: Cancer specific questions from a larger survey to assess physical and emotional impact on QoL-statement scale (no issues, very much) SDI: impact of cancer on issues such as family life, social activities, finances and work Thematic framework analysis
National Association for Crohn's and colitis UK (2006) **Qualitative**	Living with bowel problems following radiotherapy- a scoping study	Interviews: telephone, 2 written accounts	Interview data no longer available
Danielsson (1991)	Chronic diarrhoea after radiotherapy for gynaecological cancer: occurrence and aetiology	Questionnaire	No details given of how questionnaire was developed

Appendix 2: Diagnosis related to PRD

Radiation Proctopathy

Radiation-induced tissue damage to the rectal tissues can result in mucosal damage, inflammation and fibrosis (Stacey and Green 2013). Diagnosed endoscopically, telangiectasia are where fine walled vessels are attempting to re-vascularise the damaged tissue often with poor effect due to the afore mentioned fibrosis, and this is known as proctopathy . Previously wrongly described as ‘proctitis’, this often led to inappropriate treatment with anti-inflammatory medications. Treatment depends on the severity of symptoms and occasionally no intervention is required. Endoscopic treatment includes argon-plasma coagulation or instillation of formalin but both of these have a high risk of side effects such as ulcer formation and further tissue damage (Stacey and Green 2013). Sucralfate enemas act as a mucosal barrier and may stimulate healing. This treatment generally requires 2 applications a day via an enema and is recommended by both Andreyev et al (2013, 2014) and Gibson et al (2013).

Radiation Enteritis

Stacey and Green (2014) define radiation enteritis as injury to the small intestine following radiotherapy. Damage to the colonic tissue is known as radiation colitis, and proctopathy if the rectum alone is affected, as discussed above. More accurately, this condition should be known as radiation enteropathy, but this is less well known. The majority of patients may describe symptoms of acute enteropathy during or shortly after radiotherapy, including abdominal pain, diarrhoea and nausea but chronic enteropathy can continue for many years later or indeed present later (Andreyev 2007a, 2007b and Stacey and Green 2014). Moussa et al (2016) describe the complex injuries to healthy tissue caused by radiotherapy, but go on to describe what they call “encouraging” research in animal models with cell therapy as a means of repairing this damage. Theis et al (2010) describe how this damage can lead to small bowel dysfunction and structuring, leading to long-term problems such as obstructive symptoms. Treatment of radiation enteritis, or enteropathy, depends on the symptoms and any further diagnosis, which will be discussed below.

Bile Acid Malabsorption

Bile acid malabsorption (BAM) occurs when the normal reabsorption of bile in the terminal ileum (TI) is affected, and is seen in conditions such as TI Crohn's disease, previous small bowel resection, post cholecystectomy, overproduction of bile acid and post radiotherapy (Walters and Pattni 2010). A systematic review of the management of BAM diarrhoea by Wilcox et al (2014) describes how the presence of the un-absorbed bile increases colonic mucosal permeability that then increases fluid and mucous secretion and also increased colonic contraction and transit time resulting in symptoms including watery diarrhoea and bloating. Diagnosis is made via a scan to measure bile acid re-uptake, using selenium-75 labelled homocholic acid conjugated with taurine (SeHCAT). Smith et al (2000) describe normal re-uptake of the bile at >10% although the sensitivity can depend on the equipment available. The review by Wilcox et al (2014) describes how access to SeHCAT scanning remains poor and diagnosis may be made via response to treatment without obtaining an initial test result. Treatment generally depends on symptom severity and includes a reduced fat diet, symptom management such as anti-diarrhoeals or bile acid sequestrants. Colestyramine and Colestipol are licenced treatment for BAM but are often described at unpalatable. Newer treatments such as Colesevelam are thought to be advantageous due to their tablet form (Walters and Pattni 2010) but at this time are not licensed for BAM and access may prove difficult.

Small Intestinal Bacterial Overgrowth

Dukowicz et al (2007) define small intestinal bacterial overgrowth (SIBO) as "the presence of excessive bacteria in the small intestine" (p. 112). It occurs due to changes in the normal bacterial population and this can result from reduced gastric acid production and/or altered gut motility; It is recognised that pelvic radiotherapy can result in both and that SIBO can result (Andreyev 2007a and Andreyev et al 2014). Symptoms include bloating, diarrhoea, abdominal pain, vitamin B12 and iron deficiency and weight loss (Dukowicz et al 2007 and Grace et al 2013). Grace et al (2013) describe the difficulty in symptom clarification as their review highlighted the lack of validated questionnaires in most of the studies they looked at. There is a lack of evidence for a gold standard of diagnosing SIBO, which can cause problems in identifying the most appropriate treatment (Grace et al 2013 and Andreyev et al 2014). Gasbarrini et al (2007) cited that Corazza et al (1990) describes that the culture of jejunal aspirate as the diagnostic gold standard. However, a working group in which both Gasbarrini and Corazza took part, (Gasbarrini et al 2009) actually summarised that breath testing was the most accurate method. This discrepancy continues in clinical practice today (Dukowicz et al 2007) and so the diagnostic tools are likely to be whichever are most easily available. Treatment is two-pronged: if possible treat the cause and/or treat the overgrowth of bacteria with antibiotics. Andreyev et al (2014) recognises that even with direct analysis of jejunal aspirate, it may not be evident which antibiotic to use and so the guidelines recommend 5 different antibiotics to use, one at a time, to see which is most effective. Unless the cause of the SIBO is reversible it is likely that repeated courses of antibiotics may be necessary.

Carbohydrate Malabsorption

Carbohydrates, which include lactose, fructose and sorbitol, are a major source of calorific intake in a typical diet (Born 2007). They are broken down by enzymes during their transit through to the small bowel where brush boarder enzymes will further convert them into monosaccharides to allow them to be absorbed and utilised (Drozdowski and Thomson 2006). There can be many reasons why the absorption process is affected, such as Coeliac and Crohn’s disease (Born 2007) and it is recognised that pelvic radiotherapy can also result in a reduced ability of the small bowel to perform this important function (Andreyev 2007). Stone et al (2003) recognises that the small intestine is particularly susceptible to late effects of radiation damage due to the “slow turnover within tissues that contain rapidly-proliferating cells” (p. 530). Carbohydrate malabsorption is generally diagnosed by breath testing, although less common methods include blood tests or biopsies of the small bowel mucosa. Management is to avoid, or at least reduce the amount of the particular carbohydrate and ideally this should be managed via a specialist dietician to prevent dietary deficiencies such as inadequate calcium (Andreyev 2007).

Pancreatic Insufficiency

Although the pancreas sits above the pelvic organs within the abdomen, in rare cases it may be subject to varying amounts of radiation during pelvic radiotherapy (Wydmanski et al 2016). The pancreas has both endocrine and exocrine functions with the exocrine part secreting enzymes to aid the process of digestion. Irradiation of the pancreas can affect this function (Andreyev et al 2005 and Mitchell et al 1979), so reducing the production of the enzymes and therefore the breakdown and absorption of nutrients including fats, which may then result in steatorrhoea- fatty, frothy stools which patients report can be difficult to flush away. Diagnosis is generally performed via measurement of faecal elastase in a stool sample and treatment is usually life-long replacement of the enzyme via supplementation (Andreyev et al 2005).

Appendix 3: Example of Coding/notes

(Interview 3, line numbers removed)

Wife: With the enemas we nearly got arrested at the airport, they had to take them away because when he was prescribed them we booked a holiday to Benidorm[1] so he had to take them because of course he couldn't stop taking them[2] and they're liquid as well so I said well we'll have to pack them so I said we'll put them all in a clear bag and he said well put the box in, I said no don't put the box in because your name and everything is on it that they'll know your name or your medical numbers[3] so I took them out of the box. Well of course in the airport they didn't know what they were did they because there was no prescription so, well they tested them with this, they tested them with that, oh my god[4]. **Resp**: In the airport, in the security and everybody is there[5] and they're all going and I had to explain what they were for and what I done with them. **Wife**: Oh he was mortified[6]. **Int:** So you're laughing now but

Wife: Oh he was terrible. **Resp**: At the time I wished there was a big hole and I just could have been swallowed up in it. **Wife**: and I felt terrible then because it was my fault really because I took the box. **Resp**: I said you never ripped the label off, saying it was mine and who prescribed them and what have you and she said oh there's no need for that and I wanted to strangle her[7].

Hospital/medical
Shame/embarrassment
Teamwork/togetherness
Conflict

---

[1] Trying to continue as normal by booking a holiday

[2] He had been told to take the enemas so was following instructions, even though this would cause him a problem

[3] Very concerned about his medical number/information- why? Is this an age/era concern/lack of trust

[4] Mortified that the enemas were tested for illegal drugs- such shame

[5] "Everybody is there"- public humiliation

[6] "Mortified"- again, shame, humiliation

[7] When he said this is glared at his wife, then they both laughed and held hand. Teamwork amongst humiliation

Appendix 4: Cardiff University Permission Letter

School of Healthcare Sciences Head of School and Dean Professor Heather Waterman

Ysgol Gwyddorau Gofal Iechyd

Pennaeth yr Ysgol a Yr Professor Heather Waterman

20 January 2016

Cardiff University Eastgate House 13th Floor 35 – 43 Newport Road Cardiff CF24 0AB

Tel Ffon: +44 (0)29 20 688559 Email E-bost HCAREEthics@cardiff.ac.uk

Prifysgol Caerdydd 13ed Llawr Ty Eastgate 35 – 43 Heol Casnewydd

Helen LudlowDept of Gastroenterology Uni of LlandoughCF64 2XX

Dear Ms Ludlow

Using a narrative analysis, what is the lived experience of people who have gastrointestinal symptoms following pelvic radiotherapy for pelvic cancers?

At its meeting of *19 January 2016,* the School's PGT Research Review and Ethics Screening Committee considered your research proposal.

The decision of the Committee is:

The Research Governance & Ethics Committee is unable to give approval to this application as it should be submitted for NHS Research Ethics approval.

The Committee has asked that the comments of the reviewer be passed onto you and your supervisor, please see below.

1. Social or scientific value; scientific design and conduct of the study e.g.

The impact of long-term radiation toxicities, from the patient's perspective – is an important area of scientific and clinical value. It is also an under-researched area. The study should generate information that is useful beyond raising awareness, to elucidate how the toxicities impact on the individual and cause distress/have a detrimental effect on QoL – this may be through individual symptoms or as a cluster of seemingly insignificant symptoms in combination. Particularly interesting findings could point to how physical symptoms relate to other experiential domains or psychosocial impacts. The chosen methodology and methods are interesting and appropriate. As someone who is not familiar with narrative methods, I wondered how problematic it is if the two people having the 'dialogue' have differing ontologies - as acknowledged in the methodological section.

2. Recruitment arrangements and access to health information and participant selection Reviewers comments/issues for discussion:

Caerdydd

CF24 0AB

The proposed recruitment procedures are fine. It wasn't clear if carers would be full participants or just invited to accompany the patient participant at interview.

In terms of the patient population, a number of related thoughts come to mind, which are presented purely for the applicants to consider.

1. The first paragraph of the Project Summary states that '*Prostate and bowel cancers were amongst the most common tumour sites and generally males and females were equally affected.*' which is rather misleading. Men with prostate cancer are likely to be a dominant grouping of the target population (lots of them, lots of radiotherapy and common toxicities), with slightly more male rectal cancers and more female colon cancers, plus a mixed group of gynaecological patients.

The mix of participants will be interesting, as the likelihood of toxicities will vary with site, with one big difference being that, say with prostate cancer, the target is not part of The GI tract, whereas with colon cancer it is. There will also be major specific life issues, such as female sterility.

Looking at the working title made me wonder if the focus of the project was (1) the impact of the GI symptoms on life or (2) what is life like for people who have GI symptoms. Even within the GI system there is a distinction between nauseas and vomiting and lower tract toxicity. Then there are multiple distinct symptoms for specific sites e.g. urinary and sexual function for prostate that may impinge on QoL. The effects of these may or may not be easy to separate out in terms of impact on QoL/distress. Other therapies e.g. chemotherapy sensitisation will also be in the mix.

The chronological point of recruitment is also of interest, given that sampling occurs at patient's first clinic attendance. The term early (acute) and late (chronic) have quite clear meanings and distinct pathological characteristics. Early effects may be expected to resolve within say 4-5 months, whereas chronic may be largely irreversible. There are also likely to be links between the two states. More pragmatically, someone three years post treatment is likely to have quite different life insights to one three months post treatment.

Another relevant phenomena may be that more extensive radiation fields – e.g. prostate and regional nodes – is likely to lead to greater small bowel damage, but will also signify a more advanced disease state/worse prognosis. At the extreme, are palliative patients likely to be included as well as curative intent?

3. Favourable risk benefit ratio; anticipated benefits/risks for research participants (present and future) e.g.

Reviewers comments/issues for discussion:

This is a low risk study, with no obvious benefits or risks to the individuals taking part. The benefits of the research will primarily be to the service and users of the service in the future.

4 Care and protection of research participants; respect for potential and enrolled research participants' welfare & dignity. Does the proposal and accompanying participant information sheets & consent forms consider:

*permitting withdrawal from the research * protecting privacy through confidentiality *informing participants of newly discovered risks or benefits * informing participants of results of research *maintaining welfare of participants *what will happen at the end of the study *provision of appropriate indemnity and insurance

Has the proposal outlined data protection & research participant's confidentiality?

Where and how (anonymised/coded) and for how long will data be stored?

What purpose will be served by the data?

Who will access?

Are research participants informed that access to their medical notes may be required?

Have arrangements been made to deal with incidental disclosure?

Has the Cardiff University guidance been acknowledged?

Reviewers comments/issues for discussion: The participant information is very clear. There seemed to be the possibility of a second interview, but the purpose of this was not addressed in the application. Whether interview data would be kept in an anonymised form was not totally clear, but should be easy to facilitate. The need to maintain a separation between the role of researcher and clinician is touched upon, and will need considerable thought and care to protect all parties. Research interviews are clearly different from clinical consultations. One related point is how aware research participants would be as to whether their medical information would be used in the research context. Measures to ensure rigour of methods and validity of findings will also be important.

5. Informed consent process and the adequacy and completeness of research participant information e.g.

Reviewers comments/issues for discussion:

The participant information are clear and comprehensive.

6. Suitability of the applicant and supporting staff e.g.

Comments/issues for discussion:

The applicant is very well placed to conduct this research. The support team is suitably qualified Risk assessment included, which outlines the safeguarding procedure for interviews within the host hospital and within the patient's home.

7. Suitability of supporting information **Comments/issues for discussion:**

Interview schedules will need to be developed for IRAS applications. Presumably, the narrative approach means that the interviews will be relatively unstructured (?)

Please do not hesitate to contact me if you have any questions. Yours sincerely

Mrs Liz Harmer – Griebel Research Administration Manager

cc : Tina Gambling Dikaois Sakellariou

Appendix 5: Health and Care Research Wales Permissions

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan
Lywodraeth Cymru
Funded by
Welsh Government

09 June 2016

Dr Tina Gambling School of Healthcare Sciences Eastgate House Newport Road Cardiff CF24 0AB

Dear Dr Gambling

Study title:

REC reference: Protocol number: IRAS project ID:

Using a narrative analysis, what is the lived experience of people (and their partners where appropriate) who have gastrointestinal symptoms following pelvic radiotherapy for pelvic cancer?

16/W A/0126 SPON 1501-16 201783

Gwasanaeth Moeseg Ymchwil Research Ethics Service

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the Senior Ethics Service Manager, Dr. Corinne Scott, corinne.scott@wales.nhs.uk.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Wales REC 3

Health and Care Research Support Centre Castlebridge 4 15-19 Cowbridge Road East Cardiff CF11 9AB

Telephone : 029 2078 5735 E-mail : corinne.scott@wales.nhs.uk Website : www.hra.nhs.uk

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Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
IRAS Checklist XML [Checklist_02062016]		02 June 2016
Letter from sponsor		12 March 2016
Other [Partner Consent]	1	16 May 2016
Other [Interview Schedule]	1	16 May 2016
Other [Consent tracked changes]		18 May 2016
Other [PIS V3 with tracked changes]	3	01 June 2016
Other [PIS V3 Ready to use]	3	01 June 2016
Other [PIS Partner V 2 tracked changes]	2	01 June 2016
Other [PIS Partner V2 Ready to use]	2	01 June 2016
Participant consent form	2	16 May 2016
REC Application Form [REC_Form_06042016]		06 April 2016
Research protocol or project proposal		12 March 2016
Summary CV for Chief Investigator (CI)		16 May 2016
Summary CV for student		12 March 2016
Summary CV for supervisor (student research)	1	11 March 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

The HRA reporting

Notifying substantial amendments Adding new sites and investigators Notification of serious breaches of the protocol Progress and safety reports Notifying the end of the study website also provides guidance on these topics, which is updated in the light of changes in requirements or procedures.

User Feedback

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

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at

http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project. Yours sincerely

Dr. Corinne ScottSenior Ethics Service Manager Health and Care Research Wales

pp Dr Pete Wall Chair

E-mail: corinne.scott@wales.nhs.uk Enclosures: "After ethical review – guidance for researchers" Copy to: Dr Tina Gambling

Mrs Louise Hesp, Cardiff & Vale UHB R&D Department

Appendix 6: Participant Information Sheet

What is the lived experience of people who have gastrointestinal symptoms following pelvic radiotherapy for pelvic cancers?

Version:	**3**
Date:	**01.06.2016**
Sponsor:	**Cardiff University**

I would like to invite you to take part in research interviews to learn more about the experiences of living with gastrointestinal effects of pelvic radiation for treatment of pelvic cancers. This includes both those who themselves who are experiencing such symptoms, and possibly interested partners who have lived through the experience with you.

This information sheet is in two parts:

Part One provides a summary of the research study and what will happen if you take part

Part two provides more detailed information about the study

If you have any questions about the study please contact using the details at the end of the information sheet.

Part One: Information about the research study

- The purpose of the study is to improve understanding of people's experiences of living with gastrointestinal symptoms after receiving pelvic radiotherapy for pelvic cancers. This includes both the person themselves and their partners, if applicable.
- There is currently a lack of awareness of what it is like for people to have these symptoms, although there is growing knowledge about the actual symptoms themselves.
- The research study aims to use the information it produces to inform other patients, the healthcare professionals treating them and to improve services for those affected.
- The research would involve hearing about your experiences using interviews, for me to learn more about your experiences of having gastrointestinal symptoms following pelvic radiotherapy for a pelvic cancer

Thank you for reading Part One.

If you may be interested in taking part in the study please read Part two before making any decision

Part two: additional information about the research study

My contact details are at the end of this information sheet. If you would like to take part please contact me to make arrangements

1. **What is the purpose of this study?**
   The University Hospital Llandough is currently the only Hospital in Wales providing dedicated assessment and treatment for people who have gastrointestinal symptoms after receiving pelvic radiotherapy treatment for pelvic cancers. Whereas the assessment and treatment aspects are improving, it is apparent that there is a lack of awareness of what it is actually like for people with these symptoms following their treatment, as well as for their partners. In order to improve the care available it is important that knowledge and understanding of people's experiences is increased.

2. **Why have I been asked to take part?**
   You have been invited to participate in the research study because you have been referred to the Pelvic Radiation disease Clinic due to having gastrointestinal symptoms following your pelvic radiotherapy treatment. I would like to talk to you about your experiences and that of your partner if possible- they are welcome to join you at the same interview. It is hoped that learning about your experiences will help to improve services in the future and raise awareness of the issues faced.

3. **What will I need to do if I take part?**
   I will talk to you about the study and answer any questions that you may have. If you agree, I will ask you to take part in one or two interviews at the time and place of your choice, either at the clinic or your home. One interview is likely to be more than adequate- you will be offered a second interview if you feel that you would like to take more time to tell me about your experiences. You will be asked to sign a consent form prior to the start of the first interview. After the information from the first interview has been analysed, I may need to contact you to ask you to be interviewed a second time if any further information is required.

4. **What will the interviews involve?**
   The interviews will each last around 30-60 minutes. I can either talk to you alone or you can have your partner there with you also, to help us understand their experiences too. The choice is yours if you would prefer to be interviewed alone

or together with your partner. Whoever takes part in the interviews will be asked to sign a consent form before we begin. I will ask you about your experiences of having gastrointestinal symptoms after receiving pelvic radiotherapy for a pelvic cancer. Whilst you are talking, I will make some notes and the conversation will be recorded on a small digital recorder. At the end of the interview I will check again that you are happy for the conversation to be included in the study.

5. **What are the possible benefits and disadvantages of taking part?**
   The interview will not alter your clinical treatment in any way and it is unlikely that the study will help you personally. There is no payment for taking part in the study. I hope however, that the results of the study will help to improve the future care for people with gastrointestinal symptoms after pelvic radiotherapy and those close to them.

6. **What if I do not wish to take part or change my mind?**
   You do not have to take part in the study if you do not want to. If you initially decide to take part and then change your mind at any time you are free to do so, without giving a reason. Your current or future clinical care will not be affected in any way. If you withdraw from the study after starting the interviews I would ask for your permission to use any information you had previously provided. If you do not agree to this then the recorded information and written notes would be destroyed and not included in the study.

7. **What if there is a problem?**
   If you have a concern about any aspect of this study please speak to myself, Helen Ludlow and I will do my best to answer any questions. If you remain unhappy and wish to make a formal complaint please contact:

   Dr Kate Button
   Director of Research and Governance
   Ty Dewi Sant
   Heath Park Campus
   Cardiff University
   Cardiff University CF14 4XN
   hcareresearch@cardiff.ac.uk

   In the very unlikely event that something goes wrong and you are harmed by taking part in this study, there are no special compensation arrangements. If you have any concerns about your medical treatment that have not been addressed by your medical team then you can go through the NHS Complaints process as usual.

   As previously discussed, the details that you tell me will be treated with the strictest confidentiality. However please be aware that if during the interview process you disclose any information that might relate to a risk of harm to yourself or to others, or you give details regarding misconduct or bad practice by a healthcare professional involved in your care, I am required by the Nursing and Midwifery Council Code of Conduct to refer the matter to a higher authority to investigate. If this is the case I will tell you.

8. **Will my taking part in this study be kept confidential?**
All information that is collected about you during the course of the study will be kept confidential. With your permission, the interview will be audio recorded and transcribed word for word. All personal information that could identify you will not
be used and the transcript will be anonymous. The consent form will ask permission to use extracts from the transcripts in both the study report and any future publication but will be totally anonymous.

Any information, including audio recordings and transcripts, will be stored in a safe place for up to 15 years and then destroyed, in accordance with the data protection Act 1998.

9. What will happen to the results of the study?

The results of the study will contribute to a Professional Doctorate programme of study and will also be presented at meetings and submitted for health journals for publication. You will not be identified in any way during the results dissemination, although some direct quotes may be used unless you specifically do not agree to this on that section of the consent form.

10. Who has reviewed this study?

Cardiff University School of Healthcare Sciences Research and Ethics Department, the University Research Governance Department and the Health and Care Research Wales Research Ethics Service (Wales REC 3) have reviewed this study.

11. Additional support available

I am aware that some people may become distressed when thinking/talking about difficult experiences. If you would like to talk to a professional about your feelings you may find the following points of contact helpful:

- Pelvic Radiation Disease Association www.prda.org.uk
- Tenovus Helpline 0808 808 1010
- I can also refer you to a Macmillan Psychologist if you prefer

If you would like to take part in this study please contact:

Helen Ludlow
Macmillan/TrueNth Senior Nurse for Late GI Effects of Pelvic Radiotherapy.
Department of Gastroenterology
University Hospital Llandough
Vale of Glamorgan
CF64 2XX
029 20715623
Helen.ludlow@wales.nhs.uk

Or if you have any further concerns please contact:
Dr John Green Consultant Gastroenterologist
Department of Gastroenterology
University Hospital Llandough
Penarth
CF64 2XX
029 20716811
john.green2@wales.nhs.uk

or

Dr Tina Gambling
Director of Post Graduate Research
School of Healthcare Sciences
Room 12
Eastgate House
35-34 Newport Road
Cardiff
CF24 0AB

Appendix 7: Partner Participant Information Sheet

What is the lived experience of people who have gastrointestinal symptoms following pelvic radiotherapy for pelvic cancers?

PARTNER INFOMATION

Version:	**2**
Date:	**01.06.2016**
Sponsor:	**Cardiff University**

I would like to invite you to take part in research interviews to learn more about the experiences of living with gastrointestinal effects of pelvic radiation for treatment of pelvic cancers. This includes both those who themselves who are experiencing such symptoms, and possibly interested partners who have lived through the experience with them.

This information sheet is in two parts:

Part One provides a summary of the research study and what will happen if you take part

Part two provides more detailed information about the study

If you have any questions about the study please contact using the details at the end of the information sheet.

Part One: Information about the research study

- The purpose of the study is to improve understanding of people's experiences of living with gastrointestinal symptoms after receiving pelvic radiotherapy for pelvic cancers. This includes both the person themselves and their partners, if applicable.

- There is currently a lack of awareness of what it is like for people to have these symptoms, although there is growing knowledge about the actual symptoms themselves.

- The research study aims to use the information it produces to inform other patients, the healthcare professionals treating them and to improve services for those affected.

- The research would involve hearing about your experiences using interviews, for me to learn more about your experiences of having gastrointestinal symptoms following pelvic radiotherapy for a pelvic cancer

Thank you for reading Part One.

If you may be interested in taking part in the study please read Part two before making any decision

Part two: additional information about the research study

My contact details are at the end of this information sheet. If you would like to take part please contact me to make arrangements

1. What is the purpose of this study?

The University Hospital Llandough is currently the only Hospital in Wales providing dedicated assessment and treatment for people who have gastrointestinal symptoms after receiving pelvic radiotherapy treatment for pelvic cancers. Whereas the assessment and treatment aspects are improving, it is apparent that there is a lack of awareness of what it is actually like for people with these symptoms following their treatment, as well as for their partners. In order to improve the care available it is important that knowledge and understanding of peoples experiences is increased.

2. Why have I been asked to take part?

You have been invited to participate in the research study because you are a partner of someone who has been referred to the Pelvic Radiation disease Clinic due to having gastrointestinal symptoms following your pelvic radiotherapy treatment. I would like to talk to you about your experiences and that of your partner if possible. It is hoped that learning about your experiences will help to improve services in the future and raise awareness of the issues faced.

3. What will I need to do if I take part?

I will talk to you about the study and answer any questions that you may have. If you agree, I will ask you to take part in one or two interviews at the time and place of your choice, either at the clinic or your home. One interview is likely to be more than adequate- you will be offered a second interview if you feel that you would like to take more time to tell me about your experiences. You will be asked to sign a consent form prior to the start of the first interview. After the information from the first interview has been analysed, I may need to contact you to ask you to be interviewed a second time if any further information is required.

4. What will the interviews involve?

The interviews will each last around 30-60 minutes. I can either talk to your partner alone, or if they would prefer for you to be present as well it would help us understand your experiences also. Whoever takes part in the interviews will be asked to sign a consent form before we begin. I will initially ask your partner about their experiences of having gastrointestinal symptoms after receiving pelvic radiotherapy for a pelvic cancer and if your partner agrees you are more than welcome to join in the conversation so I can hear about your experiences also. Whilst you and/or your partner are talking, I will make some notes and the conversation will be recorded on a small digital recorder. At the end of the interview I will check again that you are happy for the conversation to be included in the study.

5. What are the possible benefits and disadvantages of taking part?

The interview will not alter your partner’s clinical treatment in any way and it is unlikely that the study will help them or you personally. There is no payment for taking part in the study. I hope however, that the results of the study will help to improve the future care for people with gastrointestinal symptoms after pelvic radiotherapy and those close to them.

6. What if I do not wish to take part or change my mind?

You do not have to take part in the study if you do not want to. If you initially decide to take part and then change your mind at any time you are free to do so, without giving a reason. Your partner's current or future clinical care will not be affected in any way. If you withdraw from the study after starting the interviews I would ask for your permission to use any information you had previously provided. If you do not agree to this then the recorded information and written notes would be destroyed and not included in the study.

7. What if there is a problem?

If you have a concern about any aspect of this study please speak to myself, Helen Ludlow and I will do my best to answer any questions. If you remain unhappy and wish to make a formal complaint please contact:

Dr Kate Button
Director of Research Governance
Ty Dewi Sant
Heath Park Campus
Cardiff University
Cardiff University CF14 4XN
hcareresearch@cardiff.ac.uk

In the very unlikely event that something goes wrong and you are harmed by taking part in this study, there are no special compensation arrangements. If you have any concerns about your partners medical treatment that have not been addressed by your medical team then you can go through the NHS Complaints process as usual.

As previously discussed, the details that you and tell me will be treated with the strictest confidentiality. However, please be aware that if during the interview process you disclose any details regarding misconduct or bad practice by a healthcare professional involved in your partner's care, I am required by the Nursing and Midwifery Council Code of Conduct to refer the matter to a higher authority to investigate. If this is the case I will tell you.

8. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the study will be kept confidential. With your permission, the interview will be audio recorded and transcribed word for word. All personal information that could identify you will not be used and the transcript will be anonymous. The consent form will ask permission to use extracts from the transcripts in both the study report and any future publication but will be totally anonymous.

Any information, including audio recordings and transcripts, will be stored in a safe place for up to 15 years and then destroyed, in accordance with the data protection Act 1998.

9. What will happen to the results of the study?

The results of the study will contribute to a Professional Doctorate programme of study and will also be presented at meetings and submitted for health journals for publication. You will not be identified in any way during the results dissemination, although some direct quotes may be used unless you specifically do not agree to this on that section of the consent form.

10. Who has reviewed this study?

Cardiff University School of Healthcare Sciences Research Ethics Committee, the University Research Governance Department and the Health and Care Research Wales Research Ethics Service (Wales REC 3) have reviewed this study.

11. Additional support available

I am aware that some people may become distressed when thinking/talking about difficult experiences. If you would like to talk to a professional about your feelings you may find the following points of contact helpful:

- Pelvic Radiation Disease Association www.prda.org.uk
- Tenovus Helpline 0808 808 1010
- I can also refer you to a Macmillan Psychologist if you prefer

If you would like to take part in this study please contact:
Helen Ludlow
Macmillan/TrueNth Senior Nurse for Late GI Effects of Pelvic Radiotherapy.
Department of Gastroenterology
University Hospital Llandough
Vale of Glamorgan
CF64 2XX
029 20715623
Helen.ludlow@wales.nhs.uk

Or if you have any further concerns please contact:
Dr John Green Consultant Gastroenterologist
Department of Gastroenterology
University Hospital Llandough
Penarth
CF64 2XX

029 20716811
john.green2@wales.nhs.uk

or

Dr Tina Gambling
Director of Post Graduate Research
School of Healthcare Sciences
Room 12
Eastgate House
35-34 Newport Road
Cardiff
CF24 0AB

Appendix 8: Consent Form

CONSENT FORM

What is the lived experience of people who have gastrointestinal symptoms following pelvic radiotherapy for pelvic cancers?

Version: **3**

Date: **13.06.2016**

Sponsor: **Cardiff University**

Participant name:

Participant Study Number:

Please read the following and if you agree with the statement write your initial on the line:

1. I confirm that I have read and understood the Participant Information Sheet (Version 1, date….) I have had the opportunity to consider the information and ask questions which have been answered to my satisfaction ___________

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected ___________

3. I give permission for direct quotes taken from the interviewed to be used in any publication of findings or presentations Yes / No

   I understand that any identifiable personal information (such as my name) will only be written on the consent form otherwise a number will be used to identify the different participants Yes / No

   I understand that the interview will be audio-recorded and I give my permission for this Yes / No

   ____

4. I consent to the storage of personal information, including electronic, for the purposes of this study. I understand that any information that could identify me (such as my name on the consent Form) will be kept strictly confidential and that no personal information will be included in the study report or other publications

   ____

_______________	__________	_______________
Name of participant	Date	Signature
_______________	__________	_______________
Name of person taking consent	Date	Signature

1 for participant; 1 for Site File; 1 to be kept with hospital notes

Appendix 9: Partner Consent Form

PARTNER CONSENT FORM

What is the lived experience of people who have gastrointestinal symptoms following pelvic radiotherapy for pelvic cancers?

Version: **1**

Date: **18.05.2016**

Sponsor: **Cardiff University**

Participant name:

Participant Study Number:

Please read the following and if you agree with the statement write your initial on the line:

1. I confirm that I have read and understood the Participant Information Sheet (Version 1, date….) I have had the opportunity to consider the information and ask questions which have been answered to my satisfaction ___________

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected __________

3. I give permission for direct quotes taken from the interviewed to be used in any publication of findings or presentations Yes / No

   I understand that none of my personal information will be identifiable Yes / No

   I understand that the interview will be audio-recorded and I give my permission for this
   Yes / No

   ____

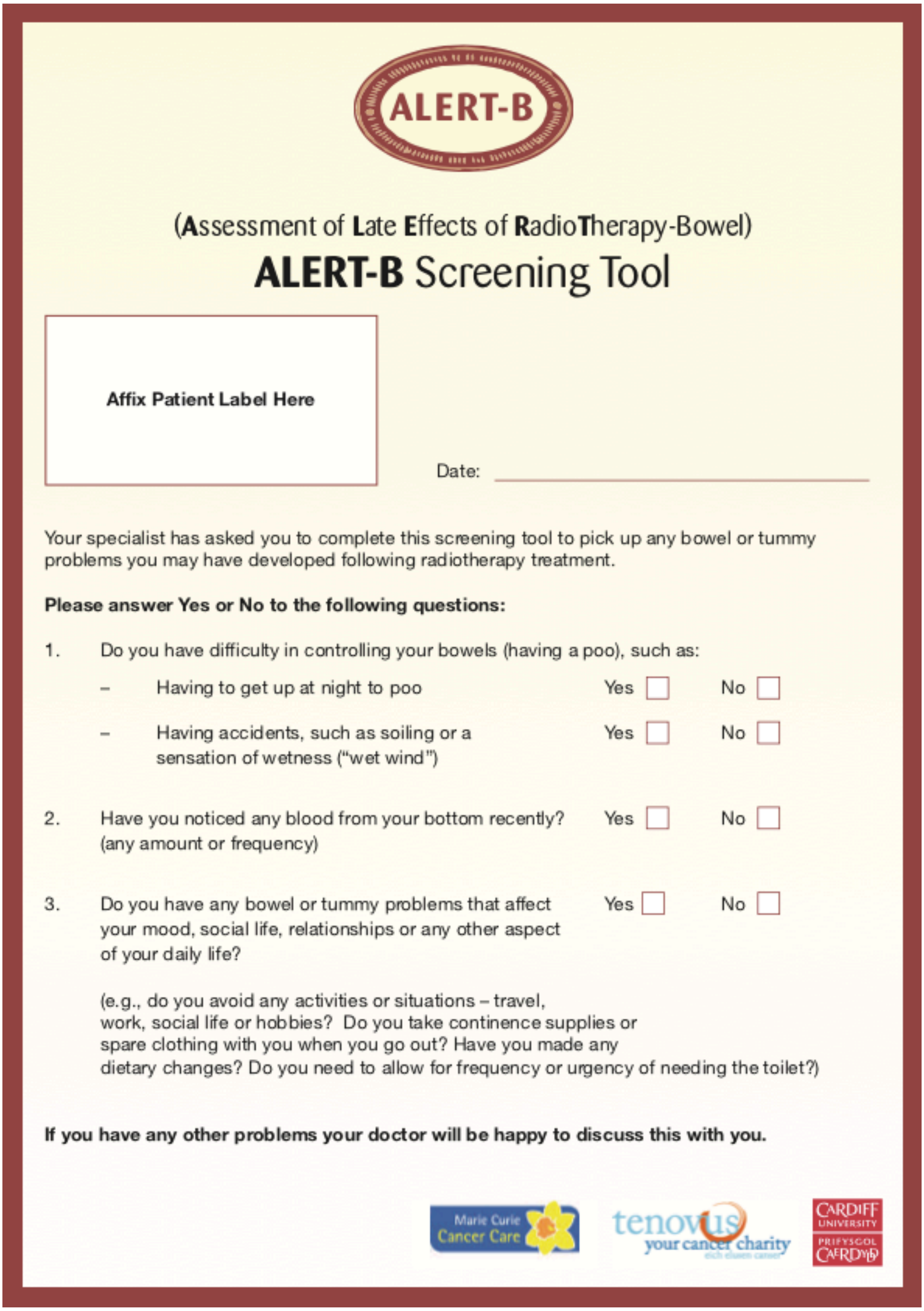
4. I consent to the storage of personal information, including electronic, for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publications

   ____

_______________	__________	_______________
Name of participant	Date	Signature
_______________	__________	_______________
Name of person taking consent	Date	Signature

1 for participant; 1 for Site File; 1 to be kept with hospital notes

Appendix 10: Alert-B Screen Tool Form



ALERT-B

(Assessment of Late Effects of RadioTherapy-Bowel)

ALERT-B Screening Tool

Affix Patient Label Here

Date: ______________________

Your specialist has asked you to complete this screening tool to pick up any bowel or tummy problems you may have developed following radiotherapy treatment.

Please answer Yes or No to the following questions:

1. Do you have difficulty in controlling your bowels (having a poo), such as:
   - Having to get up at night to poo — Yes ☐ No ☐
   - Having accidents, such as soiling or a sensation of wetness ("wet wind") — Yes ☐ No ☐

2. Have you noticed any blood from your bottom recently? (any amount or frequency) — Yes ☐ No ☐

3. Do you have any bowel or tummy problems that affect your mood, social life, relationships or any other aspect of your daily life? — Yes ☐ No ☐

   (e.g., do you avoid any activities or situations – travel, work, social life or hobbies? Do you take continence supplies or spare clothing with you when you go out? Have you made any dietary changes? Do you need to allow for frequency or urgency of needing the toilet?)

If you have any other problems your doctor will be happy to discuss this with you.