Optimising the care of patients receiving oral systemic anti-cancer treatments: a mixed methods study

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"You beat cancer by how you live, why you live and in the manner in which you live."

Stuart Scott

Abstract

Background: The use of oral systemic anti-cancer treatment (SACT) has increased significantly in recent decades. Patient experience of receiving these treatments is relatively unknown and under-reported. In response to national recommendations and the National Patient Safety alert (2008) regarding the safe care of patients receiving an oral SACT, a local cancer centre implemented a joint nurse- and pharmacist-led oral education clinic (OEC) to educate patients on how to manage their oral SACT and care at home.

Aim: To explore the experiences and views of patients receiving oral SACT to inform models of care.

Methodology: An applied health research study using a mixed-methods approach was conducted. The study included a questionnaire survey distributed to patients who attended the OEC, and a second questionnaire posted 6 weeks later. Descriptive statistics were used to analyse results from the 84 respondents. Semi-structured interviews were conducted with a sub-sample of 28 questionnaire respondents and with 23 health professionals, which were analysed using Framework (Ritchie and Spencer, 1994). Integration of data sets was achieved through 'Following a Thread' (Moran-Ellis *et al*, 2006).

Results: Patients held strong beliefs about the importance of taking their oral SACT medication, and preferred oral to intravenous administration. Patients were satisfied with the OEC, but some identified a lack of information on treatment efficacy and living well with cancer. No preference was reported regarding SACT nurse or cancer pharmacist delivered education. The idea of telephone follow-up was welcomed by most study participants; patient experience of side effects suggests this would be best placed within the first and second week of commencing oral SACT. All patients established a routine in taking their medication, which contributed to high levels of adherence. Instances of non-adherence were unintentional and attributed to forgetfulness. A typology of activation to self-manage was identified highlighting that some patients were activated to self-manage their care whilst others required enhanced support. Health professionals regarded the OEC as an effective means to prepare a patient to commence oral SACT, but identified some organisational barriers to delivering the care they perceived patients required.

Conclusion: Patients receiving an oral SACT benefit from education about their treatment, when delivered by an experienced SACT nurse or cancer pharmacist. The OEC was well received by both patients and health professionals, but findings highlight the importance of a more person-centred approach to optimise patient experience and outcomes following prescription of oral SACT.

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Abbreviations

BMQ: Beliefs about Medicines Questionnaire

CML: Chronic Myeloid Leukaemia

CLL: Chronic Lymphocytic Leukaemia

CTSQ: Cancer Therapy Satisfaction Questionnaire

DTU: Day treatment unit

GIST: Gastro-Intestinal Stromal Tumour

HCAH: Healthcare at Home Ltd.

IV: Intravenous

MCL: Mantle Cell Lymphoma

MM: Multiple Myeloma

MMAS-8: Morisky Medication Adherence Scale -8

NMP: Non-medical prescriber

OEC: Oral Education Clinic

PCN: Person-Centred Nursing

PWC: People With Cancer

SACT: Systemic Anti-Cancer Treatment

SIMS: Satisfaction with Information about Medicines Scale

SLR: Systematic Literature Review

SOP: Standard Operating Procedure

SPSS: Statistical Package for the Social Sciences®

RCC: Renal Cell Carcinoma

TFU: Telephone Follow-Up

TRT: Treatment Related Toxicity

Commonly used terms

Adherence: this term is used widely in the published literature and refers to the process of taking a treatment exactly as prescribed. Similarly, non-adherence refers to an incidence where an individual does not take their treatment as prescribed.

Adverse outcome: this refers to any event where an individual has an unsafe experience of treatment such as the experience of a side effect which resulted in a hospital admission, or an instance where treatment is not taken safely or as prescribed.

Clinically significant: this term is used in the context of discussing quantitative data, where statistical testing has demonstrated no statistical significance, but the data itself is significant for clinical practice e.g. a small number of patients not taking their oral SACT, statistically not significant, but clinically an important finding.

Co-morbidities: refers to any other medical conditions an individual has alongside a diagnosis of cancer e.g. a diagnosis of diabetes.

Non-adherence: refers to an instance where treatment is not taken as prescribed or directed e.g. forgetting to take a dose at the prescribed daily time.

Oral Education Clinic (OEC): this refers to an intervention by the study site where people with cancer (PWC) receiving an oral SACT attend an appointment, delivered face to face or by telephone, facilitated by a pharmacist or a specialist nurse, to receive education on all aspects of safe oral SACT administration and management.

People with cancer: for the purpose of this thesis, use of the term 'patient' has been minimised and its use restricted to identify the type of participant being referred to, in order to adhere to a holistic view of individuals accessing healthcare in an outpatient setting. Often in published literature, there has been a move from referring to people as patients, rather using the term 'people affected by cancer'. As an individual's family member will also be affected by cancer, I have selected the term people with cancer (PWC) to clarify that this refers specifically to the individual diagnosed with, and receiving treatment for, cancer.

OEC facilitator: this refers to either a pharmacist or a specialist nurse who facilitates and delivers the education at the OEC.

Treatment related toxicity: the experience of a side effect directly resulting from the administration of a treatment e.g. nausea and vomiting caused by a cytotoxic agent.

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Chapter One: Introduction

1.1 Chapter outline

The following chapter will provide the reader with an overview of the context of this PhD study. An introduction to cancer, its incidence, biology and treatments will be presented with a focus on oral systemic anti-cancer treatment (SACT), alongside consideration of current National Health Service (NHS) policy. The response of an NHS Foundation Trust to patients taking oral SACT will be described, and the clinical context within which this study sits, presented.

The research questions used to guide this study will be stated and a brief overview of the thesis structure provided.

1.2 Cancer incidence and biology

Globally, cancer poses a significant health-care problem. In 2015, within the United Kingdom, 359,960 people were given a new diagnosis of cancer (Cancer Research UK, 2018). Worldwide, in 2012 there were 14.1 million new cancer cases and 8.2 million deaths attributed to cancer (International Agency for Research on Cancer, 2016). As access to healthcare and diagnostic investigations improve, this figure is likely to increase.

Cancer has been described as a disorder of altered cell differentiation and growth (Porth, 2007). Developing cancer cells have unique characteristics, whereby proliferation is unregulated and uncontrolled. Hanahan and Weinberg (2011) refer to many characteristics or hallmarks of cancer development, including abilities of the cells to evade growth suppressors, resist cell death and sustain proliferative signalling.

As the cancer cells continue to grow, they form a tumour, often referred to as a neoplasm. Malignant neoplastic cells have an ability to invade surrounding tissues, such as blood vessels or the lymphatic system, and subsequently spread to distant sites of the body (Colledge, Walker and Ralston, 2010). The impact of continued growth and metastatic spread of the malignant neoplasm on the body's vital organ function ultimately results in death if the disease cannot be treated or cured.

The term cancer should be considered similar to an umbrella term referring not to one disease, but rather to numerous different diseases sharing similar characteristics. A patient with acute myeloid

leukaemia, a patient with melanoma and a patient with Ewing's Sarcoma, all have cancer, yet different diseases and consequently, different treatments and different prognostic outcomes.

1.3 Systemic Anti-Cancer Treatment (SACT)

Historically, the treatment of cancer was dominated by surgery and radiotherapy until the mid-1960s when new data suggested that combination chemotherapy was more effective (DeVita and Chu, 2008). The term 'chemotherapy' refers to the use of chemicals to treat disease and was coined by a German chemist Paul Ehrlich (Kaufmann, 2008). While the term remains widely used in healthcare, within the context of this thesis, the term 'systemic anti-cancer treatment' (SACT) will be used, a definition in keeping with the British National Formulary (British National Formulae, 2017), British Oncology Pharmacy Association (BOPA, 2004) and the National Institute for Clinical Excellence (Department of Health, 2014). SACT refers to a treatment that can interact with cancer irrespective of where it is in the body, with an exception of central nervous system malignancies, where the blood-brain barrier impedes the transfer of large molecules, such as SACT, to the brain (Dwibhashyam and Nagappa, 2008).

SACT encompasses several types of drugs: chemical cytotoxic agents traditionally referred to as chemotherapy, but also biological agents and targeted cytostatic agents (small molecule kinase inhibitors). The term SACT does not encompass anti-endocrine hormone therapies or selective oestrogen receptor modifying agents, such as tamoxifen or aromatase inhibitors (BNF, 2017).

Mortality in people with solid tumours (in most cases) is due to metastatic disease; the exception being advanced localised vital organ tumours. Localised treatment with surgery or radiotherapy alone may eradicate the body of all cancer cells; therefore, adjuvant systemic anti-cancer treatment will be considered for people with clinical metastases or suspected micro-metastatic disease (Watson *et al.*, 2006). SACT can be used for a curative intent where the goal of treatment is to cure the cancer; as an adjuvant treatment whereby the SACT follows a primary treatment, such as surgery or radiotherapy; or as a neoadjuvant treatment where the SACT precedes primary treatment to reduce tumour bulk and down-stage the disease and reduce the risk of seeding occult micro-metastases (Yarbro *et al.*, 2011). SACT is also the standard treatment approach for people who have disseminated malignant disease, such as leukaemia.

The mechanism of action of SACT will vary depending on the specific type of agent used. Cytotoxic drugs for example work by directly or indirectly disrupting the cell growth and division cycle preventing protein synthesis, damaging the DNA and/or damaging the mitotic spindle, resulting in programmed cell death by apoptosis (Birner, 2003a). Further, as cytotoxic chemotherapeutic agents

exert a more significant effect on cells with a high rate of proliferation, since those tumours are more likely to have cells in the cell cycle at the time of treatment, cells in a cancerous tumour are more likely to be killed by cytotoxic drugs than cells in healthy tissues (Watson, *et al.*, 2006).

Despite this, cytotoxic treatments are non-targeted and non-specific by nature, resulting in damage to cells other than cancer cells that happen to be progressing through the cell cycle at the time of treatment administration. This is why cytotoxic drugs are commonly given in treatment cycles, to enable healthy tissues to repair and replace dead and damaged cells prior to the next treatment cycle, which limits the overall toxicity.

An important development in the history of SACT is that of targeted therapies, which includes biological therapies e.g. monoclonal antibodies and immune cell therapies and small molecule inhibitory drugs. Small molecule inhibitory drugs often come in oral formulations and are prescribed as daily doses. They have anti-cancer effects by inhibiting enzymes or targeting proteins required to regulate cell growth, thus they inhibit growth cell signalling and prevent initiation of the cell growth and division cycle (Mohamed *et al.*, 2013).

1.3.1 Toxicities of SACT

Similarly, to cancer cells in rapidly growing tumours, cytotoxic drugs effectively kill cells in tissues with a high growth fraction (Birner, 2003a) including: epithelial cells, such as skin cells, hair follicles, mucosal cells that line the gastro-intestinal (GI) and respiratory tracts; and bone marrow haemopoietic stem cells; and germ cells. It is, therefore, common for patients receiving SACT to develop multiple GI toxicities, or side effects, such as nausea, vomiting, mucositis, and diarrhoea.

Erythrocytes (red blood cells) and lymphocytes (white blood cells) are produced in the bone marrow from haemopoietic stem cells. Depending on the haemopoietic cell lineage, blood cells mature at different sites of the body including the bone marrow and thymus. As the bone marrow stem cells and differentiating blood cells have a high growth fraction, they are killed by cytotoxic drugs, so the concentration of blood cells in circulating blood plasma significantly decreases, which is referred to as myelosuppression (Porth, 2007). This results in fatigue, anaemia, thrombocytopenia, and leucopenia – but most notably neutropenia.

Neutropenia is the reduction of a type of white blood cell, the neutrophil, to a concentration of <1.0 x109 cells/litre blood. Neutrophils are the major cell that provides non-specific immunity; therefore, neutropenia significantly increases a person's susceptibility to opportunistic infections. If a person with neutropenia develops a localised infection they can develop systemic neutropenic sepsis and if this is not treated as a medical emergency with broad spectrum IV-antibiotics, they could develop

septic shock, which is a life-threatening condition (National Institute for Health and Clinical Excellence (NICE), 2012). Strategic and careful monitoring of side effects, combined with the ability to manage or dose-reduce treatments early to avoid higher grade side effects is imperative (Barton, 2011).

The different mechanisms of action that different SACTs have means that the side effects also differ. A common type of targeted therapy used is an epidermal growth factor receptor – tyrosine kinase inhibitor (EGFR-TKI), for example erlotinib used in the treatment of EGFR-mutant positive non-small cell lung cancer (NSCLC). EGFR is a receptor found on the surface of most cells. It is highly-overexpressed in many tumours (Harari, 2008). EGFR mutations cause constitutive activation of the tyrosine kinase in the receptors cytoplasmic dome, which enables the cell to avoid apoptosis, and triggers various cellular events leading to cell proliferation, survival and angiogenesis (Gridelli *et al.*, 2007). EGFR is, however, also present in high numbers of cells forming the basal layer of the epidermis of the skin, so inhibition results in impaired cell growth, migration of keratinocytes and inflammatory chemokine expression (Lacoutoure and Melosky, 2007). Clinically, this results in the patient presenting with multiple skin toxicities like acneiform rash, pruritus and paronychia (Kiyohara *et al.*, 2013). Treatment related toxicity of oral targeted therapies varies depending on the drug, and while some common toxicities can be avoided others cannot (Bhattacharyya, 2010).

1.3.2 SACT Administration

SACT has traditionally been administered intravenously (IV) (O'Neill and Twelves, 2002). IV treatments are usually administered in a hospital outpatient or inpatient setting. IV access is gained by the insertion of a cannula either into a peripheral vein or a permanently inserted central venous catheter. SACT treatments are then administered by specialist trained nursing staff. SACT nurses have a substantial role in managing the treatment and care of patients receiving SACT (Roe and Lennan, 2014) and typically prior to any administration carry out pre-treatment assessment including: blood tests, review of current side effects or medical issues and administer pre-medications.

Treatment administration in the hospital setting provides opportunity for patients to receive education regarding treatments as health professionals are available to answer potential questions from patients (Moore, 2007), and regulate clinical governance for safe administration (Bedell, 2003; Department of Health, 2014; Komatsu, Yagasaki, and Yoshimura, 2014). Such governance is essential to protect not only the patient, but also the health professional and the environment. In some cases, the IV SACT might be delivered over a relatively short period of time, such as docetaxel that can be delivered within an hour; however some treatments, such as platinum agents, can be

burdensome as they require longer administration with multiple pre- and post-infusion medicines, which might take over 6 hours'. The result for the patient can be numerous and lengthy treatment visits, increased risk of infection and thrombosis from invasive devices, risk of extravasation injury from cytotoxic drugs, and other adverse treatment experiences associated with IV chemotherapy administration.

1.4 Oral SACT

The first oral SACT used was chlorambucil in 1951 (Rai *et al.*, 2001) followed by melphalan, busulfan and methotrexate (Bedell, 2003). In recent decades, there has been a significant increase in the availability of SACT administered orally, as a tablet or capsule (Mancini and Wilson, 2012). Some of these medications have substituted an IV medication, and in other instances the oral SACT is used in combination with IV therapy (So, 2010). The availability of oral SACT to patients is likely to increase as pharmaceutical developments continue (Weingart *et al.*, 2008).

Oral treatments have proved to be as effective as their parenteral counterparts (von Pawel *et al.*, 2001; O'Shaughnessy *et al.*, 2002) and in some instances more effective, as in the case of treatment of chronic myeloid leukaemia with oral imatinib compared to parenteral cytarabine and interferon (O'Brien *et al.*, 2003). Patients prefer oral SACT that has equivocal treatment efficacy to IV SACT and report that oral SACT provides an increased sense of control of their treatment in comparison to IV SACT (Liu *et al.*, 1997; Twelves *et al.*, 2006).

As stated previously, the term SACT does not encompass anti-endocrine hormone therapies or selective oestrogen receptor modifying agents (BNF, 2017) however as this study will highlight, there is a limited body of knowledge regarding the experience of individuals receiving oral SACT. In the context of this study therefore, oral SACT will refer to any medication taken orally to treat cancer.

1.4.1 Advantages and disadvantages

There are significant advantages to oral SACT (Williamson, 2008). Oral administration enables prolonged drug exposure and daily administration schedules are relatively-well tolerated, such as anti-angiogenic drug regimens (O'Neill and Twelves, 2002). Treatment can largely take place in the patient's own home, preventing regular hospital visits and increasing a sense of independence and control (Liu *et al.*, 1997; Bedell, 2003;). Receiving treatments at home is arguably advantageous and in keeping with recommendations from the UK Cancer Reform Strategy (Department of Health, 2007), which recommends that people with cancer (PWC) should receive the care they require in the most appropriate setting. The patient also avoids the painful process of cannulation while the risks

of extravasation and infusion related complications are non-existent (Hartigan, 2003; Halfdanarson and Jatoi, 2010). When the advantages of oral SACT are considered in their entirety, it is clear to see why PWC report such convenience and an improved quality of life (Segal *et al.*, 2014), most preferring oral therapy to IV administration (Fallowfield *et al.*, 2006).

It is, however, essential to acknowledge the disadvantages of oral SACT. PWC receiving and oral SACT are significantly distanced from healthcare providers and have reduced clinical contact (Birner, 2003b; Hartigan, 2003). Some PWC perceive IV therapy to be more effective (Findlay, von Minckwitz, and Wardley, 2008), but there is also a misconception that oral treatments result in fewer side effects (Bedell, 2003) whilst in reality, in some regimens the side effects may be more severe (Halfdanarson and Jatoi, 2010). Furthermore, the regimen itself and dosages of the drug(s) can be complex, with complicated dosing schedules (timings and changes of dose from day to day) resulting in issues with adherence (Given, Spoelstra, and Grant, 2011). Some PWC have also commented a preference toward IV therapy, because IV SACT is given intermittently so they can achieve periods of forgetting about cancer and its treatment between treatment cycles (Mancini and Wilson, 2012). A further consideration to note is that for some PWC, depending on stage or type of cancer or other co-morbidities, may have swallowing difficulties. In a study of 669 patients with advanced cancer, 15.4% of patients presented with dysphagia (Mercadente *et al.*, 2015). Such swallowing problems would be assessed by the prescriber or lead consultant prior to the allocation of treatment; however symptoms may develop after diagnosis or once treatment has commenced, resulting in difficulty in swallowing oral SACT. Oral SACT may also be difficult to swallow, as the capsules and tablets are often large and high in the number required per dose.

1.4.2 Pharmacology and adherence

It is also essential to consider the pharmacological activity of treatment. When drugs are taken orally, they are metabolised prior to systemic circulation, resulting in a significant decrease in the blood serum drug concentration, which might not reach a therapeutic dose (Thanki *et al.*, 2013). Secondary to uncertainty about bioavailability within an individual, IV administration was traditionally preferred as it was possible for healthcare providers to control and record the exact dose administered (Conde-Estevez, Salas, and Albanell, 2013). Oral SACT are often referred to as having a narrow therapeutic index, as capsules or tablets have fixed doses; thus the difference between therapeutic dose and the administered dose might result in low bioavailability, decreasing efficacy, or excessive bioavailability resulting in significant toxicities (Neuss *et al.*, 2013). Within this context, adherence and correct administration of the medication are paramount.

Predictions indicate adherence to oral SACT is poorer than that of their intravenous counterparts (Weingart, *et al.*, 2008). Under-adherence to oral SACT has been reported in 20% to 80% of people (Spoelstra and Given, 2011), while over adherence has also been reported (Mayer *et al.*, 2009). It has been proposed that in order to maintain effective, optimum therapeutic dosage, a multidisciplinary approach is required (Vioral *et al.*, 2014).

1.5 Health policy and oral SACT governance

The British Oncology Pharmacy Association (BOPA, 2004) published recommendations about the safe care of patients receiving oral anticancer therapy. The recommendations detail the requirements of a lead oncologist and the support of a health care Trust with relevant policies and procedures in place. They provide guidance on the prescribing, dispensing and labelling of oral SACT, and patient education and information, which should be given by a specialist pharmacist or nurse before commencement of treatment.

In 2008, the National Patient Safety Agency (NPSA, 2008) released a statement highlighting the risks associated with oral SACT. The document detailed the report of three deaths and four hundred safety incidents between November 2003 and July 2007 attributable to the mismanagement of patients receiving oral SACT - namely incorrect dosage, frequency, quantity and duration. There is also likelihood of a substantial number of unreported incidents. Immediate policy changes were actioned within the NHS whereby the treatment of PWC receiving oral SACT was to be held in the same regard, and using the same standards of practice as that for people receiving IV therapy in relation to prescribing, dispensing and administration.

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) (Mort *et al.*, 2008) analysed the care given to patients receiving SACT in 2006 over two months and found only 35% of cases were judged to have been given good care, with 8% of patients receiving less than satisfactory care. Specific to oral SACT, there were examples when oral SACT had been given to a patient who had severe dysphagia, but also while IV chemotherapy was commonly prescribed on pre-printed prescriptions, oral treatments were not. In addition to highlighting several areas for improvement with regard to oral SACT practice, this report demonstrated that the therapy is associated with as much clinical risk as parenteral treatment, if not more.

The National Chemotherapy Advisory Group Report (NCAG, 2009) aimed to ensure quality and safety in chemotherapy services in England. The report recommended that, *"[…] each chemotherapy service should ensure that exactly the same process of care is used for oral chemotherapy as in the case for parenteral chemotherapy"* (National Chemotherapy Advisory Group NCAG, 2009, P. 24).

This recommendation has been echoed by standards in The Manual for Cancer Services (NHS Improving Quality, 2014).

The NCEPOD (2008) and NPSA (2008) (Mort, *et al.*, 2008; NPSA, 2008) reports were shortly followed by a position statement from the United Kingdom Oncology Nursing Society (UKONS) (Oakley *et al.*, 2010) detailing their recommendations for practice. UKONS outlined their position on safe practice including prescribing, consent, monitoring and follow-up, while placing an emphasis on patient education and information. An individually-tailored consultation was advocated. Here patients would have a consultation that spoke directly to their needs as individuals concerning their knowledge, perception and psychological status in enabling self-management of their treatment. They further comment that staff involved with the consultation should rehearse with the patient the information given, to ensure maximum learning retention, a recommendation in keeping with the Multination Association for Supportive Care in Cancer (MASCC) oral agent teaching tool (MOATT) (Kav *et al.*, 2010) while giving written, oral and pictorial advice.

Similarly, recommendations for providing care to PWC receiving oral SACT have been published by the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) (Neuss, *et al.*, 2013). A multi-stakeholder group met in 2011 to address the practice and use of oral SACT under the leadership of ASCO/ONS. Together they recommended standards that were approved after public critique. The standards specifically address all aspects of oral SACT including planning, dispensing, patient education, administration, monitoring and follow up.

While an array of recommendations are available specifically addressing oral SACT, the Chemotherapy Patient Experience Survey (Quality Health, 2014, P. 4) - a survey run within the context of the NHS in 2013 – commented:

> *"[…] there appears to be a difference between the care accompanying intravenous versus oral chemotherapy in that patients receiving intravenous treatment were more likely to be offered a written treatment plan and information, a discussion as to side-effects and information concerning the telephone information service."*

1.6 Patient education

To achieve optimal benefit from oral SACT, its administration requires continued patient monitoring and service improvement to ensure safety. One strategy to ensure best practice is the provision of patient education (Hartigan, 2003; Halfdanarson and Jatoi, 2010). Following the conduct of an international survey of patients receiving oral SACT, Kav and colleagues (2008) highlighted that the

amount and quality of patient education directly affected the way the patient took their treatment. Information plays an essential role in helping individuals make informed decisions (McPherson, Higginson and Hearn, 2001); thus not only has a role in safe treatments, but also in informed consent. With correct information, it is possible to improve outcomes by adopting a preventative approach, for example PWC having the knowledge of when and how to react to events.

Prior to commencing treatment of an oral SACT, PWC must be given a great deal of information. The structure and delivery of that information is dependent on the patient and provider. Guidelines produced by BOPA (2004) may facilitate the delivery of education. An applied practice-based example of this information can be found below:

Patients should be told how and when to take their medicines i.e. take your medicine on an empty stomach in the morning at least one hour before eating and one hour after eating with a 200ml glass of water. If a dose is missed, and within 6 hours of when the dose should have been scheduled (assuming once a day administration), it would still be ok to take, but if longer than 6 hours, then wait until the next day to resume the schedule. It is vital in this instance, not to take a double dose the next day but only take as prescribed. If a patient was to vomit after taking their medicine, and this is shortly after ingestion where the medicine can be seen intact, then the patient may take it again when their nausea or vomiting has settled. If the medicine cannot be seen or is not intact, the patient should not take another dose. Clothes that have been stained with vomit must be washed in a 90-degree wash with laundry detergent. Care must be taken when handling vomit as the oral SACT may be dangerous if in contact with other persons. Any skin contact should be washed immediately with warm soapy water and monitored for any signs of redness or irritation – if such happens, contact must be made with the individual's hospital oncology team as soon as possible for advice.

A list of expected adverse events, including severity and how to manage these, should be explained to the patient. For example, in the case of capecitabine, the possibility of diarrhoea and what to do if a PWC gets diarrhoea should do needs to be discussed. People with cancer should, keep hydrated ensuring consumption of at least two litres of water per day, and if diarrhoea occurs more than four times than their usual number of stools in 24 hours, then they should contact the hospital as soon as possible. It should be explained to the individual when they will return for review at the hospital, how and when they will get a new supply of the medication and the role of their GP. Oral SACT must also be handled safely. It should be stored out of reach from children, kept in its original packaging and all direct handling avoided. A non-touch technique should be used to dispense the medications i.e. into a plastic pot, or into a disposable gloved hand. In the event that the patient cannot dispense their own medication, the person administering the medicine must use the same precautions. If

medicine spoons or pots are used, these are for once only use and should be disposed of for incineration after use. This activity should be followed by thorough handwashing. Emergency contact telephone numbers should be provided to the patient, along with the number for the chemotherapy unit (if different). Patients should be reassured to contact the hospital team in the eventuality of any concern or question.

It is recommended the above information be given in its entirety at the first pre-treatment visit and reinforced at subsequent opportunities. Further, hospital Trusts should not rely on BOPA guidance alone, but rather use as a template to include in their own clinical governance policies and procedures (Williamson, 2008). Similar guidelines from UKONS (Oakley *et al.*, 2010) have been produced that include further points, such as education regarding possible interactions with other drugs, advice on the provision of written material and regarding side effects, symptoms that can be managed at home, and when hospital contact should be made.

The delivery of education about oral SACT can vary, but should always be individually-tailored to the patients' needs (Oakley, Johnson, and Ream, 2010). In practice, education for patients receiving IV therapies is an ongoing process and is embedded across the patient pathway (Macmillan Cancer Support, 2012). Designated oral SACT clinics aim to provide care to PWC prescribed oral SACT to help them manage the complexities associated with administration and ongoing treatment, such as side effect management (Neuss, *et al.*, 2013). Health professionals should be aware of the impact a cancer diagnosis has on an individual's psychological function, which might affect an individual's ability to both understand and or retain information (Schumacher *et al.*, 2013).

1.7 Current practice in managing patients taking oral SACT

A survey of 557 oncology nurses in outpatient settings in the United States highlighted that oral SACT practices raise safety concerns (Roop and Wu, 2014); throughout the country oral SACT administration practice varied, with only 51% of the practices surveyed having specific policies and procedures to manage oral SACT. Within the UK, no national survey has yet been completed to identify oral SACT practices; however Williamson (2008) reported a survey of 56 cancer pharmacists that had a response rate of 52%. All respondents expressed a keen interest in being involved in oral SACT management, but the survey also highlighted a need for specific standards and the findings supported the NPSA safety alert (NPSA, 2008).

In the UK, the 'Manual for Cancer Services Chemotherapy Measures' governs practice (Department of Health, 2014) and recommendations on practice from BOPA (2004) and UKONS (2010) guide practice in the administration principles for oral SACT. Despite an array of published health policy

surrounding the care of patients taking oral SACT, no benchmarking standards have been recommended. Guidance from the NCAG (2009) detail PWC should receive the same process of care when taking an oral SACT as compared to patients receiving an intravenous (IV) SACT. While this guideline is clear, healthcare systems need to provide the same process of care to patients receiving very different treatments and address the challenges previously discussed for PWC receiving oral SACT. With variance in models of care, there is a need to identify what method should be regarded as best practice in terms of patient experience and logistical delivery.

1.8 Local practice at the study site

A local NHS hospital Trust, which regards itself as a world-renowned centre of clinical excellence and is one of the largest teaching trusts within the UK, incorporates four hospital sites. The regional cancer centre, which includes a haematology centre, is situated in one of these four hospitals. The cancer and haematology centre offers a wide range of cancer services including imaging, surgery and radiotherapy. Within the centre there is also a dedicated day treatment unit (DTU) where anti-cancer treatment can be administered and delivered, an on-site cancer pharmacy service, in-patient oncology and haematology wards, an oncology triage unit, cancer clinical trials units and a Maggie's Centre. The acute oncology service is delivered at another hospital in the local NHS Trust, which hosts the accident and emergency department and is within a mile of the cancer centre.

One purpose of this study is to evaluate the oral education clinic (OEC) delivered by SACT advanced nurse practitioners and cancer pharmacists at the cancer centre. The clinic was set up in response to the NPSA (2008) alert and delivers education sessions to an average of 600 patients per year that have varying oncological and haematological tumour types. At the time of commencing this study, a total of two nurses and six pharmacists facilitated the clinic.

PWC are referred to the clinic by their primary oncologist/haematologist who will have prescribed a course of oral SACT. A standard operating practice (SOP) document details the delivery of the service (Appendix 1). Once a referral is received, the patient is contacted by the SACT team and an appointment made to attend the OEC. At this appointment the individual returns to the hospital and meets with either an advanced SACT nurse practitioner or a SACT-trained cancer pharmacist. Some of the staff, both nursing and pharmacy, also are non-medical prescribers (NMPs). The appointment at the education clinic serves as a prime opportunity for nursing and pharmacy staff to introduce the individual to his/her new medication. If the oral medication has been dispensed by the hospital, the health professional facilitating the clinic will collect the medication and this will be the first time the individual receives their tablets. The treatment regimen will be explained in detail

and education delivered to the individual and their carer regarding administration, management of side effects, and any questions the individual(s) may have will be answered. A SACT diary will be issued, alongside relevant written material about the oral SACT, and contact numbers for staff within the clinic and the 24-hour contact number issued. As per recommendations (Oakley *et al.*, 2010; Rittenberg, 2012) it is common practice for staff to rehearse scenarios with PWC attending the OEC and also observe individuals taking their medicines to ensure full understanding and promote concordance with advice.

Secondary to physical circumstances, such as disability or access requirements, it might not be appropriate for all patients to attend a face-to-face clinic appointment, and therefore, a small number of patients are offered education about the oral SACT delivered via telephone. The majority of patients receive face-to-face education, but in some cases, education is delivered over the phone and written material posted. For patients refusing to attend the clinic, telephone follow up phone calls are strongly recommended.

Some PWC will have their oral SACT products delivered at home by Healthcare at Home Ltd (HCAC). These patients will have their medication delivered pre- or post the OEC dependent on availability of delivery teams. Several high-cost drugs may be supplied in a primary care setting in this way due to cost associated with tax.

With regard to prescriptions and follow-up, patients are seen by the nursing or pharmacy staff following a cycle of treatment, where they can be reviewed by a NMP and a further cycle prescribed and issued if appropriate. Figure 1.1 below represents the patient pathway at commencement of the study.

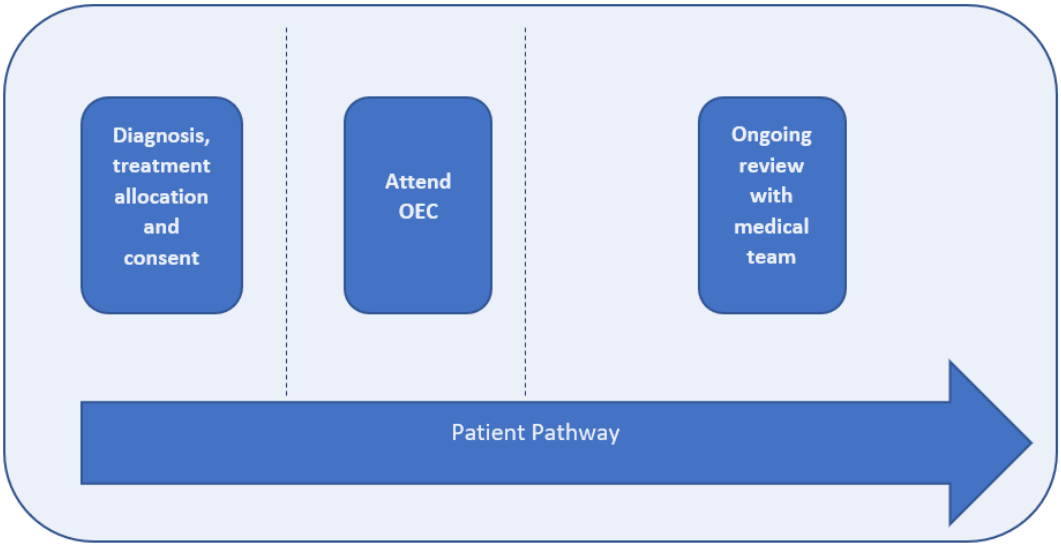

Figure 1.1 Patient pathway on commencing oral SACT

1.9 Rationale for conducting a PhD study

Having worked within healthcare for 15 years, I have always had a personal passion for delivering the best care. After qualifying from Queens University Belfast as a registered nurse I began work within the NHS as a nurse on a haematology oncology ward. In this environment, with a personal drive to deliver the best possible care, I learned first hand the importance of developing and implementing high quality, evidence-based care. While undertaking my MSc at University College London, I undertook several modules in medical statistics and began to develop an understanding of the analysis and application of statistics. Working as a nurse however, I would often rely on qualitative studies to inform an in-depth understanding of patience experience, pivotal to providing direct nursing care.

The rationale for undertaking this study was two-fold. Firstly, I wanted to utilise the skills I had developed during my MSc to contribute to the body of knowledge and gain experience with conducting and applying qualitative health research. Secondly, I recognised that with oral SACT, there was limited understanding of both patient experience and gold standard approaches to care. Together, these formed the motivation to undertake this PhD study.

1.10 PhD aim and research questions

The aim of this doctoral project is to explore the experiences of patients receiving oral SACT and the views of key health professionals to inform models of care.

In order to meet the aim of the project the following the research questions will be addressed:

- What are the experiences of patients receiving oral SACT?
- How satisfied are patients with the clinical care they've received?
- How useful is the oral education clinic (OEC) for patients?
- What strategies do patients use to manage both their oral SACT and treatment related toxicity?
- What are the perceptions and experiences of health professionals involved in managing patients receiving an oral SACT?

These questions have been carefully considered by the research student and all members of the supervisory team. Expert advisors and clinical collaborators have also contributed to their development.

1.11 Thesis overview

This section will provide a brief overview of structure of this thesis, detailing the main elements of each chapter.

Chapter one: This chapter has presented a summary of the background information relevant to this PhD study, identified the guiding research aim and research questions, and provides the reader with the overall structure of this thesis.

Chapter two: A presentation of the findings from a systematic review of the published literature regarding safe care in oral SACT practices and identifying validated measures which were used when investigating patient experience.

Chapter three: The methodology used for this study will be presented including a short discussion on the philosophical and theoretical underpinnings of mixed methods research. The development of study materials including questionnaire design will be described. Methods used to conduct the study will be presented.

Chapter four: This chapter will present findings from two questionnaires issued to people with cancer who received education through the OEC. Descriptive statistics will be used to analyse the data and findings presented. Findings will address the patient experience of receiving an oral SACT and the experience of care.

Chapter five: Findings from qualitative interviews with participants who returned both questionnaire 1 and questionnaire 2 and consented to interview will be presented. This chapter will address all research questions relating to patient experience.

Chapter six: This chapter will present findings of interviews with health professionals involved in the management of care of patients receiving oral SACT.

Chapter seven: In this final chapter, a summary of findings following data integration will be presented. These findings will be discussed in the context of the current body of knowledge. Personal reflections from the PhD student will be presented alongside consideration of the strengths and limitations of the study. Recommendations for research and practice will be presented before drawing this thesis toward a close in a conclusion.

1.12 Chapter summary

The care of PWC receiving an oral SACT presents a significant challenge to healthcare providers. As health policy recommends, a set of standards is required to ensure the safe management of PWC receiving oral SACT and guide the health professionals managing their treatment and care. The aim and research questions have been presented. In order to further refine the research questions and identify what current practice is being used in the UK, a systematic review of the literature was required.

Chapter Two: Systematic Literature Review

2.1 Chapter outline

This chapter will detail the process of conducting a systematic, literature review. Background information on the importance of a review before undertaking a research project will be discussed and the case for a systematic literature review as a method presented. A systematic search strategy will be explained alongside presentation of the results. Data analysis involving content and thematic analysis will be discussed to address the current published evidence regarding the care and research of PWC receiving an oral SACT.

2.2 Evidence-based practice in healthcare

A systematic literature review can serve multiple purposes; predominantly they are used to increase understanding of a topic or problem or to inform the development of a research project (Parahoo, 2006). Through a process of systematically searching, appraising and summarising appropriate studies, an objective assessment of the evidence available can be achieved, thus improving both reliability and accuracy of conclusions made (Neale, 2009).

The term 'evidence-based practice' is an adaptation of the term 'evidence-based medicine', which Sackett *et al.* (1996) describe as the integration of clinical expertise coupled with the best available clinical evidence discovered through systematic research. In all healthcare interventions and practice, it is vital that care given to patients is informed from the best available evidence. Within this context, conducting a systematic literature review is a vehicle to identify best practice in the management of care of patients taking an oral systemic anti-cancer treatment (SACT).

2.3 Systematic literature review as methodology

Preliminary searches were conducted to identify any published systematic reviews about oral SACT, but at the time of searching no review was identified. Considering the background and proposed methods to this PhD project, the systematic literature review aimed to examine the existing published evidence to review best practice in the management of care of this patient group and to identify validated measures that have been previously used in researching PWC receiving oral SACT.

As methods of a systematic review aim to be systematic, explicit and reproducible (Tricco *et al.*, 2010) a detailed search strategy will be explained. Results from this search will be assessed for eligibility against a set inclusion and exclusion criteria. The selected articles will be appraised for quality preceding a process of data extraction, content and thematic analysis. The findings will then be synthesised into a discussion and the impact upon this PhD project design and delivery explored.

2.4 Aims and objectives of the systematic literature review

Considering the context of this review within a PhD study, the aims and objectives of the review are:

- To identify evidence of effective interventions in the management of care of PWC receiving an oral SACT
- To identify existing models of care for PWC receiving oral SACT
- To identify and assess the appropriateness and validity of measures used in previous research with this patient group to inform PhD study design

2.5 Methods

2.5.1 Developing a search strategy

Cooke *et al.* (2012) comment that confidence in the literature search is vital to all research and, therefore, a clear systematic search strategy is key. Several approaches to search strategies exist. A well-known example is that of the PICO tool – Population/Problem, Intervention/Exposure, Comparison and Outcome. The PICO tool is most appropriate when there is an intervention being tested; thus is used widely when conducting quantitative systematic reviews with its use advocated by the Cochrane Collaboration (Higgins and Green, 2011).

Preliminary searches identified a limited body of evidence surrounding this topic; particularly a limited number of interventional trials, but a number of qualitative studies were retrieved. When considering qualitative evidence, PICO is not appropriate given the indexing of qualitative studies on online databases. To have confidence in the search, a wider search strategy was required encompassing multiple subject heading search words and synonyms.

Cooke *et al.* (2012) (in consideration of the difficulties qualitative researchers face when conducting searches) devised a more thorough approach to searching: The SPIDER tool. This tool asks the researcher to consider: sample (S), phenomenon of interest (PI), design (D), evaluation (E) and research type (R).

Using the SPIDER tool (Cooke *et al.*, 2012) as a framework to systematically identify search terms, the following subject headings were identified (Table 2.1).

Table 2.1 Subject headings derived from use of SPIDER (Cooke et al., 2012)

SPIDER Tool		Themes for searching
S	Sample	Patients with Cancer
PI	Phenomenon of Interest	Treatment with oral SACT, Education
D	Design	questionnaires, interviews, surveys, case studies
E	Evaluation	Patient experience
R	Research Type	Qualitative, quantitative and mixed methods

Rigorous testing was conducted with the above search terms in order to identify a search strategy that was both sensitive and specific. Initial searches identified minimal results despite using synonyms, truncations and wildcards. The term 'adherence' was added to broaden the search to retrieve relevant studies.

2.5.2 Search strategy

The final search headings decided upon for this search were 'oral chemotherapy', 'cancer', 'education', 'adherence', 'patient experience' and 'research design'. Synonyms, truncations and wildcards were used as per Table 2.2. The search strategy was also reviewed by a librarian and the supervisory team who are all experienced in literature searching.

Table 2.2 Search strategy: key words and synonyms used

Keyword 1	Keyword 2	Keyword 3	Keyword 4	Keyword 5	Keyword 6
'oral chemotherapy'	'cancer'	'education'	'adherence'	'patient experience'	'research design'
"oral chemo" OR "oral cyto*" OR "oral antineopla*" OR "oral systemic anti-canc*" OR "anti-cancer treat*" OR "anti-cancer drug*" OR "oral oncolyt*" OR "target* therap*"*	*Cancer* OR neoplas* OR malignan* OR carcinoma* OR tumor* OR tumour**	*"pre-educat*" OR "pre educat*" OR educat* OR "pre-chemo educat*" OR "pre chemo educat*" OR informat* OR assess* OR counsel* OR "patient counsel*" OR "info* provi*" OR teac**	*"patient compliance" OR "patient adherence" OR adhere* OR complian* OR comply OR complied OR noncompli* OR nonadhere* OR nonpersist* OR overadhere* OR overcompli* OR overpersist**	*View* OR experienc* OR "lived experience" OR safe* OR toxic* OR "adverse event" OR adherence OR complian* OR concordance OR "unscheduled care" OR "unplanned care" OR outcome* OR "patient reported outcomes" OR "self-reported outcome" OR perspectiv* OR perception OR thought OR satisfaction OR evaluat* OR 'side effects' OR iatrogenic*	*survey OR questionnaire OR interview* OR focus group* OR intervention OR diary OR 'patient held record' OR schedule* OR structured OR 'semi-structured' OR experimental OR quasi-experi* OR cohort OR 'cross-sectional' OR 'case study' OR observational OR prospective OR retrospective OR telephone OR 'face to face' OR randomised OR randomized OR controlled OR 'controlled trial' OR "RCT"*
Rationale					
To identify patients taking oral chemotherapy.	To identify patients receiving treatment for cancer.	To identify the role of patient education.	To broaden the search to retrieve more relevant studies.	To identify the patients experience including outcomes of receiving oral SACT.	To identify research studies using primary data collection.

2.5.3 Database selection

Databases used in this search were: MEDLINE (U.S. National Library of Medicine), CINAHL (Cumulative Index to Nursing and Allied Health Literature), BNI (British Nursing Index), PsychINFO (produced by American Psychological Association) and Web of Science. These databases were selected due to relevance to the aim and objectives of this review and the increased likelihood of retrieving published evidence related to nursing, pharmacy, cancer care and healthcare services.

The search strategy was entered into each database shown in Figure 2.2.

Search strategy
Search 1: *"oral chemo*" OR "oral cyto*" OR "oral antineopla*" OR "oral systemic anti-canc*" OR "anti-cancer treat*" OR "anti-cancer drug*" OR "oral oncolyt*" OR "target* therap*"*
Search 2*: Cancer* OR neoplas* OR malignan* OR carcinoma* OR tumor* OR tumour**
Search 3*: "pre-educat*" OR "pre educat*" OR educat* OR "pre-chemo educat*" OR "pre-chemo educat*" OR informat* OR assess* OR counsel* OR "patient counsel*" OR "info* provi*" OR teach*
Search 4*: "patient compliance" OR "patient adherence" OR adhere* OR complian* OR comply OR complied OR noncompli* OR nonadhere* OR nonpersist* OR overadhere* OR overcompli* OR overpersist**
Search 5*: view OR experienc* OR "lived experience" OR safe* OR toxic* OR "adverse event" OR adherence OR compliance OR concordance OR "unscheduled care" OR "unplanned care" OR outcome* OR "patient reported outcomes" OR "self-reported outcome" OR perspective OR perception OR thought OR satisfaction OR evaluat* OR "side effects" OR iatrogenic*
Search 6*: survey OR questionnaire OR interview* OR focus group* OR intervention OR diary OR "patient held record" OR schedule* OR structured OR "semi-structured" OR experimental OR "quasi-experi*" OR cohort OR "cross-sectional" OR "case study" OR observational OR prospective OR retrospective OR telephone OR face to face OR randomised OR randomized OR controlled OR controlled trial OR "RCT"*
Search 7: (search 1 AND search 2)
Search 8: (7 AND 3)
Search 9: (8 AND 4)
Search 10: (9 AND 5)
Search 11: (10 AND 6)

Figure 2.2 Search strategy as entered into databases

2.5.4 Search expansion

The search was expanded by a process of snowballing, where reference lists of relevant articles were snowballed, and citation chaining on the Web of Science database performed to search for and retrieve publications that cited a relevant article. The search was further expanded by searching grey literature using Google, Google Scholar and EThOS. Grey literature was searched as not all publications are published in peer-review journals and, therefore, may not be retrievable on electronic databases. Recommended reading on each online database was also reviewed.

2.5.5 Inclusion and exclusion process

In order to refine the results and analyse their relevance to the subject area, predetermined inclusion and exclusion criteria were set (Table 2.3). All articles reviewed were required to meet the inclusion and exclusion criteria to be included in the review.

Inclusion criteria:

- Adult patients
- Patients receiving or have received oral SACT
- Education and information provision included in study as intervention, or discussed
- Primary research: intervention / prospective / retrospective
- Feasibility studies – if clinical implications relevant

Exclusion criteria:

- Study protocols
- Studies not published in English
- Literature reviews
- Expert opinions

Table 2.3 Rationale for inclusion and exclusion criteria

Inclusion criteria	Rationale	Exclusion criteria	Rationale
Adult patients over 18	Models of care for paediatric settings will differ due to involvement of parents, carers and level of understanding of child.	Study protocols	No data to inform systematic review
Patients receiving oral SACT	Relation to patient group being studied in this PhD	Studies not published in English	No funding available for translation
Education included in study as intervention, or discussed	Education plays a key role in the model of care used for the patient group being researched	Literature reviews	Researchers seeking primary data to include in review
Primary research: intervention / prospective / retrospective	To make inferences from primary research to inform systematic review	Expert opinions	Researchers seeking primary data to include in the review
Feasibility studies – if clinical implications relevant	To make inferences from primary research to inform systematic review		

2.5.6 Data extraction

When the final sample of retrieved articles was collated, data extraction was completed by inputting the data into a table under the terms study (author, date, title), study site (country), sample (size, gender, tumour type, treatment type, age), study design and outcome measures (intervention), main findings and strengths and limitations (quality appraisal).

2.5.7 Quality appraisal

The quality appraisal step within a systematic literature review is an essential step within healthcare research. In a traditional systematic review, quality appraisal is often used to exclude studies secondary to results lacking sufficient rigour or due to problematic study design. As limited evidence was available regarding this particular topic area, quality appraisal was used to determine the 'weight' attributed to data from a given study within the body of evidence being reviewed. If a study had several limitations, the results or findings were interpreted in consideration of the quality of the study and study reporting, rather than exclude the study.

Several tools exist in order to critically appraise research (Polit and Hungler, 1997; Burns and Grove, 2001; Health Evidence, 2013); however these tools are typically aimed at specific types of studies i.e. quantitative studies or qualitative studies.

Several quality appraisal tools were used due to varying research design of retrieved sources: the Critical Appraisal Skills Programme (CASP) Randomised Controlled Trial Checklist (2013), the Critical Appraisal Skills Programme (CASP) Qualitative Checklist (2013), the Joanna Briggs Institute Checklist for Analytical Cross Sectional Studies (2016), the Quality Checklist for Mixed-methodology Case Studies and Other In-depth Complex Designs (Greenhalgh *et al.*, 2007), Quality Checklist for Questionnaire Surveys (Boynton and Greenhalgh, 2004) , and the Quality Checklist for Comparison of 'Real-World' Implementation Studies (Gomm, 2000). Sources were rated as low-, moderate-, moderate-high-, or high-quality, depending on the scores given using the relevant appraisal tools. Quality appraisal was independently conducted by the student, and a member of the supervisory team.

2.5.8 Data analysis

In consideration of the aims and objectives of this systematic literature review, a content and thematic analysis was performed on the included articles as demonstrated in Table 2.4.

Table 2.4 Data analysis in relation to aims of review

Aim	Data analysis
To identify and assess the appropriateness and validity of measures used in previous research with this patient group for potential use in this PhD study	Content analysis
To identify existing models of care for patients taking oral SACT	Thematic analysis
To identify evidence of effective interventions in the management of care of patients taking oral SACT	

Content analysis refers to a process of examining data for recurrent instances (Silverman, 2014). An aim of this systematic review has been to identify validated measures used with patients who are receiving an oral SACT. Part of this study involves questionnaires distributed to patients. A key aim of this systematic review has been to identify and assess the appropriateness and validity of measures used in research with this patient group. The included articles identified from the search strategy will be assessed for measures used in the authors research and the appropriateness of those measures examined against the aims of objectives of this PhD.

While content analysis refers to the process of identifying recurrences in the data, thematic analysis refers to the process of identifying 'themes' arising from the data set (Silverman, 2014). Thematic analysis was approached systematically and guided by the data extraction table. Identified articles were grouped together by study type to identify key findings. A matrix was then developed in order to summarise the key findings identified from all included articles to highlight the themes arising from the articles. All key findings in their entirety were then mapped together and tabulated to allow key findings from each article, whether qualitative or quantitative in nature, to be integrated under the relevant theme. By approaching the thematic analysis in this way, data of mixed types (quantitative and qualitative) was integrated under a key theme.

2.6 Results

2.6.1 Results of the literature search

Using the search strategy as described, a total of 1028 articles were retrieved across five healthcare related databases. Titles of the 1028 articles were reviewed and 844 were deemed not relevant by the research student. Of the remaining 184 articles, 62 were duplicates leaving 122 articles for abstract review. At the abstract review stage, 38 articles were removed as they were irrelevant or had no reference to patient education leaving a total of 84 articles for full text review. The 84 articles were reviewed in the first instance by the research student and reviewed by two further academic supervisors experienced in completing systematic reviews. A total of 59 articles were excluded leaving a remaining 25 articles to be included in the review from the database search. Articles were excluded namely due to no reference or explanation regarding patient education, or irrelevance.

2.6.2 Other sources results

In order to increase the sensitivity of the search, reference lists of all included articles were reviewed to identify any studies that may have been overlooked or not available from the database search. Searches of PubMed, EThOS, Google Scholar and Google were performed along with citation chaining on Web of Science and accessing database recommended articles on the individual databases. This resulted in a further six articles being identified, leaving a complete total of 31 articles included in this systematic review.

The original search was performed in June 2015 at the commencement of this PhD programme. The search was updated by repeating search terms and accessing grey literature in June 2018 and

resulted in the addition of nine articles. A flow chart clarifying this process can be found in Figure 2.3.

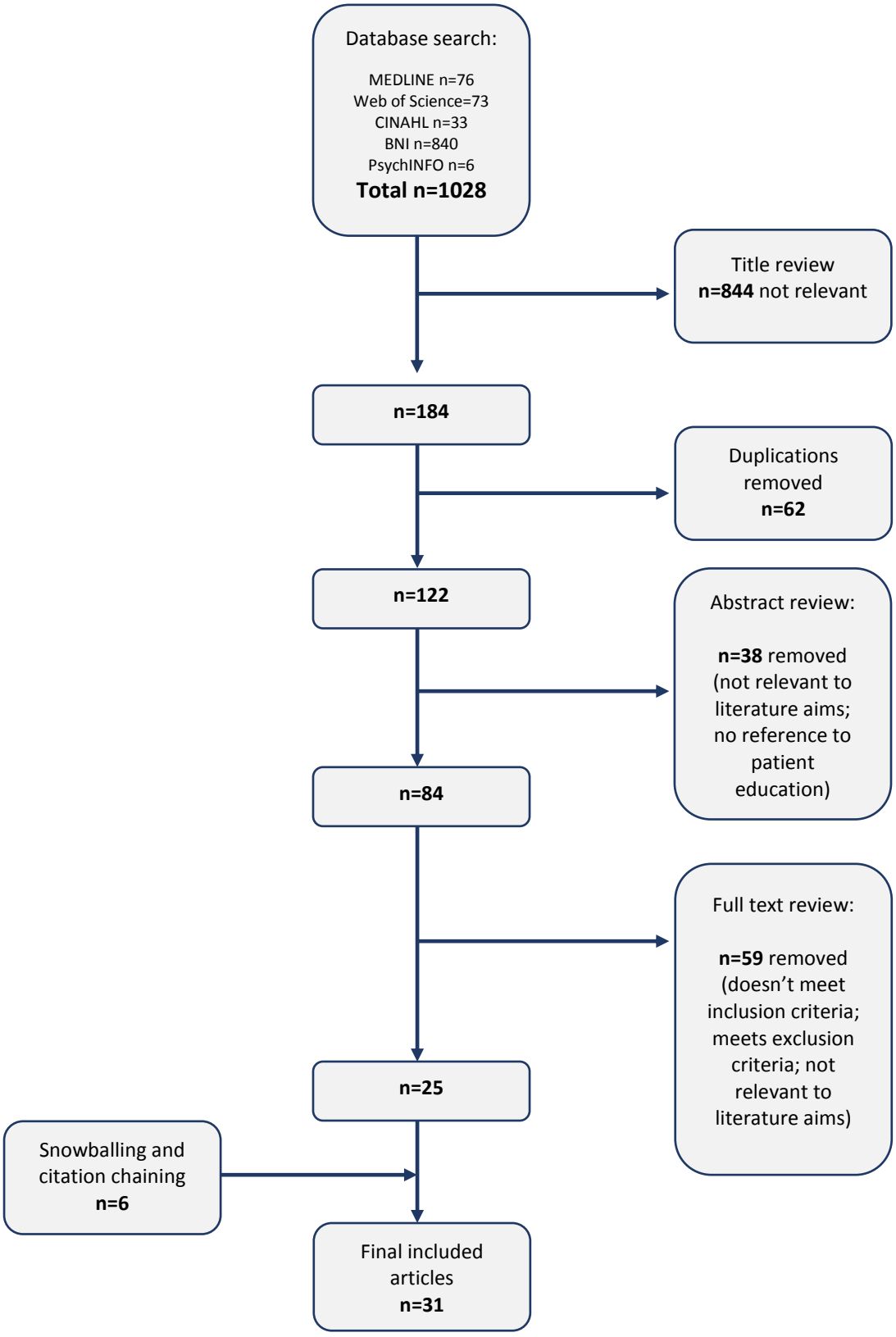

Figure 2.3 Flowchart detailing search process - adapted from Moher et al. (2009)

2.6.3 Description of included papers

31 sources were included in this review and were grouped by study type as found in Table 2.5.

Table 2.5 Retrieved sources grouped by design

Randomised interventional studies	Non-randomised interventional study	Questionnaire studies	Mixed method case studies	Qualitative studies	Service reports
N=6	N=1	N=6	N=2	N=3	N=13

Data were extracted from each source and tabulated (please see Table 2.6). A total of seven intervention studies were identified. These ranged in quality following appraisal from low (Williams *et al.*, 2011) to high (Molassiotis *et al.*, 2009). Most intervention trials were randomised, but one study used a cross-sectional, non-randomised intervention (Moon *et al.*, 2013). Six questionnaire studies included surveys to health professionals or individuals working within a cancer centre, and one study surveying patients with CML (Efficace *et al.*, 2012). Quality ranged from 'moderate' to 'moderate to high' quality. Two studies employed a mixed method design: Arber *et al.* (2015) used an author designed questionnaire (n=64) and interview (n=2) to investigate patient knowledge to support optimal adherence to oral SACT. Oakley, Johnson and Ream's (2010) study was based on a complex interventions framework and described the process of developing a generic patient diary to support patients receiving oral SACT. Both studies were appraised as moderate in quality. Three qualitative studies ranged in quality from high (Wu *et al.*, 2015), moderate (Denois *et al.*, 2010) to low (Simchowitz *et al.*, 2010). Two studies conducted interviews with both health professionals and patients, with one study focussing only on people with cancer, or parents of a child with cancer. All three studies reported perspectives, experiences, behaviours and representations. The largest number of studies were grouped under 'service reports', which referred to studies that were service improvement projects, observational studies, implementation studies, feasibility studies or retrospective studies. Quality of the studies ranged from low to high with most studies (n=7) scoring as moderate and only one study (Bhattacharya *et al.*, 2012) achieving a high-quality appraisal.

2.6.3a Study settings

Most oral SACT interventions were delivered within an acute clinical care/hospital setting; one was in primary care (Bordonaro *et al.*, 2014); and one intervention spanned both primary and acute care settings (Molassiotis *et al.*, 2009). Of the 19 interventions described, a majority took place in the USA (n=11), 3 in Germany (Simons *et al.*, 2010; Krolop *et al.*, 2013; Ziller *et al.*, 2013), two in Italy (Cirillo *et al.*, 2011; Bordonaro *et al.*, 2014) two in the UK (Oakley, Johnson and Ream, 2010;

Bhattacharya *et al.*, 2012) with one intervention described in Korea (Moon *et al.*, 2013). One survey was international (Kav, 2008) with two based in the USA (Weingart *et al.*, 2007; Roop and Wu, 2014), one in Canada (Ahmad *et al.*, 2015), one in Italy (Efficace *et al.*, 2012) and one in Spain (Conde-Estevez *et al.*, 2013).

2.6.3b Profile of participants

The cancer diagnosis of patient participants was varied (Table 2.6). The most common cancers were breast, prostate and colorectal cancer. Numerous types of oral SACT drugs were reported, these included cytotoxic drugs, targeted therapies and endocrine therapies. There was also significant variation in the number of participants ranging from 17 (Oakley, Johnson and Ream, 2010) to 1115 (Kav *et al.*, 2008). This was sometimes due to the study design not demanding large sample sizes, e.g. qualitative interview studies; however some studies that used quantitative research designs had small sample sizes. Where age was reported, mean ages of sample participants ranged from 53 years (Sommers, Miller and Berry, 2012) through to 67.8 years (Bordonaro *et al.*, 2014). Studies that reported survey results recruited the following types of professionals: nurses, pharmacists, physicians and administration leads.

Table 2.6 Data extraction table

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
Randomised interventional studies (CASP Trial)						
1	**Schneider, S. M., Adams, D. B. and Gosselin, T. (2014)** A tailored nurse coaching intervention for oral chemotherapy adherence	Multisite USA	N=48. 64.6% female. 68.8% Caucasian. Cancer types: Breast, colorectal, renal, hepatocellular, multiple myeloma and chronic leukemia. Oral SACT: capecitabine, other targeted agents, tamoxifen, aromatase inhibitors Average age 59.85 years old.	Randomised controlled trial. Standard care (control group) includes chemotherapy education delivered by chemo nurse, oncologist or nurse practitioner at the study site. Intervention group is standard care with added tailored adherence plan developed by advanced practice nurse, administered via telephone. Outcome measures: Beck Depression Inventory-II; Memorial Symptom Assessment Scale. Adherence measured using pharmacy refill rates and patient self-report.	Self-report and pharmacy refill measures of adherence rates were superior in intervention group at 2 months (91.3% and 80.0% intervention vs 80.0and and 65.0% control) and 4 months (95.1% and 73.7% intervention vs 82.4% vs 68.8%). Due to small sample size, no statistical difference. No correlation between age, gender and depression with adherence rates. System barriers (factors not related to patient actions) interfered with adherence in 10% of participants e.g. late prescription.	Moderate to high 8/11 using CASP. Single health system therefore results not generalizable. Small sample size for RCT.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
2	**Spoelestra, S. L. *et al.* (2013a)** An intervention to improve adherence and management of symptoms for patients prescribed oral chemotherapy agents	Multisite USA	N=119 adults. 69% female. Tumour type: breast, colon/rectal, lung, other (not specified) Oral SACT: capecitabine, erlotinib, lapatinib, imatinib, temozolomide, sunitinib, sorafenib, methotrexate, cyclophosphamide and others (8%) Mean age 59.6 years.	Randomised trial, exploratory study. Group 1: use of an automated voice response (AVR) system and symptom management toolkit (SMT) Group 2: use of AVR and SMT with strategies to manage symptoms and adherence Group 3: AVR and SMT with strategies to manage adherence alone. Outcomes measures: Depressive symptoms using Center for Epidemiological Studies Depression Scale [CES-D]. Symptom Experience Inventory. Adherence by self-report.	Group 1 and group 2 had significant decrease in symptom severity (P=0.3 group 1, P=0.4 group 2). Overall 42% nonadherence rate. No significant difference in adherence between groups. Incidence of missed doses increases with regime complexity. AVR alone (group 1) as effective at managing symptoms and adherence as the AVR plus nurse strategies.	Moderate to High quality 7/11 using CASP. Significant limitation – when addressing symptom severity, at baseline there is a significant difference before intervention has begun. No adjustment made. Randomisation procedure not reported.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
3	**Spoelestra, S. L. *et al.* (2013b)** Issues related to overadherence to oral chemotherapy or targeted agents	As above.	As above.	As above. Longitudinal secondary data analysis.	In patients who had difficulty with adherence, overadherence was more likely to occur compared to underadherence (20% compared to 13%). Increasing regimen complexity more likely to be overadherent. Reasons for overadherence identified as confusing timings and medication delivered early resulting in early commencement of treatment.	High quality 10/11 using CASP.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
4	**Ziller, V. *et al.* (2013)** Influence of a patient information program on adherence and persistence with an aromatase inhibitor in breast cancer treatment – the COMPAS study	Single site Germany	N=181 patients. 100% female. Cancer type: hormone receptor positive primary breast cancer Oral SACT: aromatase inhibitors	Single-centre, three-armed, randomized and partially-blinded parallel group study. Group 1 (control): no intervention Group 2 (letter group): received written information at 1, 2, 10, 20 and 33 weeks and at month 15, 18 and 21. Group 3 (telephone group): contacted by study nurse and given verbal information/semi-structured interview at week 1, 2, 10, 20 and 33 and month 15, 18 and 21 via telephone.	Post hoc pooled analysis with a one-way hypothesis for both interventions versus control group indicated significant difference between groups, favouring intervention (p=0.039). Patients receiving extra information appeared to have improved adherence (Adherence after 12 months: Group 1 48.0%, Group 2 64.7%, Group 3 62.7%) despite differences between groups having no statistical significance for primary endpoint.	Moderate to high quality 8/11 using CASP. Well-balanced randomisation with no significant difference between 3 groups. Statistical analysis clear and appropriate.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
5	**Williams, P. D. *et al.* (2011)** An intervention to manage patient reported symptoms during cancer treatment	Single site USA	N=20 patients. 17 females. Tumour type: breast cancer (n=16), others not reported. Oral SACT: not reported Mean 58.3 years intervention group. Typing error in control group – reported mean of 4.1 years.	Randomised interventional trial. Increased, focussed education delivered by a nurse on symptom management. Outcome measures: Therapy-Related Symptom Checklist HRQOL-LASA Karnofsky Performance Status Scale and Health Form (KPS)	Intervention group reported lower symptom occurrence and severity overall. Only slight variations in QOL scores. KPS scores no significant difference – scores for both decreased at midpoint and endpoint.	Low quality 6/11 using CASP trial. Reported probability values however sample size was 10 participants in each of 2 groups. Small sample size – underpowered for quantitative analysis.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
6	**Molassiotis, A. *et al.* (2009)** Effectiveness of a homecare nursing program in the symptom management of patients with colorectal and breast cancer receiving oral chemotherapy: a randomized, controlled trial	Single site USA	N=164. 62% Female Tumour type: colorectal cancer (n=110) breast cancer (n=54). Oral SACT: capecitabine. Mean age 61.08 years	Randomised controlled trial. Patients receive standard care (control) or homecare programme (intervention). Homecare programme involves one standard home visit during first week of treatment delivered by nurse, subsequent home visits offered when patients experienced multiple grade 3 toxicities. Routine weekly monitoring phone call during all cycles. Outcome measures: Primary outcome toxicity grading using NCI-CTC. Secondary outcomes were Hospital Anxiety and Depression scale, EORTC-QLQ-C30 and evaluation of utilisation of healthcare services	In all occurrences the experimental group scored significantly less toxicity than the control group. Anxiety improved in both groups over time, but trend in experimental group to have higher improvement than control group (P=0.001 vs P=0.23). No differences between groups in depression. No difference in health-related quality of life between groups with exception of financial problems which was highly significant in homecare group (P=0.004 vs P=0.248). Use of healthcare services lower in homecare group. The intervention enabled patients to manage treatment adverse effects more effectively than those receiving standard care.	High quality 10/11 using CASP tool. Design clear and appropriate to aim. Sample size appropriate and justified. No discussion of limitations.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
Non randomised interventional studies (Joanna Briggs analytical cross-sectional)						
7	**Moon, J. H. *et al.* (2013)** Patient counselling program to improve the compliance to imatinib in chronic myeloid leukemia (CML) patients	Multisite Korea	N=114. Gender not reported Tumour type: CML (patients in chronic phase) Oral SACT: imatinib Age groups included: 11-30, 31-51, 51-70 and >70.	Cross-sectional, non-randomised intervention. Counselling session within 1-2 weeks by a nurse, followed by 1-2 phone calls every month. Daily text reminders to take imatinib. Outcome measures: Clear definitions provided of meaning attributed to 'follow-up rate', 'persistency', 'dose compliance', 'overall compliance' and 'drop out'.	Attrition rates higher in non-happy club programme during 36 months (P=0.001). Follow-up rates were higher in the 'happy club' compared to 'non-happy club' (98.2% vs 79.3%) which was statistically significant P=0.001. Persistency greater in the 'Happy club' (P=0.001). No difference in dose compliance between groups. Overall compliance (reflecting both persistency and dose compliance) in the 'happy club' was higher and significantly different to the 'non-happy club' (P=0.001). Programme most efficient for patients receiving the higher dose of imatinib (>400mg dose).	Moderate to high - using Joanna Briggs cross-sectional study Data collection method not reported.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
Questionnaire studies (Boynton and Greenhalgh questionnaire survey checklist)						
8	**Ahmad, N. *et al.* (2015)** Oral chemotherapy practices at Ontario cancer centres	Multi-regional Canada	N=13 regions of Ontario province Respondents were medical oncologists, pharmacists, nurses, administrative leads and support staff.	Survey using questionnaire using semi-structured interview. Questions asked by phone (11 regions) or email (2 regions). Questionnaire pre-circulated before responses collected. Covered topics of prescribing, dispensing, patient education, adherence, disposal and funding.	13 of 14 regions responded. Prescribing: process for oral less rigorous than intravenous. Dispensing: only 2 regions have formal guidelines. Education: 23% provide extensive, co-ordinated education. Adherence: few tools consistently used, mostly use calendars, diaries, blister packs, manual pill counts and patient discussions.	Moderate – using quality checklist for questionnaire surveys Rationale for item generation explained. Methods for item generation not described. Oral chemotherapy not pre-defined Missing data from some regions.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
9	**Roop, J. C. and Wu, W. (2014)** Current practice patterns for oral chemotherapy: results of a national survey	USA	N=577 Outpatient oncology nurses	Survey using questionnaire. 5-point Likert-type scale used ranging from 1 (strongly agree) to 5 (strongly disagree) with additional "I don't know" option. 17 forced choice items, one free text item.	51% respondents worked in environments with specific policies, procedures and resources for patients on oral chemotherapy. Barriers to treatment adherence were believed to be cost (81%) and adverse effects (72%). Practices where policies in place differed in clinical and statistical difference than practices without in almost every questionnaire item. Free text responses indicate erratic procedures and inadequate interdisciplinary communication.	Moderate to high – using quality checklist for questionnaire surveys Low response rate – n=577 small for a national survey. No analysis of 'strength' of agreement or disagreement - Likert scale condensed for analysis. Response rate 13%.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
10	**Conde-Estevez, D., Salas, E. and Albanell, J. (2013)** Survey of oral chemotherapy safety and adherence practices of hospitals in Spain	Multisite Spain	N=86 pharmacy services	Survey by questionnaire. Specific questionnaire designed and sent by email with personalised letter. 11 multiple choice items addressing prescribing, dispensing, patient education and monitoring with aim on gathering information on safety and adherence practices. Free text option per item and several free text questions. Authors describe 3 levels of care: Level 1 – no specific practice Level 2 – visit with pharmacist giving written information and monitoring adherence Level 3 – level 2 + electronic chemotherapy ordering and extra safety practices	50.9% response rate. Percentage of pharmacy services at 3 defined levels of care: 37.2% level 1 44.2% level 2 18.6% level 3 Main discrepancies in electronic prescription and monitoring adherence.	Moderate to high - using quality checklist for questionnaire surveys Not validated. Didn't describe pilot. Didn't understand how to manage to maintain accuracy of data.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
11	**Efficace, F. *et al.* (2012)** Investigating factors associated with adherence behaviour in patients with chronic myeloid leukaemia: an observational patient-centered outcome study	Multisite Italy	N=413 patients. 40.44% female. Tumour type: CML Oral SACT: imatinib. Median age: 56.83	Validated and standardised patient questionnaire. Multivariate logistic regression analysis used to analyse data. Nil intervention.	A higher level of social support, satisfaction with information received and concomitant drug burden were the main factors associated with greater adherence to long0term imatinib therapy.	Moderate to high quality – using quality checklist for questionnaire surveys. Range of cancer centres (n=26). Statistical analysis clear and appropriate.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
12	**Kav, S. *et al.* (2008)** Role of the nurse in patient education and follow-up of people receiving oral chemotherapy: an international survey	Inter-national: Australia, China, Denmark, Finland, Greece, India, Israel, Kenya, Lithuania, Palestine, Serbia, Spain, Thailand, UK, USA.	N=1115 oncology nurses	Survey using questionnaire. 16 open-ended multiple-choice questions: demographics, common used treatments, policy/guidelines, nurse education, involvement in patient education, reasons for not being involved and problems/difficulties faced.	Significant difference in nurses' education, availability of guidelines/protocols, educational materials, responsibilities for patient education and follow-up for patients taking OC.	Moderate to high quality - using quality checklist for questionnaire surveys. No reported response rate. Publication date might not reflect current knowledge.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
13	**Weingart, S. N. *et al.* (2007)** Oral chemotherapy safety practices at US cancer centres: questionnaire survey	Multi-regional USA	N=42 comprehensive cancer centres	Survey using written questionnaire of pharmacy directors of cancer centres.	Prescribing practices vary considerably. Majority (29 centres) using handwritten prescriptions. Lack of standardisation in informed consent. Few of the safeguards used for infusional chemotherapy apply for oral chemotherapy with no consensus about safe medication practices.	Moderate – using quality checklist for questionnaire surveys. Publication date might not reflect current practice. Not all sites responded. No shared definition of oral chemotherapy. 78% response rate.
Mixed method case study (Greenhalgh *et al.* adapted from Mays *et al.* – Mixed methodology checklist)						
14	**Arber, A. *et al.* (2015)** Do patients on oral chemotherapy have sufficient knowledge for optimal adherence? A mixed methods study	Multisite UK	N=64. N= 32 (50%) male. Tumour type: multiple myeloma. Oral SACT: CTD – cyclophosphamide, thalidomide and dexamethasone. Interviews: one man, one woman.	Self-report questionnaire (n=64) and semi-structured interview (n=2). Questionnaire consisted of 13 fixed choice questions and 2 open ended questions. Five sections of the questionnaire were: confidence in taking OC, knowledge of side effects of OC, knowledge of when to take OC and what to do if side effects occurred and what to do if a dose was missed.	Support at home needs to include primary care practitioners (GPs, practice nurses, pharmacists) so timely support is accessible.	Moderate quality – adapted from Mays *et al.* Patients may overestimate adherence in self-report. Small sample of interviewed patients affecting transferability of findings. Adherence over time not explored.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
15	**Oakley, C., Johnson, J. and Ream, E. (2010)** Developing an intervention for cancer patients prescribed oral chemotherapy: a generic patient diary.	Single site UK	N=8 patients: 5 males. Tumour type: colorectal cancer or lymphoma. Oral SACT: capecitabine. Mean age 65 years. N=9 health professionals: 5 nurses, 4 doctors with 2-10 years' experience working in cancer care.	Developing complex interventions framework underpinned design: literature review, ethnographic study and feasibility study. For feasibility study, diary provided to patients at commencement of treatment and before each subsequent treatment cycle over a 3 month period by clinical nurse specialist.	Ethnographic – ineffective preparation for patients to manage OC due to lack of service structure. Patient adherence to treatment may be promoted through provision of scheduling advice and symptom management guidance. Feasibility - Use of a generic patient diary proved effective and useful for patients. Association demonstrated between symptom management and self-efficacy.	Moderate -adapted from Mays *et al.* Small sample. Small range of cancer type and treatment used. Use of only one cancer centre for both phases of study. Mean age of patients included not representative of younger adults with cancer.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
Qualitative studies (CASP – qualitative study)						
16	**Wu, S. *et al.* (2015)** Lack of congruence between patients' and health professionals' perspectives of adherence to imatinib therapy in treatment of chronic myeloid leukemia: a qualitative study.	Site of treatment not reported. Australia	N=16 patients. 56% male. Tumour type: Chronic Myeloid Leukemia (CML). Oral SACT: imatinib N=10 health professionals. Job role: haematologist (n=4), nurse (n=3) and pharmacist (n=3).	Phenomenological analysis. Nil intervention.	Unintentional non-adherence: forgetfulness. Intentional non-adherence: to reduce dose-dependent side effects and/or insufficient support. Patients with high non-adherence: felt complacent, or received conflicting advice. Health professionals' difficulty in measuring adherence and utilizing patient self-report.	High quality – 9/10 using CASP. Reported data saturation. Good demographic spread. Process of coding described clearly and debated by research team. No measure of non-adherence but rather a context for non-adherence.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
17	**Denois, V. R. *et al.* (2010)** Adherence with oral chemotherapy: results from a qualitative study of the behaviour and representations of patients and oncologists	Multisite France	N=42 patients. 37 female (88%). Tumour type: breast (76%), metastatic colon (14%), adjuvant colon (10%). Oral SACT: capecitabine Age: mean 65.4 N=10 health professionals. Job role: oncologists	Use of several analytical methods but not explicitly stated: comprehensive approach to connect discourses during interviews; content analysis; Nil intervention, questionnaire used to survey patients. Setting: two comprehensive cancer centres.	Diversity in prescribers' practices. Results do not suggest deliberate non-adherence but show poor observance of dose schedule. Patients inability to identify and report important signs of harmful toxicity.	Moderate quality – 6/10 using CASP. Results cannot be generalised due to potential biases from recruitment process. Data analysis not clear.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
18	**Simchowitz, B. *et al.* (2010)** Perceptions and experiences of patients receiving oral chemotherapy	Single site USA	N=15 adult patients or parent of child with cancer. 73% female. 93% Caucasian Tumour type: Not reported. Oral SACT: sunitinib, capecitabine, mercaptopurine, temozolomide, lapatinib and imatinib. Age: mean 56	Methods of analysis not described. Nil intervention.	Participants felt unprepared for commencing oral chemotherapy – specifically managing side effects and techniques to mitigate drug toxicity. Participants suggested more education at prescribing encounter and greater follow-up with healthcare practitioners.	Low to moderate – 5/10 using CASP. Methods of data analysis vague. Participant characteristics grouped, no clear distinction between patient or parent. No reference to diversity of sample. Selection bias as patients selected by own oncologist. Limited number of oral SACT. Participants from single cancer centre.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
Service improvement/observational/implementation/feasibility study/retrospective study (Greenhalgh *et al.* adapted from Gomm)						
19	**Muluneh, B. *et al.* (2018)** Improved adherence rates and clinical outcomes of an integrated, closed-loop, pharmacist-led, oral chemotherapy management program.	Single site USA	N=107 patients 55% female. Tumour type: Haematological malignancies (9 types) and oncological malignancy (13 types). Oral SACT: bosutinib imatinib, nilotinib, ibrutinib, idealisib, sorafenib, dasatinib, bexarotene, capecitabine, everolimus, lapatinib, regorafenib, temozolomide.	Descriptive observational study. Evaluation of an integrated, closed-loop, pharmacy-led oral chemotherapy management program. Specialist pharmacist services offered to patients included: prior authorization, copay assistance, clinical education, clinical and refill follow-up via telephone calls, and home delivery of medications. Outcome measures: Adherence (using patient self-report and medication possession ratio); patient understanding; and patient satisfaction.	Understanding of treatment increased from 43% to 95%. Patient-reported adherence was 86% and 94.7% for the GI/breast and malignant haematology patient populations respectively and validated using medication possession ratio revealing 85% and 93.9% adherence. 350 encounters with a clinical pharmacist, 318 adverse effects reported, and 235 interventions initiated. Increase in achieving early molecular response and major molecular response compared with preintervention historical patient data (early molecular response, 88.9% v 54.8%; P=0.0138; major molecular response, 83.3% v 57.6%; P=0.575, respectively). High levels of patient satisfaction (97.8% patients reporting teaching received was good or excellent).	Moderate – using Gomm. Able to compare findings to historical patient data pre intervention, however no direct comparison as not a controlled sample. Single site study.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
20	**Boucher, J. *et al.* (2015)** A structured nursing intervention to address oral chemotherapy adherence in patients with non-small cell lung cancer.	Single site USA	N=29. 76% female. Tumour type: lung cancer. Oral SACT: erlotinib. Age not reported	Longitudinal, descriptive feasibility study. 4 sessions utilising MOATT* (oral agent teaching tool) delivered by . S1 = patient education + consent to study S2 = (by phone or in person) MOATT S3 = 72-hour phone follow up S4 = End of cycle 1, r/v drug log, MMAS-8 + KRS Outcome measures: Knowledge Rating Scale (KRS) Morisky Medication Adherence Scale-8 (MMAS-8)	Use of MOATT feasible in clinical practice. Adherence scores high (mean 7.12/8) and knowledge scores also high (mean 8.9/10).	Moderate – using Gomm. First study to evaluate MOATT. Findings cannot be generalized beyond similar samples, settings or to other oral agents. Single-arm design: no claim to have improved adherence with the intervention. Only follows participants for 6-8 weeks.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
21	**Koselke, E. A. *et al.* (2015)** Implementation of and satisfaction with an outpatient oral anticancer therapy program.	Single site USA	N=30 providers – Physicians (14), physician assistants (6) and nurse practitioners (10). N=41 patients Tumour type: not reported. Oral SACT: not reported. Age: not reported.	Survey of patients and providers about implementation of an outpatient oral anticancer therapy program. Program involves pharmacist and nurse led medication and adherence education, medication acquisition assistance and side effect management. Providers – online questionnaire using Qualtrics. 5 point Likert type scale, yes/no questions and short answer questions. Questions developed from previous trials examining patient experience. Patients – written questionnaire with reply paid envelopes. 5 point Likert type scale, yes/no questions and short answer questions. Questions developed from previous trials examining patient experience.	Providers divided on which they felt was most important aspect of the program (33% assisting with medicine acquisition, 30% drug interaction screening and 27% reinforcing education). Only 10% of providers felt patient follow-up was important. Overall, providers highly satisfied with program. Patients' strongly felt information received was useful (mean score 4.4/5). Knowledge of when and how to take medication higher after education (4.5 vs 4.1; P=0.035).	Moderate – using Gomm. Poor response rate to patient aspect of study. Response rate for providers of 49.2%. Response rate for patients of 25.5%.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
22	**Holle, L. M., Puri, S. and Clement, J. M. (2015)** Physician-pharmacist collaboration for oral chemotherapy monitoring: Insights from an academic genitourinary oncology practice.	Single site USA	N=20. 100% male. Tumour type: prostate cancer (n=17) and renal cancer (n=3). Oral SACT: abiraterone acetate, bicalutamide, diethyelstilbetserol, estrogens, enzalutamide, flutamide, ketoconazole, nilutamide, prednisone, axitinib, everolimus, pazopanib, sorafenib, sunitinib. Median age 80.	Observational study. Recorded frequency and content of encounters had between pharmacist and patient. Pharmacist provided education, medication therapy management, monitoring for adherence and treatment toxicities and recommended treatment of toxicity and supportive care issues to patients receiving oral chemotherapies.	Over an 18 month period, pharmacist followed 20 patients with a total of 123 encounters. 37.9% encounters were collaborative clinic visits 36.3% were telephone follow-ups 14.5% solo clinic visits 8.9% emails to providers 2.4% email follow-up. Median 5 encounters per patient. Majority of recommendations from encounters were for lab monitoring (25.2%) but 6.9% of encounters resulted in advice to discontinue treatment and 3.8% of encounters resulted in referring a patient for evaluation e.g. attending hospital for assessment.	Low quality – using Gomm All male patients. Small sample. From one hospital. No generalizable results.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
23	**Bordonaro, S. *et al.* (2014)** Effect of a structured, home-based cancer treatment program for the management of patients on oral chemotherapy	Multi-centre Italy	N=62 patients. 26 Male. Cancer types: breast, colon, lung, renal, astrocytoma, hepatocellular, gastrointestinal stromal tumour, pancreatic, uterine, ovarian, Kaposi's sarcoma, multiple myeloma, bladder and occult primary cancer. Mean age 67.8. Oral SACT: capecitabine, vinorelbine, imatinib, sunitinib, sorafenib, temozolomide, ibandronate.	Observational, longitudinal study. Weekly home visits with a trained nurse who delivers home-based chemotherapy and reviews patient compliance and treatment toxicity. 24-hour telephone available for patients' emergency calls. Outcome measures: EORTC QLQ-C30 (Baseline and 3 months after enrolment) Healthcare utilisation. X2 self-designed questionnaire – one examining satisfaction with the programme, the other asking about acceptability of oral chemotherapy.	Total of 460 home visits performed. Significant improvements in symptom and physical functioning ($P<0.05$) and in several individual items. Acceptability of OC high, all patients finding it more convenient and 88.7% considering it as effective as intravenous chemotherapy. 96.7% patients found home monitoring useful. All patients report taking medications as indicated. 67% (42) of patients needed help from care to take OC. Reported cancer/treatment side effects decreased from 68.9% at baseline to 62.1% at 6 months.	Low quality – using Gomm Word effect should not have been used in title – no investigation of cause and effect as no control group. Association in place demonstrating effect over time which might be attributed to intervention. Resource intensive intervention.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
24	**Deutsch, S. *et al.* (2014)** Utilization patterns for oral oncology medications in a specialty pharmacy cycle management program	Single site USA	N=557. 292 (52%) male. Tumour type: cutaneous T-cell lymphoma, chronic myelogenous leukemia, lung, breast, renal and hepatic. Oral SACT: bexarotene, dasatinib, erlotinib, nilotinib, pazopanib, sorafenib, sunitinib and vorinostat. Overall age of 60.	Retrospective review of patient-reported data. Aim to evaluate utilization patterns of oral oncology medication within a cycle management program (CMP) including adverse event occurrences, medication discontinuation and adherence markers. Intervention: CMP provides specialized counselling and monitoring for patients taking select oral oncology medications to improve their therapy experience.	Common trend throughout results is prevalence and influences of adverse events (AEs) on medication utilization – AEs attribute 39% of discontinuations and 28% of missed/held doses. Medication should therefore be dispensed by pharmacies with specialized oncology experience.	Moderate quality – using Gomm. No reported limitations. Only for patients taking select oral SACT due to incidence of side effects in first three months of therapy.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
25	**Wong, S. *et al.* (2014)** Implementation and preliminary outcomes of a comprehensive oral chemotherapy management clinic	Single USA	N=30. 70% female. Tumour type: breast, colon, rectal, lung. Oral SACT: capecitabine (53%), erlotinib, everolimus, hydroxyurea, lapatinib, lenalidomide, neratinib, tamoxifen. Mean age 64.5	Retrospective, observational study. Report of the development of an oral chemotherapy management clinic (OCM) with medication therapy management (MTM). Patients have initial face to face visit at OCM clinic, a telephone follow-up days 3-5 and days 7-10 concluded with a 3 month follow-up OCM clinic visit. Outcome measure: Zung Self-Rating Depression Scale questionnaire.	OCM resulted in decreased rates of adverse events including nonadherence, drug to drug reactions and medication errors. 70% of OCM clinic interventions were associated with positive outcomes with 67% and 35% resulting in cost avoidance and savings respectively.	Moderate – using Gomm 70% female sample. Range of cancer types and treatments. Conclusions can't be justified by data presented.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
26	**Krolop, L. *et al.* (2013)** Adherence management for patients with cancer taking capecitabine: a prospective two-arm cohort study	Multisite Germany	N=73. 44% female. Cancer types: breast, colorectal, gastric, oesophageal, ovarian, unknown primary, pancreatic, endometrial. Oral SACT: Capecitabine. Age ranges <50 (n=11), 51-60 (n=21), 61-70 (n=20), 71-80 (n=15), >80 (n=6).	Claims to be prospective two-arm cohort study – in reality is an interventional study. Participants given oral and written pharmaceutical care. Adherence assessed using MEMs. Patients identified as initially non-adherent given additional adherence support. Outcome measures: Adherence using MEMs.	58 patients initially adherent and 15 non-adherent. Mean daily adherence of initially non-adherent patients increased from 85.7% to 97.6% during first 6 cycles. Initially adherent patients maintained mean daily adherence of 100%. Daily adherence not associated with sociodemographic and disease-related factors. No patient was non-persistent.	Low quality – using Gomm. Limitation - although described as a cohort study, this is in fact an interventional study. Small sample of initially non-adherent patients.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
27	**Bhattacharya, D. *et al.* (2012)** Capecitabine non-adherence: exploration of magnitude, nature and contributing factors.	Single site UK	N=43. 55.8% female. Tumour type: colorectal (81.4%) and breast (18.6%). Oral SACT: capecitabine.	Descriptive, prospective, observational study. Nil intervention. Questionnaire used to survey patients and medical notes accessed. Outcome measures: Belief about Medicines Questionnaire (BMQ); Satisfaction with Information about Medicines Scale (SIMS).	Participants had unmet information needs specifically regarding monitoring efficacy and determination of therapy duration. Health professionals may wish to consider greater focus on involving patients in monitoring their care.	High quality – using Gomm. Small sample from one hospital site.
28	**Sommers, R. M., Miller, K. and Berry, D. L. (2012)** Feasibility pilot on medication adherence and knowledge in ambulatory patients with gastrointestinal cancer	Single site USA	N=30. 76% male. Tumour type: gastrointestinal cancer. Oral SACT: not clearly reported but includes temozolomide, capecitabine, sorafenib, sunitinib, everolimus. Mean age 53.	Descriptive, feasibility pilot study. All patients receive verbal and written education, nurse-initiated phone call within 72 hours of receiving education at outpatient department. Patients complete home diary and complete eight-item Morisky Medication Adherence Scaled at end of first cycle. Outcome measure: MMAS-8.	23 participants verbalised satisfaction with follow-up telephone call and teaching. Most participants experienced side effects within 72 hours of commencement of treatment. Early reporting of side effects and symptoms critical to patient safety.	Moderate – using Gomm. Small sample over a very short period - adherence may have declined if patients continued longer. Principal investigator administered medication adherence scale - possibility of response bias. High risk patients for adherence issues may not speak English but not included in study.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
29	**Cirillo. M. *et al.* (2011)** Management of oral anticancer drugs: feasibility and patient approval of a specific monitoring program	Single site Italy	N=81. 46% male. Tumour type: breast, colorectal, stomach, liver, lung, kidney, pancreas, stromal, small bowel, anus. Oral SACT: capecitabine, lapatinib, sorafenib, erlotinib, capecitabine and vinorelbine, imatinib, capecitabine and lapatinib, vinorelbine, gefitinib, sunitinib, everolimus. Median age 68 years	Observational study, service evaluation. Implementation of a new nurse monitoring program: Following physician appointment, nurse gives education, administers questionnaire, treatment diary and toxicity self-report form. Phone calls to patient planned on days 7 and 14. End of cycle 2, second questionnaire to evaluate levels of satisfaction with program. Outcome measures: Self-designed questionnaire. NCI-CTCAE 3.0 used to grade toxicities.	Improvement to knowledge levels on questionnaire before and after education on all 6 topic areas. No reports of statistical testing or significant differences. 78% planned phone calls made. 6% of patients required unplanned admission due to toxicity. 51% complete approval, 46% moderate approval.	Moderate – using Gomm. Not clear how confidence assessed – reference to figure demonstrating confidence is absent from publication. No comparative arm. 68 patients completed 2 cycles of treatment and period of observation.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
30	**Khandelwal, N. *et al.* (2011)** Impact of clinical oral chemotherapy program on wastage and hospitalisation	Single USA	N=1069 patients. Gender not reported. Cancer type not specified. Oral SACT: sorafenib, sunitinib or erlotinib. Age not reported.	Retrospective observational data analysis of patients receiving care through the CMP. The CMP: intensive oncology care including education and supervision. Patients contacted day 10 and 20 when commencing treatment. Contacted monthly thereafter. Patients given half cycle supply at a time, if demonstrates adherence and lack of serious adverse effect, rest of prescription dispensed.	Retrospective test-control study: patients before CMP initiation used as control group. Medication wastage due to early discontinuations lower in CMP group. If split-fill (half supply of cycle) available, CMP could have saved over approximately $900 per patient. Linear probability regression model showed CMP group 2.9% probability for reduction in hospital admissions. Therefore, combined cost savings (reduced wastage and hospital admissions) saving $1,374 per patient.	Low to moderate – using Gomm. Samples not necessarily similar (CMP vs Non-CMP) – propensity score matching method used.

#	Study (author, date, title)	Study site (country)	Sample (Size, gender, tumour type, treatment type, age)	Study design and Outcome measures (intervention)	Main findings	Strengths and Limitations (quality appraisal)
31	**Simons, S. *et al.* (2010)** Enhancing adherence to capecitabine chemotherapy by means of multidisciplinary pharmaceutical care	Multisite Germany	N=48. 77% female Cancer types: colorectal and breast. Oral SACT: capecitabine. Age: Mean 62.3	Non-randomised, prospective, multi-centre observational cohort study with control group across three hospital sites and three ambulatory oncology practices. Intervention group, studied after control group, received intensified pharmaceutical care consisting of a combination of written and spoken information provided by pharmacists.	Intervention led to improvement of both overall and daily adherence – (96.8% vs 87.2%, p=0.029). Results demonstrate a potential of intervention to improve treatment outcome of oral chemotherapy.	Low to moderate using Gomm. Statistical difference between groups before study commencement.

2.6.4 Content analysis

A total of 23 different measures, questionnaires and data collection tools were identified within the retrieved sources. Table 2.7 provides a summary of these measures.

Table 2.7 Summary of identified measures, questionnaires and data collection tools

Article Number	Measure
1	Beck Depression Inventory-II (BDI-II) Memorial Symptom Assessment Scale (MSAS) Adherence measured using: patient self-report when questioned by research assistance pharmacy records medical records
2	Center for Epidemiological Studies Depression Scale (CES-D) Symptom Experience Inventory (SEI) Adherence self-report
4	Self-reported adherence using a specifically designed questionnaire with added items surrounding side effects, attitude towards breast cancer, patients specific treatment, knowledge about breast cancer and quality of life Assessed prescription refill and calculated medication possession ratio (MPR)
6	National Cancer Institute Common Toxicity Criteria (NCI-CTC) Hospital Anxiety and Depression Scale European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC-QLQ-30)
11	Morisky Medication Adherence Scale (MMAS) Multidimensional Sale Of Perceived Social Support (MSPS) Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36; version 1) FACIT fatigue scale Psychological General Well-Being Index (PGWB-S)
14	Self-reported questionnaire
15	Memorial Symptom Assessment Scale Short Form (MSAS-SF) Cancer Behaviour Inventory Brief Form (CBI-B)
19	Adapted Morisky Medication Adherence Scale-8 (MMAS-8 Knowledge Rating Scale (KRS)
22	Patient self-report of adherence by pharmacist asking patient
23	30-item European Organisation for Research and Treatment of Cancer (EORTC-QLQ-C30 version 3.0) Self-administered questionnaire specifically designed to identify adherence to therapy and degree of satisfaction with oral chemotherapy compared to intravenous therapy. Second questionnaire specifically designed to estimate clinical, social and

Article Number	Measure
	economic impact of home-based care
25	Zung Self-Rating Depression Score Questionnaire
26	Medication Event Monitoring (MEMS) (electronic recording of date and time of every opening)
27	Beliefs about Medicines Questionnaire (BMQ) Satisfaction with Information about Medicines (SIMS) Medication Adherence Reporting Scale (MARS)
28	Eight-item Morisky Medication Adherence Scale (MMAS-8) Medication diary
29	Self-designed questionnaires
31	Electronic medication event monitoring system (MEMS)

Microelectromechanical systems (MEMS), patient self-report and researcher self-designed questionnaires were not relevant to this review. The NCI-CTC is a grading tool used to identify the severity of many common treatment toxicities, so used as a point of reference as opposed to investigation. Patients attending the OEC could be offered a range of oral SACT including cytotoxic agents, targeted cytostatic agents and anti-endocrine hormone therapies. Each of these treatments are associated with different side effect profiles. The aim and research questions guiding this study focus on the experience of individuals taking an oral SACT within the context of the OEC. As a range of oral SACT will be observed, a specific side-effect patient reported outcome measure was not deemed relevant, rather this study required a non-specific means to monitor experience of a range of possible side effects.

The remaining 19 questionnaires were assessed for relevance.

The 19 questionnaires can be categorised as investigating the following:

- Medication adherence (MEMS; MARS; MMAS; MMAS-8)
- Experience of side effects (MSAS; MSAS-SF; SEI)
- Quality of life (EORTC-QLQ-C30; SF-36 version 1; CBI-I)
- Experience of fatigue (FACIT)
- Depression (BDI-II; CES-D; PGWB-S; Hospital Anxiety and Depression Scale; ZS-RDSQ))
- Belief about medicines (BMQ)
- Satisfaction with information and patient knowledge (SIMS; KRS)
- Level of social support (MSPS)

To further evaluate the validity of these questionnaires, they were translated into a matrix where they could be rated for validity against the aims and objectives of this PhD study (Table 2.8).

Table 2.8 Validity by relevance of identified tool against aims and objectives of this review

	What are the experiences of patients receiving oral SACT?	How satisfied are patients with the clinical care they have received?	How useful is the oral education clinic (OEC) for patients?	What strategies do patients use to manage both their oral SACT and treatment related toxicity?
EORTC-QLQ-30	SR	U	U	U
ZS-RDSQ	SR	U	U	U
BMQ	**R**	U	SR	SR
SIMS	SR	**R**	**R**	U
MARS	U	U	SR	**R**
MMAS	U	U	SR	**R**
MMAS-8	U	U	SR	**R**
MSPS	SR	U	U	U
SF-36; version 1.0	SR	U	U	U
FACIT	SR	U	U	U
PGWB-S	SR	U	U	U
HADS	SR	U	U	U
MSAS-SF	SR	U	U	SR
CBI-B	SR	U	U	U
CES-D	SR	U	U	U
SEI	SR	U	SR	SR
BDI-II	SR	U	U	U
MSAS	SR	U	U	SR
KRS	U	SR	SR	U

KEY: R=related; SR=slightly related; and U=unrelated

Measures were evaluated as related, slightly related and unrelated. The following measures related to the aims of the project and may be used in this study to collect survey date from PWC:

- Belief about Medicines Questionnaire (BMQ)
- Satisfaction with Information about Medicines (SIMS)
- Medication Adherence Reporting Scale (MARS)
- Morisky Medication Adherence Scale (MMAS) and MMAS-8

While these measures have been identified as related to the aim of the study, the evaluation, validation, integration and adaptation of these measures into the patient questionnaires will be explored in the methods chapter of this thesis.

2.6.5 Thematic analysis

Five key themes were identified from the retrieved sources: processes for the delivery of oral SACT care; approaches to models of care; patient education is paramount; the challenge of adherence; and supportive interventions provide opportunity to assess treatment related toxicity.

2.6.5a Processes for the delivery of oral SACT care

Weingart *et al.* (2007) identified a lack of a shared definition of oral SACT and prescribing practices, with the majority of cancer centres using handwritten prescriptions (n=29) and a lack of standardised processes to obtain informed consent. Roop and Wu (2014) also reported that only 51% (294/577) of respondents work in environments with specific policies, procedures and resources for patients prescribed oral SACT. Furthermore, health professional study participants described oral SACT prescribing processes as less rigorous than IV SACT, with only two of fifteen regional cancer centres having guidelines on oral SACT dispensing procedures (Ahmad *et al.*, 2015).

Conde-Estevez, Salas and Albanell (2013) described three levels of care for patients receiving oral SACT in Spain. Level 1 – no specific practice, Level 2 – visit with pharmacist giving written information and monitoring adherence and Level 3 – Level 2 + electronic SACT ordering and extra safety practices. 37.2% of 86 pharmacy services provided Level 1 care, 44.2% Level 2 and 18.6% Level 3.

Kav *et al.* (2008) reported findings of an international survey of oncology nurses (n = 1115 from 15 countries) about oral SACT using a multiple-choice questionnaire with one open-ended question asking nurses for suggestions about improving education, adherence and follow-up care. 28.8% (n = 394) of nurses suggested a need for professional education about oral SACT.

2.6.5b Approaches to models of care

31 studies reported 18 different models of care. Most of these interventions (ten) were nurse-delivered, two utilised both nurses and pharmacists, and six were pharmacist-delivered.

Nursing staff roles included providing education (Cirillo *et al.*, 2011; Williams *et al.*, 2011; Ziller *et al.*, 2013; Schneider, Adams and Gosselin,2014; Boucher *et al.*, 2015), reinforcing education delivered by clinicians (Molassiotis *et al.*, 2009), providing tailored adherence support (Spoelstra *et al.*, 2013a; Ziller *et al.*, 2013; Bordonaro *et al.*, 2014; Schneider, Adams and Gosselin, 2014) and assessing treatment toxicities through follow-up contacts (Molassiotis *et al.*, 2009; Cirillo *et al.*, 2011; Sommers, Miller and Berry, 2012; Moon *et al.*, 2013; Ziller *et al.*, 2013; Bordonaro *et al.*, 2014; Boucher *et al.*, 2015). In one study, participants receiving nurse education reported significant

alleviation of symptom occurrence and severity and appreciated closer follow-up (Williams *et al.*, 2001); however, this was a small-scale pilot study and did not achieve statistical significance. Cirillo *et al.* (2014) reported that 90% patients felt confident with oral SACT following education from nurses regarding treatment dosage, schedule, toxicity and unplanned interruptions.

Two studies had both pharmacists and nurses working together to support patients (Khandelwal *et al.*, 2011; Koselke *et al.*, 2015). Khandelwal *et al.* (2011) aimed to evaluate the effect of a nurse- and pharmacist-led oral SACT programme on the volume of drug wastage and hospital admissions. This study found that by using split-fill prescriptions (where patients receive the second half of the prescription if they are tolerating treatment), through the nurse pharmacist program there could be cost savings of up to $900 per patient. There was also a reduction (2.9% linear probability) of hospital admissions in patients receiving the nurse- and pharmacist-led intervention; however, samples between intervention arm and control arm were not similar and no propensity score matching method was reported.

Koselke *et al.* (2015) evaluated the implementation of an oral SACT program where nurses and pharmacists delivered medication and adherence education, medication acquisition assistance and side effect management. Providers (n=30, response rate 49.2%) and patients (n=41, response rate 25.5%) were both surveyed. Overall, providers were highly satisfied with the program. 10% felt patient follow-up was important. Patient's strongly felt information received was useful (mean score 4.4/5) and knowledge of when and how to take medication was higher following education (4.5 vs 4.1; P=0.035); however, these findings need to be considered in the context of a low response rate.

Six studies reported pharmacist-led programmes. Roles of the pharmacist were identified in delivering education (Simons *et al.*, 2010; Krolop *et al.*, 2013; Deutsch *et al.*, 2014; Wong *et al.*, 2014; Holle, Puri and Clement, 2015; Muluneh *et al.*, 2018), monitoring adherence and treatment toxicities (Simons *et al.*, 2010; Deutsch *et al.*, 2014; Holle, Puri and Clement, 2015; Muluneh *et al.*, 2018) giving additional adherence support to patients identified as non-adherent (Krolop *et al.*, 2013; Muluneh *et al.*, 2018), recommending treatment of toxicities, providing supportive care (Simons *et al.*, 2010; Deutsch *et al.*, 2014; Holle, Puri and Clement, 2015; Muluneh *et al.*, 2018), and participating in follow-up contact (Simons *et al.*, 2010; Deutsch *et al.*, 2014; Wong *et al.*, 2014; Muluneh *et al.*, 2018).

No studies compared effectiveness between nurse-delivered and pharmacist-delivered interventions. All studies reported a positive impact of the various methods of delivery for patients receiving oral SACT. Some reported feasibility in the clinical setting where the model of care worked

appropriately (Sommers, Miller and Berry, 2012; Cirillo *et al.*, 2014: Boucher *et al.*, 2015) and some reported an increased knowledge in patients receiving an oral SACT (Boucher *et al.*, 2015).

2.6.5c Patient education is paramount

Patient education was considered to be a key component of most interventions, but the content, quality or duration of education delivery was rarely reported. Boucher *et al.* (2015) utilised the Multinational Association for Supportive Care in Cancer Oral Agent Teaching Tool (MASCC MOATT) (Kav *et al.*, 2010), a four-part structured approach to delivering patient education involving assessment questions, points for discussion, drug-specific information and evaluation questions. Its use aimed to promote medication adherence. Adherence was measured using Morisky Medication Adherence Scale-8 and knowledge by an author-designed knowledge rating scale (KRS); validation of the KRS was not reported. Results for both adherence and KRS were analysed numerically and interpreted as high by predetermined grading's (Boucher *et al.*, 2015. *P.* 386) reporting high levels of adherence to treatment and high levels of knowledge.

Patient education reported by Schneider, Adams and Gosselin (2014) was tailored to individual need. Advanced practice nurses in collaboration with the patient identified individual barriers to taking oral SACT with a view to developing strategies to promote adherence, guided by the Self-Regulatory Model of Antiretroviral Adherence (Reynolds, 2003). Education reported by Khandelwal *et al.* (2011) and Simons *et al.* (2011) was not described, but referred to as intensified and superior pharmaceutical support involving both oral and written information (Simons *et al.*, 2011). Education delivered by a nurse was focussed (Williams *et al.*, 2011) in response to patient reported symptom and experience.

Deficits in knowledge were identified regarding when to take SACT, what to do when a patient forgets to take their dose and when to report side effects (Arber *et al.*, 2014). Statistical analysis identified these deficits were associated with being female and from an ethnic minority. Further deficits in the identification and reporting of toxicity was apparent in several studies (Denois *et al.*, 2010; Oakley, Johnson and Ream, 2010; Simchowitz *et al.*, 2010; Arber *et al.*, 2014) where patients were unsure of how severe a side effect should be before they should report it. Bhattacharya (2012) identified only 65% of participants were completely satisfied with the information given, echoing the findings by Simchowitz *et al.* (2010) where patients reported feeling unprepared to commence oral SACT and desired more comprehensive education. Some patients were identified to be at higher risk for complication or problems with their SACT treatment. Arber *et al.* (2015) directly recommended that a focus should be placed on high-risk patients when delivering patient education and considering follow-up, identifying high-risk patients and screening for anxiety and depression

secondary to its links with adherence. The home-care program implemented by Bordonaro *et al.* (2014) was found to be particularly beneficial for patients with co-morbidities or those with a lower performance status enabling them to continue oral treatment.

Much of the evidence reviewed about ongoing education specifically focused on adherence and safety outcomes. Adopting a tailored approach was commonly reported, and the importance of continued and reinforced patient education was highlighted. Boucher *et al.* (2015) highlighted that a role of the nurse is to reinforce education, particularly in the first 6-8 weeks of treatment commencement, which was also recommended by Wu *et al.* (2015). Tailored approaches recommended by Schneider *et al.* (2014) and Cirillo *et al.* (2014), acknowledged that patients' needs vary at different times in the treatment trajectory, and responding to individual needs might affect adherence rates. Furthermore, Arber *et al.* (2015) recommends that adherence education during treatment have a more central role. Spoelstra *et al.* (2013) and Krolop *et al.* (2013) recommended that support should focus on the management of side effects and strategies to enhance adherence, such as medication reminders.

2.6.5d The challenge of adherence

Many of the studies aimed to promote adherence to oral SACT and reported adherence as an outcome. Approaches and tools used to measure adherence varied including self-report, medication electronic monitoring systems (MEMS) and pharmacy refill rates. Conde-Estevez, Salas and Albanell (2013) identified that 37.2% of 86 pharmacy services in Spain did not monitor adherence. Ahmed *et al.* (2015) identified few tools consistently used to measure or promote adherence. Calendars, diaries, blister packs, manual pill counts and patient discussion were reportedly used across 13 regions in Canada.

Schneider, Adams and Gosselin (2014) measured adherence by using both patient self-reporting of adherence and pharmacy refill rate. Although this concept is debated, significant positive correlation ($p=0.0048$) between the two methods suggests that self-report of adherence can be used as an outcome measure. Similarly, Muluneh *et al.* (2018) used both self-report and medication possession ratio with minimal differences between adherence rates.

Krolop *et al.* (2013) used Medication Event Monitoring System (MEMS) to identify initially non-adherent patients. If patients were identified as non-adherent, extra support was given with the authors reporting it to enhance adherence; however, the patients identified as non-adherent were a small sample (n=15). Khandelwal *et al.* (2011) were the only authors to report the health economics of non-adherence. In their method of care delivery, patients were dispensed a half supply of medication. On review and monitoring, if patients were found to be adherent and not struggling

with treatment toxicity, the remaining prescription was dispensed. Eight sources reported five reasons for non-adherence: treatment toxicity (Decker *et al.*, 2009; Denois *et al.*, 2010; Sommers, Miller and Berry, 2012; Spoelestra *et al.*, 2013a; Roop and Wu, 2014; Deutsch *et al.*, 2015; Wu *et al.*, 2015), forgetfulness (Decker *et al.*, 2009; Bhattacharya *et al.*, 2012; Sommers, Miller and Berry, 2012; Cirillo *et al.*, 2014; Deutsch *et al.*, 2014; Roop and Wu, 2015), deficits in knowledge (Denois *et al.*, 2010; Spoelestra *et al.*, 2013a; Spoelestra *et al.*, 2013b; Schneider, Adams and Gosselin, 2014; Arber *et al.*, 2015), insufficient support (Schneider, Adams and Gosselin, 2014; Wu *et al.*, 2015) and system barriers (Spoelestra *et al.*, 2013b; Roop and Wu, 2014; Schneider, Adams and Gosselin, 2014; Wu *et al.*, 2015).

2.6.5e Supportive interventions provide opportunity to assess treatment related toxicity

Implementation of a specific method of care delivery and/or monitoring and follow-up enabled the identification and management of treatment related toxicities (Williams *et al.*, 2011; Cirillo *et al.*, 2014; Wong *et al.*, 2014; Holle, Puri and Clement, 2015). Using continued contact by telephone following treatment initiation, Sommers, Miller and Berry (2012) reported that treatment toxicities within the first 72 hours of treatment were common. Decker *et al.* (2009) identified the benefit of an automatic voice response system in flagging patients with treatment toxicities. If patients had side effects greater than four on a Likert-type rating scale for three consecutive weeks, a phone call from a nurse was triggered. In addition, Sommers, Miller and Berry (2012) used a patient satisfaction survey. They reported that nurses identified the need for side effect management in eight out of 30 patients within 72 hours of commencing treatment.

Molassiotis *et al.* (2009) identified statistically significant improvements between groups concerning treatment related toxicities, notable particularly in the first two cycles of treatment. A statistically significant difference was also observed between groups for unplanned service utilization. Side effects/adverse events (AE's)/treatment toxicities and use of unscheduled care were referred to in the majority of papers included in this review and are a key factor in the safe management of patients taking an oral SACT. Early reporting of side effects and symptoms are critical to patient safety. Sommers, Miller and Berry (2012) identified that most participants experienced AE's within 72 hours of commencement of treatment, similar to the findings of Deutsch *et al.* (2014) where 76% of AE's occurred in the first month.

It is critical for patients to report side effects that cannot be safely managed at home and require medical intervention. Participants were either unprepared to manage side effects (Simchowitz *et al.*, 2010) or were reluctant to report side effects due to fear of dose reduction or treatment cessation (Denois *et al.*, 2010); however reasons for non-reporting of side effects were not explored.

Patients that received ongoing care to monitor and manage side effects were reported to tolerate treatments for a longer duration (Simons *et al.*, 2009; Krolop *et al.*, 2013) and have improved overall survival (Schneider *et al.*,2014). Molassiotis *et al.* (2009) reported several patient outcomes on the effectiveness of a homecare nursing program. Through weekly follow-ups and the use of validated self-report tools in a sample of 164 patients, the research team demonstrated that home care nursing program assisted patients to managed treatment of adverse events more effectively than that of those receiving standard care. Fewer toxicities were observed in the experimental group, but this did not equate with an improved quality of life despite unplanned service utilisation being lower in the home care group. Anxiety levels in both participant groups improved over time, but notably quicker in the homecare group.

Quality of life was found to improve over time after commencing treatment by Bordonaro *et al.* (2014) alongside an improvement in physical function and cancer-related symptoms. Of the 62 participants in this study, nine emergency admissions were required; however notably only four were related to cancer or it's treatment, and all were managed as day cases. Cirillo *et al.* (2014) demonstrated the effective role of the nurse in assisting in managing AE's with 19% of AE's being resolved by a nurse with only 14% requiring medical intervention, of the total 81 participants enrolled, only five patients resulted in unplanned admissions. Oakley, Johnson and Ream (2010) found that over time, patients gained confidence in managing their treatment with an association demonstrated between symptom management and self-efficacy.

2.7 Discussion

The most commonly described model of care for patients prescribed oral SACT was standardised, patient-tailored education delivered by non-medical health professionals, which often included ongoing monitoring of self-administration of oral SACT and treatment-related side effects.

Research that evaluates models of care for patients receiving oral SACT is lacking. Few high-quality randomised controlled trials were identified in this review; which meant it was not possible to recommend one model of care or equitably evaluate the effectiveness of interventions described. Further, various outcome measures were reported leading to difficulties in comparing effectiveness of interventions.

Internationally practice is variable (Weingart *et al.*, 2007; Kav *et al.*, 2008) and to date some countries still require standardised practices (Conde-Estevez, Salas and Albanell, 2013; Ahmad *et al.*, 2015) and considering the NPSA alert released in the UK (NPSA, 2008) it is understandable that many health care services have opted to implement different models of care in response to patient need

rather than model upon inadequate evidence. Few of the safeguards used for IV SACT were translated to oral SACT services (Weingart *et al.*, 2007) in the studies reviewed, suggesting policies and procedures should be standardised based on the best available evidence.

The importance of education for patients receiving oral SACT is widely-reported (Smith *et al.*, 2004). While it may be feasible to implement standardised patient education, for example using the MASCC MOAT (2015) template, health professionals involved in delivering education should remember that individual learning styles and education needs vary among patients (Blanchard and Cox, 2014). Therefore, a patient-tailored approach to providing education about oral SACT is likely to be needed alongside the use of standardised approaches, to ensure optimal patient outcomes (Schneider, Adams and Gosselin, 2014).

The goals of patient education should remain the same: to help patients understand both their illness and its management, while maintaining safe treatment and a personal sense of control (Alexander *et al.*, 2006; Blanchard and Cox, 2014;). As several studies in this review have reported patient knowledge deficits (Spoelestra *et al.*, 2013a; Spoelestra *et al.*, 2013b; Schneider, Adams and Gosselin, 2014), findings in keeping with other published literature (Simchowitz *et al.*, 2010; Bhattacharya *et al.*, 2012; Ziller *et al.*, 2013; Arber *et al.*, 2015) it is vital approaches to thorough and effective patient education are further researched and implemented.

Under-adherence to oral SACT has been reported in a number of studies (range of 20-80%) (Spoelstra and Given, 2011), while over adherence has also been reported (Mayer *et al*., 2009). Several factors may contribute to non-adherence (Bourmaud *et al.*, 2015). Optimal adherence to oral SACT is associated with a higher level of satisfaction about information received (Efficace *et al.*, 2012); therefore, effective patient education about oral SACT might improve adherence-related outcomes.

It has been proposed that in order to maintain an optimum therapeutic dosage of an oral SACT a multidisciplinary approach is required (Vioral *et al.*, 2014). This review has demonstrated the role of both nursing and pharmacy staff in managing the care of patients receiving an oral SACT. Nursing staff are key health professionals in managing the care of patients receiving an oral SACT with patients reporting confidence in the education delivered by nurses (Cirillo *et al.*, 2014) and nurses identifying need for side effect management (Sommers, Miller and Berry, 2012). Pharmacists were also reported to have a key role in identifying significant adverse effects (Deutsch *et al.*, 2014; Holle, Puri and Clement, 2015) and facilitating inter-health professional communication (Deutsch *et al.*, 2014). Multidisciplinary pharmaceutical care has further been shown to increase the probability of continued treatment with capecitabine (Simons *et al.*, 2010). While the education and training of

pharmacists predominantly focusses on pharmacology, pharmacodynamics, pharmacokinetics and pharmacy practice, findings of this review suggest their valuable role in patient education.

No standardised model for continued care/follow-up contact has been identified. Vioral *et al.* (2014) and Wood (2012) argue for follow-up contact, e.g. by telephone, to improve patient outcomes. This review identified some evidence supporting the use of continued care to improve outcomes in patients prescribed oral SACT; however, studies described various modes of providing ongoing care and assessment. Within these studies it is difficult to determine which method of follow-up could serve as best practice due to there being no randomized controlled trial specifically exploring effective follow-up care; however all studies demonstrated its importance, and the benefit and feasibility of implementation, which was most commonly by telephone.

The strengths of this review include a systematic approach to identifying studies addressing the management of patients receiving an oral SACT. The search was conducted in collaboration with the research team and rigorous reviewing methods were implemented. Limitations of this review are secondary to a small number of studies, most of which were descriptive with few high-quality intervention studies identified. Further, across the 31 studies, a range of outcome measures were used by researchers preventing a direct comparison of outcomes, and thus the development of a recommendation for a gold standard model of care.

The majority of studies included in this review were observational, implementation and feasibility studies. While an attempt has been made to identify effective models of care for managing patients receiving an oral SACT, despite a systematic search strategy there is a substantial lack of high-quality RCTs evaluating care interventions. A total of four randomised controlled trials were identified, but these studies were small and use of different outcome measures made it difficult to compare the effectiveness of interventions.

2.8 Implications

Health professionals managing the care of patients receiving oral SACT should assess their patients for comprehension of patient education and ability to manage at home. Strategies to promote adherence and self-management should be discussed, promoted and reinforced. A model incorporating continued care contact might improve patient outcomes and experience however little research demonstrated how receiving follow-up care can impact the patient journey. Education can be delivered within an acute hospital setting, but nurses should consider the role of follow-up care to provide patients with ongoing support. As the research questions of this PhD study include aspects of both patient and health professional experience, a key line of enquiry should include the

perspective of providing follow-up care and the proposed benefits this might have to both patients experience and health professionals assurance of safe oral SACT management.

Nursing and pharmacy professionals should work together to both deliver education, but also support patients in taking their oral SACT. Adherence may be a challenge for patients with complex regimens and the requirement to take oral SACT on a regular basis, how a person with cancer manages this level of complexity is under-reported in the literature and there is a need to identify the coping strategies or techniques used by individuals taking these treatments. Education should encompass strategies and approaches to both assist patients to take their oral SACT correctly, but also implement safe guards to prevent non-adherence, such as development of routine or the use of reminders. Patients taking an oral SACT should be assessed for adherence and counselled in how to trouble shoot or seek help appropriately, however there is no clear recommendations as to whether this information should be repeated at future encounters or how best this counselling can be assimilated.

Finally, health professionals should recognise where safeguards applied to IV SACT have not yet been translated to oral SACT care. Local health systems should ensure they have appropriate policies for ensuring the safe care of patients receiving an oral SACT. Feasibility studies have suggested a positive impact of various models of care; however, there is a need for high-quality, randomised controlled trials to test the effectiveness of models of care for supporting patients receiving oral SACT. Over-arching implications of this review highlight the need to identify and investigate the experience of an individual receiving patient education and support through the OEC, but also the health professional experience of delivering support to identify how best to safely support individuals receiving an oral SACT.

2.9 Conclusions

Patients benefit from tailored education delivered by pharmacy and/or nursing staff and continued care contact is indicated to be effective in assisting patients with adherence to treatment and managing treatment related toxicities. While no standardised approach to care exists or has been recommended, several approaches have been detailed and the findings suggest the approach should encompass tailored education, delivered by nurses or pharmacists, with regular continued care support. While this review could not identify a gold standard model of care, further research is required to help determine what is or are the most effective and feasible models of care. This study therefore will explore both the patient and health professional experience of involvement with the OEC and aim to describe in detail the patient experience of receiving education through the OEC, the

experience of taking an oral SACT, and the perspectives of health professionals involved in managing this patient group. The next chapter will present the methodology and methods used to undertake this research.

Chapter three: Methodology and Methods

3.1 Chapter outline

The following chapter will present both the methodology and methods used to conduct this PhD study. The justification for using a mixed methods approach will be discussed including an overview of mixed methods methodology and its philosophical underpinnings. Details of all methods used will be presented including design of study tools and analysis of data. The chapter will close with a summary of how integration of qualitative and quantitative data sets was achieved.

3.2 Methodological approach

3.2.1 Justification for using mixed methods

The aim of this study was to explore the perceptions and experience of patients receiving oral systemic anti-cancer treatments (SACT) and to consider the views and insights of key health professionals to inform models of care. To provide an in-depth and grounded understanding, several approaches to data collection and analysis were required.

In recent decades there has been a rise in complexity of healthcare systems (Halcomb and Hickman, 2015) therefore when conducting research, careful choice of design and method is essential to ensure rigour and quality. Mixed methods was chosen as a methodology for this study for a number of key reasons. Firstly, as highlighted in the background and systematic review chapters, very little is known about the patient experience of receiving an oral SACT. The use of interview enabled the research student to fully explore patient perceptions and experiences and thus develop an understanding of the impact of oral SACT on an individual's life. Further, the views of health professionals involved in the provision of oral SACT services is relatively unknown; through interview, these views and experiences could be explored, and conclusions drawn upon what health professionals believe to be the challenges faced by healthcare providers. This exploration from two different perspectives (patient and health professional) is key to informing the future development of models of care combining knowledge of both patient and health professional experience so the service delivered is acceptable and effective for both the patient and the organisation delivering the service.

Secondly, the OEC is a newly established model of care to provide support for PWC commencing oral SACT. A key feature in ascertaining the quality and efficacy of this service is developing an understanding of how useful this service was, to identify what worked well and any areas requiring further improvement. Through the use of survey, a series of questions could be asked of participants to identify satisfaction and perceived usefulness. Closed-ended questions and validated measures enabled collection of data on perceptions of participants towards the OEC and further enabled comparisons to other published studies.

Finally, considering the breadth of research questions, qualitative or quantitative data alone could not achieve an in-depth answer. By using qualitative data to enrich the meaning behind the quantitative data it was hoped a more detailed understanding could be achieved (Greene, Caracelli and Graham, 1989; Creswell, 2015).

3.2.2 Overview of mixed methods methodology

In terms of methodological history, the use of mixed methods is a relatively newly established research approach, encompassing the use of both qualitative and quantitative data within a single study (Creswell and Plano Clark, 2011). It is further claimed to closely resemble nursing practice given healthcare professionals use a variety of measures gathered to indicate the health status of a persons' condition (Fawcett, 2015). For example, an individual's pain score may be quantified on a scale of 1-10, yet enquiry to the patient's condition through conversation may give a clearer indication to experience of severity of pain. Mixed methods have been widely used in healthcare research to address satisfaction with and impact of healthcare practice (Desborougha *et al.*, 2016; Giltenane, Frazer and Sheridan, 2016) and it was considered the best method to achieve the aim and objectives of this study. As Creswell and Plano Clark (2010, P. 5) comment:

> *"Its [mixed methods] central premise is that the use of quantitative and qualitative approaches, in combination, provides a better understanding of research problems than either approach alone."*

Quantitative approaches find their roots in positivism where the worldview aligns with empirical observations and measurements (Neale, 2009); there is often an emphasis placed on quantitative data, where theories can be tested and measured, where a cause will relate to an outcome generating propositional knowledge. The researcher assumes a real and absolute existence, connecting theory and data through deduction with an objective relationship to the research process (Morgan, 2007). Quantitative approaches therefore often seek to generalise findings from their data, applying an inference to a wider population.

Qualitative approaches find their roots in social constructivism, where the research is more concerned with a participants subjective meaning of experience (Neale, 2009) resulting in the collection of qualitative data. The researcher therefore assumes reality is individualistic and relative, connecting theory and data through an inductive approach with a subjective relationship to research processes (Morgan, 2007). Qualitative approaches thus do not seek to generalise findings, but are rooted in their context, where findings provide explanations of the participants and the situations in which they find themselves only. Inferences made from qualitative research are grounded within the context from whence they came (Sechrest and Sidani, 1995), however if a researcher gives sufficient contextual detail, then transferability could be considered following considered application to another or wider setting.

The use of mixed methods is closely aligned with the philosophy of pragmatism where researchers will use the most appropriate methods to seek answers to their questions (Feilzer, 2010). Pragmatism is not committed to any one system of philosophy, but arguably is a paradigm in its own right (Morgan, 2007); the goal of research is the resolution of the problem (Florczak, 2014) and thus the researcher will use the best means to address that problem. Within a pragmatic approach, the ontology and epistemology of quantitative and qualitative paradigms are both equally valid, but the researcher will often pertain to no assumptions about reality (Morgan, 2007). The choice of methods for a research study is therefore dependent on the research question, rather than being bound to a particular ontology or epistemology. Complementarity (Greene, Caracelli and Graham, 1989) therefore offsets the limitations of each approach (positivism and social constructivism) by combining their strengths. Pragmatism allows social researchers to combine a mix of methods and viewpoints to achieve an adequate answer (Greene, Benjamin and Goodyear, 2001). Robert Walker in Neale (2009) P. 269 summarises this:

> *"Pragmatism sidesteps ontology by arguing that all that is known about reality is known through human experience of it. It therefore offers an epistemological basis for what scientists do; namely seek to solve problems identified through their experience"*

This study was conceived by health professionals (clinical collaborators, supervisors and research student) with a working knowledge that further research was required regarding the safe care of PWC receiving an oral SACT. Design has therefore been guided by the research questions, and thus approached from a pragmatic philosophical worldview. A strength of using mixed methods research is approaching data with an abductive approach where findings can be generated inductively (a bottom up approach) through qualitative enquiry but also deductively (a top down approach) through quantitative enquiry.

3.2.3 Patient and Public Involvement

Patient and Public Involvement in the design of research studies has been referred to as the 'cornerstone' of a patient-led NHS (Hogg, 2007). National recommendations (National Institute for Health Research, 2018) now stipulate that involvement of 'service users' or patients, and members of the public should be included in the design of a research study. In light of this requirement, a patient representative known to the local Cancer Alliance with experience of critiquing research and cancer related quality improvement initiatives was involved from the outset of this study.

3.3 Study design

3.3.1 Longitudinal mixed methods approach

This mixed methods study is similar to a sequential explanatory design (Creswell and Plano Clark, 2010; Halcomb and Hickman, 2015) where qualitative and quantitative data sets were collected sequentially (Figure 3.4) and qualitative data could be used to explain findings from quantitative data from an explanatory perspective. In order to conduct health professional interviews, approval was required only from the University Research Ethics Committee (UREC), therefore data collection and analysis could commence promptly within a challenging PhD timescale. Health professional interviews were therefore conducted first in this study, and took place while the study tools for the patient experience element of the study and associated ethics application could be created.

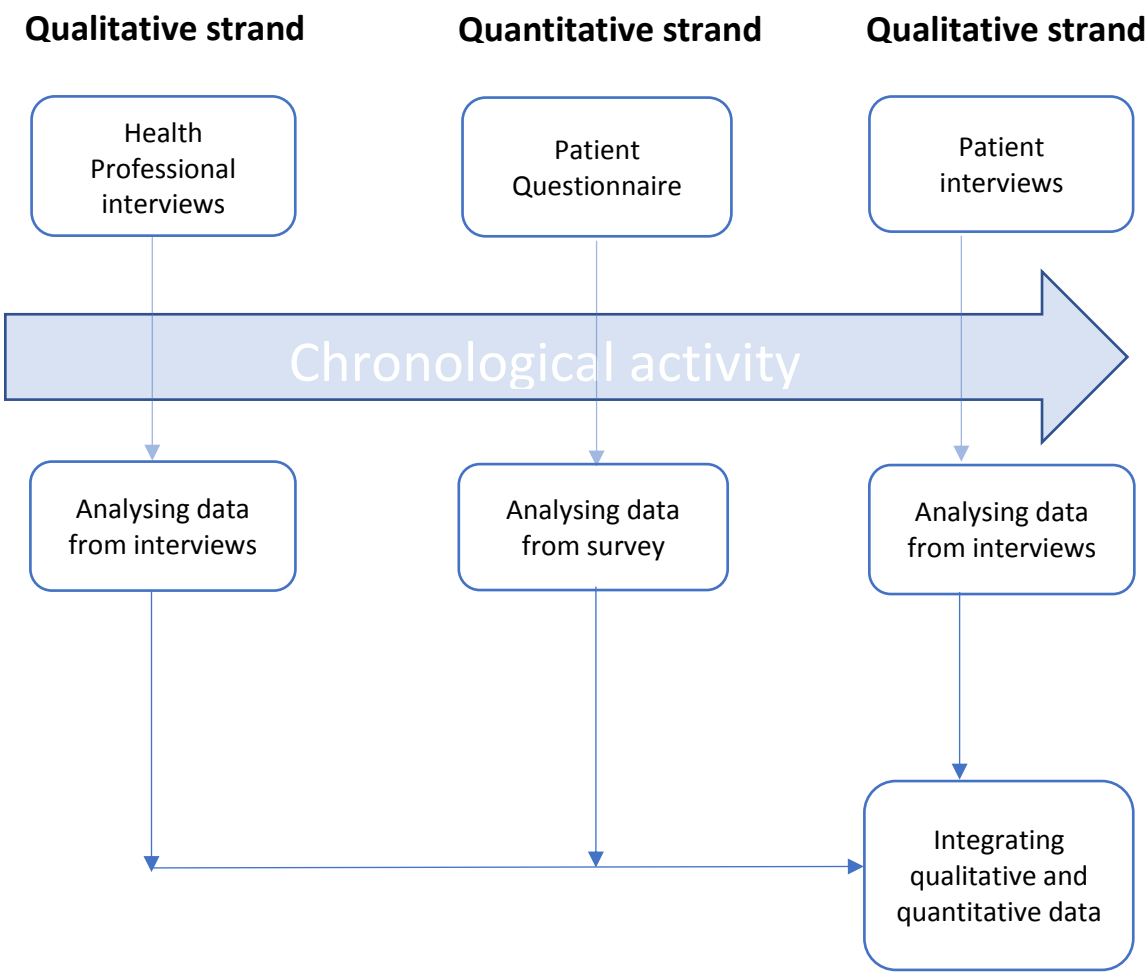

Figure 3.4 A parallel convergent mixed methods design

3.3.2 Use of survey

Quantitative data allows the researcher to collect data that can be measured and interpreted using statistics. Similar to qualitative data, there are various approaches utilised in the collection of quantitative data. Arguably the most common is that of the survey approach, also widely used within the NHS to address patient experience and satisfaction (Dyer *et al.*, 2016; Quality Health, 2017). In survey research, information is "... *systematically collected from a relatively large sample taken from a population"* (de Leeuw *et al.*, 2008, P. 2).

In this study, information concerning patient satisfaction and experience was systematically collected from a sample of people receiving education through the OEC. The advantage of using a questionnaire is the ability to ask a larger population the same question and therefore compare the findings derived from the sample with a view to generalisation. Use of a questionnaire is however not without disadvantage, Dillman *et al.*, (2014) highlight four key areas to be considered: coverage

error, sampling error, nonresponse error and measurement error. In order for data to be generalisable, all members of a target population should be represented so that all potential data collected is representative of the population. The sampling process must ensure that appropriate members of the population have been approached. Nonresponse error is concerned with the case where only certain respondents, perhaps with a similar opinion, respond therefore if a low response rate is found, results in turn may not be representative. Finally, measurement error should also be considered, where respondents might not give accurate answers, or may not be able to do so secondary to design of the question.

3.3.3 Use of interview

A common objective in qualitative research methods is the interpretation and understanding of the participant's social world (Ritchie *et al.*, 2014). The most common method to collect qualitative data is by interview (DiCicco-Bloom and Crabtree, 2006). Several types of interview style exist, but for this study a semi-structured interview was used. The advantage of a semi-structured interview is in essence the structure; the interviewer will have an agenda, usually in the form of a topic guide and interview schedule containing predetermined questions. This ensures that during the interview, key questions and content will be covered. However, the interview is not limited to these questions alone and the interviewer is encouraged to develop rapport with the interviewee and allow other questions to emerge from the dialogue (DiCicco-Bloom and Crabtree, 2006; Polit and Beck, 2006).

Conducting an effective research interview is a skill encompassing several components. Interviewers are required to be self-aware and maintain reflexivity, being aware of how biases may occur, while having the skill set to guide the interview without leading the participant. In light of this skill set, I attended a course at the University of Oxford on qualitative interviewing receiving theoretical and practical teaching on the formation of questions and facilitation of semi-structured interviews. An effective qualitative interview question is one that is open-ended, neutral, singular and clear (Patton, 2002, P.353).

3.4 Data analysis

3.4.1 Quantitative analysis

Quantitative data was analysed using descriptive statistics like frequency, distribution and where appropriate, tests of significance. PWC attending the OEC have a wide range of diagnoses and considering the volume of attendance there were insufficient numbers to complete inferential

statistical analysis to identify causation. In light of this, no power calculation was performed, instead a focus was taken on describing experience through questions of satisfaction and confidence. Planned approaches to questionnaire analysis and use of quantitative data were reviewed by the supervisory team, an independent senior academic at Oxford Brookes University and finally by statisticians at the University of Ulster where I attended for training in the use of descriptive statistics.

3.4.2 Qualitative analysis

Qualitative data was analysed thematically using the Framework approach (Ritchie and Spencer, 1994). Originating from social policy research, (Ritchie and Spencer, 1994) thematic analysis using Framework is now widely used in qualitative healthcare research (Furber, 2010; Swallow *et al.*, 2011). Framework is a method of conducting thematic analysis rather than a research methodology such as phenomenology or ethnography (Ward *et al.*, 2013).

Framework adopts a 5-stage approach toward analysis (Ritchie and Spencer, 1994; Ritchie *et al.*, 2003) and summarised in Table 3.9.

Table 3.9 Five stages included in Thematic Analysis using Framework

Stage	Process	Rationale
Stage 1	Familiarisation	Researcher becomes immersed in and familiar with each transcript
Stage 2	Developing a theoretical framework	Researcher identifies themes and sub-themes, often referred to as codes.
Stage 3	Indexing and pilot charting	Application of themes and sub-themes to all transcripts
Stage 4	Data summaries created	Create Framework matrix by hand or using a computer software and reduce data into summaries (see Table 3.10)
Stage 5	Data synthesis and abstraction	Comparisons made between themes and sub-themes, checking summaries relate correctly to transcript

Framework was selected as a means to analyse the qualitative data due to the systematic approach to data analysis that allowed both an inductive and deductive approach to be used concurrently. Some members of the supervisory team also had experience in conducting thematic analysis using Framework as authors and commented that an experienced researcher should be involved in using this type of analysis. One of the benefits of using the Framework method of thematic analysis is the development of framework matrices that enabled case by case typology analysis as well as thematic analysis. As demonstrated in Table 3.10 below, participant IDs are listed down the left-hand column,

thematic categories and sub-categories are found along the top right-hand row. Summaries can then be inserted into each cell where a participant refers to the category in the interview. This process of managing and summarising data directly enables the researcher to explore the data across and between cases.

Table 3.10 Theoretical example of populating a Framework matrix

Participant ID	Category 1		Category 2	
	Sub-category	Sub-category	Sub-category	Sub-category
PT_Interview01	*Insert data summary*	*Insert data summary*	*Insert data summary*	*Insert data summary*
PT_Interview02	*Insert data summary*	*Insert data summary*	*Insert data summary*	*Insert data summary*
PT_Interview03	*Insert data summary*	*Insert data summary*	*Insert data summary*	*Insert data summary*
PT_Interview04	*Insert data summary*	*Insert data summary*	*Insert data summary*	*Insert data summary*

3.4.3 Data integration

Through a process of data integration, Greene et al. (1989, P. 259) comment that the researcher can expand the scope of a study by seeking to capture method-linked dimensions of a target phenomenon. In the context of this study, the aim of integrating data is to achieve a deeper level of understanding with regard to the experience of people with cancer taking an oral SACT. High quality examples of the actual process of integrating data sets however remains scarcely reported in the literature, with only a few publications detailing a range of methods demonstrating examples of authentic integration (O'Cathain et al., 2010; Bryman, 2006; Moran-Ellis et al., 2006; Morgan, 1998).

Several approaches to data integration exist but this study used a process described by Moran-Ellis *et al.* (2006) called 'Following a Thread'. This approach has been selected because each data set (quantitative and qualitative) is analysed individually within its own right, yet interpretation of findings is completed following data integration (Moran-Ellis *et al.,* 2006).

In discussion of data integration Sandelowski (2000, P.252) comments:

> *"The results of the qualitative analysis of qualitative data and of the quantitative analysis of quantitative data are then combined at the interpretive level of research, but each data set remains analytically separate from the other".*

By 'Following a Thread', a clear process guides this interpretive level of research. The researchers select a question or theme and follow this through the data sets. Adamson et al. (2009) used the

principles of Following a Thread in a mixed methods study incorporating 22 qualitative interviews and 911 survey respondents. The authors report being able to test a theme identified from qualitative interviews by interrogating quantitative data. In essence, the thread of a theme was followed through all data sets and comparisons made resulting in a firm conclusion, as Moran-Ellis et al. (2006, P. 50) comments:

> *"[by integrating data sets] The material differences of those separate entities are not erased, but work synergistically to produce a whole that is greater than the sum of its parts"*

The process for 'Following a Thread' in this study will be described in section 3.6.

3.5 Methods

3.5.1 Development of study materials

3.5.1a Patient and clinician engagement

Two members of senior staff from the study site were identified as clinical collaborators – a pharmacist and a nurse. Both collaborators have been involved with this study during its development and planning, but also in establishing the OEC. Their purpose was to facilitate the delivery of the study at the study site and to facilitate recruitment of participants. Collaborators further contributed towards the development of questionnaire design and topic guides to investigate the patient experience element of this study.

A patient representative was also consulted who reviewed the development of both the questionnaire tool and proposed interview schedules.

3.5.1b Questionnaire design

In this study, quantitative data required questions regarding the participants' demographic, cancer diagnosis and outcomes from treatment. Specific measures and validated data collection tools were also incorporated to assess the participant's satisfaction with the service provided, beliefs about their medicines and to measure adherence to oral SACT. As identified from the systematic literature review and from conducting searches to identify tools used in measuring patient satisfaction, the following validated measures were incorporated into questionnaire design:

- Beliefs about Medicines Questionnaire (BMQ)
- Satisfaction with Information about Medicines Scale (SIMS)
- Morisky Medication Adherence Scale – 8 (MMAS-8)
- Cancer Therapy Satisfaction Questionnaire (CTSQ)

The Beliefs about Medicines Questionnaire (BMQ)

The BMQ is a widely recognised tool used to measure the beliefs of an individual about their medicine (Horne, Weinman and Hankins, 1999). There are two versions of the BMQ: the BMQ-General and the BMQ-Specific. The BMQ-General asks questions about a person's view on medicines in general such as 'doctors use too many medicines' and 'natural remedies are safer than medicines'. The BMQ-Specific seeks to ascertain patient beliefs on a specific medicine and therefore asks questions specific to the medicine in question such as 'my medicine disrupts my life'. Responses to all questions are in the form of a Likert-type scale: 'strongly agree', 'agree', 'uncertain', 'disagree' and 'strongly disagree'. Questions within the BMQ-Specific address either concerns about the medicine, or the necessity of the medicine. Beliefs can therefore be grouped into beliefs surrounding the concern in taking the medicine, and beliefs about the necessity of taking the medicine. Horne, Weinman and Hankins (1999) describe in detail their process of psychometric testing of the BMQ. Criterion-related validity was confirmed by demonstrating a negative correlation between scores on the necessity scale and scores for the statement 'I can cope without my medicines'. Similarly, scores on the concerns scale were positively correlated with the statement 'I cannot always trust my medicines'. Discriminant validity was confirmed by comparing scores within groups of asthmatics, psychiatric samples and diabetic samples. Where a medicine omission could have a significant impact on severity of illness rather than symptom relief e.g. insulin omission, scores on the concerns were confirmed to be significantly higher than other illness groups supporting the discriminant validity of the scale. Internal consistency of the scale was measured using Cronbach alpha with values which ranged 0.55 – 0.86 across a range of health conditions. Finally, reliability testing was confirmed when test-retest reliability was revealed to be satisfactory. Whilst the BMQ has not been specifically designed for use with oral SACT, the psychometric properties have been rigorously tested across a range of illness, some chronic and some acute, and therefore can be viewed as a reliable instrument for addressing an individual's belief about their medicines. As adherence to oral SACT is essential for safe and effective treatment and sufficient psychometric testing has been reported, this tool was selected to investigate patient beliefs about their oral SACT, thus the BMQ-Specific was selected.

The Satisfaction with Information about Medicines Scale (SIMS)

The SIMS tool is a 17-item questionnaire which aims to create a profile of patient satisfaction with information received about their medicine (Horne, Hankins and Jenkins, 2001). The questions are holistic in content where they cover not only medical aspects of education delivery such as how to take the medicine, but also information on the impact of medication on their daily life such as a

question on their sex life. Respondents have the option of rating a response on one of the 17 topic areas as: too much, about right, too little, none received, or none needed.

Horne, Hankins and Jenkins (2001) report a high degree of acceptability when conducting psychometric testing of the SIMS measure. Significant correlations were identified between SIMS scores and patient reports of beliefs about and adherence to medicines, confirming criterion related validity. Discriminant reliability was not reported. Cronbach's alpha coefficients were used to assess internal consistency, scores ranged from 0.61 – 0.91 across cardiac rehabilitation and insulin-treated diabetes. Test-retest validity was also reported demonstrating statistically significant correlations using Pearson correlations, however the action and usage sub-scale was found to be unsatisfactory for patients classed as 'unstable' concerning anticoagulant medications. Overall, sufficient psychometric testing was conducted with the SIMS scale to warrant inclusion within this study and the tool selected as it relates directly to patient experience of the OEC and enabled the research student to identify patient satisfaction with education received and subject areas where patients might desire more or less information about their oral SACT.

The Morisky Medication Adherence Scale – 8 (MMAS-8)

Several ways of measuring patient adherence to an oral SACT have been utilised by researchers as identified by the systematic literature review. The majority of researchers used patient self-report, where respondents would complete a questionnaire or interview with the research team. Due to the design and aim of this study, it would not have been feasible to use Medication Event Monitoring (an electronic medicine pot which records the exact time it was opened, thus inferring the medicine taken) due to costs incurred therefore the research required a measure employing patient self-report. The MMAS-8 has been used widely as a tool for patients to self-report their adherence to treatment within a two-week period (Morisky *et al.*, 2008; Krousel-Wood *et al.*, 2009; Morisky and DiMatteo, 2011). The tool uses eight questions, seven of which have yes/no responses and the final using a Likert-type scale to ask respondents about their recent adherence behaviours such as:

> *Question: Do you sometimes forget to take your (name of health condition-related medicine)? Answer: yes/no*
>
> and
>
> *Question: How often do you have difficulty remembering to take all your medication? Answer: Never/Rarely, once in a while, sometimes, usually, all the time.*

The MMAS-8 tool has not been validated for use within a cancer population, however its psychometric properties have been validated within the context of hypertension management (Morisky *et al.,* 2008) and found to be valid for assessing medication adherence in people with asthma and in predicting their treatment outcomes (Janezˇič *et al.,* 2017). Further, the MMAS-8 tool has been used to assess adherence within several cancer populations (Boucher *et al.,* 2015; Sommers, Miller and Berry, 2012). While a variety of research tools to address adherence have been identified, the MMAS-8 tool was selected as it was short in length but also reads in a manner that is non-judgemental as perceived by the research student.

The Cancer Therapy Satisfaction Questionnaire (CTSQ)

The CTSQ (Abetz *et al.*, 2005) was developed specifically for people with cancer and aims to identify patient satisfaction across three domains: Expectations of Therapy (ET); Feelings about Side Effects (FSE); and Satisfaction With Therapy (SWT). The tool is a 16-item questionnaire and provides respondents with a variety of categorical options relevant to the question on a Likert-type scale, for example:

> *Question: Overall, how worthwhile has your cancer therapy (IV/pills) been? Answer: Very worthwhile, quite worthwhile, moderately worthwhile, a little worthwhile, not worthwhile at all.*

The questionnaire was developed in collaboration with oncology patients, clinicians and nursing staff across the United States, United Kingdom and France and was designed for use in patients receiving either or both intravenous or oral treatments. The CTSQ further underwent detailed psychometric validation (Trask *et al.*, 2008) and was found to have strong psychometric properties and constructs not captured by the Quality of Life Questionnaire – Core 30.

Internal consistency was assessed using Cronbach's alpha with scores across the three domains ranging from 0.77 to 0.87. Using Spearman correlations, the interdomain correlations were found to be small to moderate in magnitude ranging from r=0.18 to r=0.56. Test-retest was assessed by using the intraclass correlation coefficient with findings exceeding the desired test-retest reliability value of 0.7, however of note, ET was found to be 0.56 in the whole sample. Overall, the testing reported by Trask et al. (2008) support the internal consistency, test-retest reliability and overall validity of the CTSQ. This validated tool was therefore selected as it provided questions of satisfaction across the whole patient pathway enabling the research student to consider patient experience of oral SACT within a broader context, rather than limited to the OEC.

3.5.1c Questionnaire design and pilot testing

In addition to inclusion of validated measures, a list of questions was created to collect information on specific areas of the cancer journey, one example such as experiences of parking at the study site. This list was reviewed by clinical collaborators, the supervisory team and a patient representative. Once the questions had been agreed, these were arranged into sections and formatted using the tables function in a word document. Following recommendation from the supervisory team and patient representative, the questionnaires were coloured into white and blue and formatted to allow ample white space and appropriate text size.

As PWC receiving an oral SACT are significantly distanced from healthcare providers, and further at the time of conducting this study, received their education at only one occasion, the questionnaire was designed to be delivered at two-time points, to identify any changes in satisfaction over time, but also to allow further questioning regarding the experience of side effects. The OEC is available to patients receiving a wide and differing range of oral SACT, therefore secondary to different side effect profiles, it was not feasible to incorporate specific patient reported outcome measures for different groupings of oral SACT. However, with utilising two questionnaires administered six weeks apart, an understanding of the side effects experienced was required and would enhance analysis of data. By gaining an understanding of the type of side effect, and its self-reported severity, themes might be identified between the type of side effect and experience of receiving oral SACT. A list of the most common side effects of cancer treatments was drafted in collaboration with the supervisory team, and a scale based on the NCI-CTC was created to give an approximate idea of severity (see page 6 of questionnaire 2 in Appendix 3).

Both questionnaires were tested on an acute in-patient oncology ward. 20 in-patients completed both questionnaires and provided verbal and/or written feedback to the student. All test respondents found the questionnaires easy to follow due to the colouring and found the questionnaire being structured into different sections helpful. On checking written responses to the questionnaire, there were no apparent errors in recording responses and no criticisms were provided on language or content with individuals agreeing that the questionnaire was clear and understandable. On review of these answers, it was decided that the tool was suitable for use and could address the appropriate research questions guiding this study. Questionnaire 1 (Q1) and Questionnaire 2 (Q2) can be found in Appendix 2 and 3, respectively.

3.5.2 Ethical approval and informed consent

Two separate ethics applications were submitted. As approval for health professional interviews would only require University level ethics approval, this application was submitted first enabling

commencement of data collection, while simultaneously designing the study tools required to investigate patient experience.

3.5.2a Approvals for health professional interviews

Approval from Oxford Brookes University Faculty Research Ethics Committee (FREC) was given on 12th November 2015 with reference number 1015/10. The internal trials steering committee at the study site reviewed the study on 22nd December confirming it would be possible to facilitate the study. Research and Development (R&D) approval was obtained on 8th January 2016 PID number: 11707 (Appendix 4). When reporting health professional interview data, the decision was made not to include reference to the participant's role to prevent disclosure of any identifying characteristics of the participant.

3.5.2b Approvals for patient experience

The internal trials steering committee at the study site reviewed the study on 22nd December 2015 confirming it would be possible to facilitate the study. Approval from Oxford Brookes University Faculty Research Ethics Committee (FREC) was given on 14th July 2016 with reference number 2015-41. Following FREC approval, the study was submitted to the Health Research Authority (HRA) and allocated to North West Research Ethics Committee (REC). Final HRA approval was obtained on 15th September 2016 (REC reference 16/NW/0586). R&D approval was obtained on 6th October 2016; PID number: 12217. Copies of these confirmations can be found in Appendix 5 [identifiable data redacted].

3.5.2c Informed consent

Informed consent for the questionnaire study was implied by return of a completed questionnaire 1, and the provision of participant details to post questionnaire 2. Patient respondents could indicate on the back page of questionnaire 2 a willingness to be approached to arrange an interview; health professional participants made initial contact with the research student to indicate a willingness to participate in an interview. Prior to conducting an interview with health professionals or patients, it was confirmed that the participant had received, read and understood the information provided on the respective participant information sheet and then explained the informed consent form. Informed consent was provided and documented by participants before the interview commenced. Health professional informed consent form can be found in Appendix 6, and the informed consent form for PWC can be found in Appendix 7.

3.5.3 Health professional experience

3.5.3a Sample

Potential participants were required to have a direct role in the care of patients receiving an oral SACT and have a minimum of six months clinical experience.

3.5.3b Data collection

The study was advertised as open to recruitment on 14th January 2016. Clinical collaborators sent emails internally to relevant staff groups, advertised the study at staff meetings and in face to face interactions with potential participants. Posters (Appendix 13) were also placed in staff communal areas in the Haematology and Oncology Cancer Administration Centre.

A participant information pack containing a participant information sheet (Appendix 14); and a copy of the consent form (Appendix 6), was given by clinical collaborators to potential participants who expressed an interest in participation. Potential health professional participants made contact with me by email or telephone to arrange an interview. The first interview took place on 4th March 2016 and the final interview was conducted on 6th June 2016 with the study closed to recruitment thereafter. The study site R&D department were informed the study had completed recruitment to this stage.

The process of recruitment can be seen in Figure 3.6.

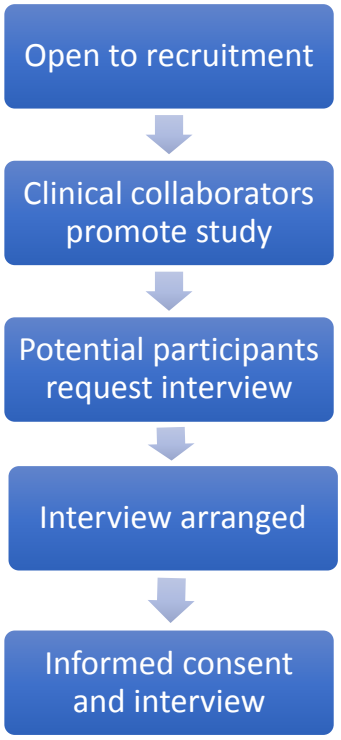

Figure 3.5 Process of recruitment for health professional participants

Semi-structured interviews took place at a time and location of the participants choosing. 21 interviews took place at the study site in small meeting rooms away from clinical areas to promote confidentiality and two interviews took place at Oxford Brookes University in a meeting room. In line with best research practice all interviews took place in a space which was private and quiet (Burns and Grove, 2005; Clarke, 2006).

I conducted interviews using an open conversational style, providing an opportunity for participants to speak freely about their perceptions and experiences, guided by a topic guide (Appendix 15) and interview schedule (Appendix 16). The supervisory team provided guidance and support in the conduct of interviews and a training course was attended at the University of Oxford.

3.5.3c Data management

Interviews were recorded using an electronic digital recorder. They were transferred to a portable, password protected laptop before being transcribed verbatim into a word document by the research student. Word documents were locked with a password, only accessible by the student investigator and supervisory team. Unique study IDs were applied to each participant. 3 transcribed interviews were both read and listened to by the supervisory team to ensure accuracy in transcription, and appropriate interview style of the research student.

Paper copies of the interviews were created and stored in a locked filing cabinet in a lockable office at Oxford Brookes University. Electronic backups were also created and stored with paper copies. Audio recordings were deleted, and transcript data imported into NVivo11© for analysis.

3.5.3d Data analysis

Data analysis was approached systematically as described in section 3.4.2. Each interview was transcribed verbatim by the research student and imported into NVivo11©. Immersion in data was achieved due to the research student completing each interview transcription and the use of a reflective diary (Finlay and Gough, 2003).

Interviews were coded (indexed) creating a list of descriptive codes (referred to as 'nodes' within NVIVO). An electronic and printed copy of the transcribed interview with associated nodes were provided to members of the supervisory research team. Where there was disagreement within the supervisory team between labelling an index or category, this was discussed until a unanimous decision was made. Coded data was sorted into categories and sub-categories resulting in analytical framework.

As interviews continued, pilot charting took place, applying this framework to interviews (Ward *et al.*, 2013). Iterative changes were made until a final analytical framework was created, representing coded findings from all the interview transcripts (Appendix 12). This analytical framework was agreed by the supervisory team. Using NVivo11©, framework matrices were created of the categories. Practically, each matrix listed the individual participants down a left-hand column, with sub-categories within the analytical framework along the top row. Within this table or matrix, the research student could insert a summary of the participant interview data that was coded; electronic links were created from the original data source to the data summary created. Completion of the framework matrices enabled the process of abstraction where categories were synthesised until main themes were identified.

To illustrate a framework matrix, Table 3.11 demonstrates an excerpt from three different health professional interview participants from two different framework matrices: patient education and families and carers.

Table 3.11 Excerpt from two different framework matrices derived from HP interview data

Participant ID	Patient Education		Families and carers	
	Consultation style	Information overload	Assisting with patient care	Education with families and carers
HP_Interview03	Participant likes to draw a grid on a blank piece of paper to clarify to the patient when to take tablets.	*"Perfectly intelligent"* people can struggle due to volume of information and find this overwhelming	Elderly patients especially often need help in managing multiple medications.	*blank*
HP_Interview16	Purpose of the OEC appointment is to make sure the patients knows as much as they want to know.	*blank*	*blank*	Families/carers should always be invited to attend. Families often missed out with oral SACT as education is often drip fed to patients receiving an IV in the presence of their families.
HP_Interview22	Using a checklist helps the participant prep for an OEC session. Difference between a good and a bad OEC session is in being organised. Not a random conversation, as it's scripted all important information is covered.	*blank*	*blank*	Participant feels families are as welcome to participate in the OEC as much as the patient is.

3.5.4 Methods to investigate patient experience

3.5.4a Sample

Potential participants were required to be fluent in English, have received a diagnosis of cancer either haematological or oncological, received education through the OEC by means of a face to face appointment or telephone appointment and be able to provide informed, written consent.

3.5.4b Data collection

The study was advertised as open to recruitment on 24th October 2016. Clinical collaborators sent emails internally to all staff involved in the OEC who were then requested to distribute a prepared questionnaire pack to eligible patients attending the OEC. The questionnaire pack contained: a study invitation letter (Appendix 8), a participant information sheet (Appendix 9), questionnaire 1 (Appendix 2) and a reply paid enveloped. I arranged a study visit to meet with all pharmacists providing patient education and nursing staff. Two site files were provided to the study site which provided details of the study and an overview of the study design, content of questionnaires and overall aims and objectives of the research. A site file was stored in the pharmacy office, and in the nursing office for ease of access to all members of staff involved in the OEC.

All staff were provided with training on how to explain the study to potential participants. Staff were requested to emphasise the importance of discussing the voluntary nature of the study, but to explain to potential participants that the feedback would be valuable to help inform the future of oral SACT services. Questionnaire packs were initially stored with the respective site files.

Response to the questionnaire was lower than expected. Several meetings were held with the OEC facilitators to provide updates on recruitment and encourage recruitment to the study. Ethical approval had been granted for me to attend the study site and administer patient packs to PWC directly, however the clinic ran in an ad-hoc fashion, often with no scheduled appointments and therefore it was not possible for me to stay in the clinics and give out the questionnaire packs directly.

A member of the cancer administration team prepared written information packs for PWC attending the OEC. I met with this member of staff regularly and provided the member of staff with multiple, numbered ‘questionnaire packs’. This patient pack would be given to the potential participant along with other written information provided as a standard during the OEC appointment. As questionnaire patient packs were numbered, I was able to keep a record of how many questionnaires had been given out on a monthly basis and provide feedback to the OEC facilitators.

Following this, recruitment to the questionnaire study improved slightly but response rate remained low.

Respondents who returned questionnaire 1 and completed their address, were sent questionnaire 2 (appendix 3) 6 weeks after their OEC appointment. Respondents returning questionnaire 2 had an option on the back page to indicate a willingness to participate in an interview. If a participant had agreed to participate in an interview, I would use the contact details provided to speak to the participant and arrange a time to conduct the interview. All interviews took place at a time and location of the participants own choosing but study documentation offered individuals the options of their own home, study site or Oxford Brookes University. Most interviews (n=21) took place at the individuals own home. The Oxford Brookes University lone working policy was adhered to for each interview. A small number of interviews (n=5) took place at the study site in a private, quiet space at Maggie's Centre and finally, two interviews were conducted at Oxford Brookes University in a quiet meeting room. A flowchart depicting this recruitment process can be found below in Figure 3.5.

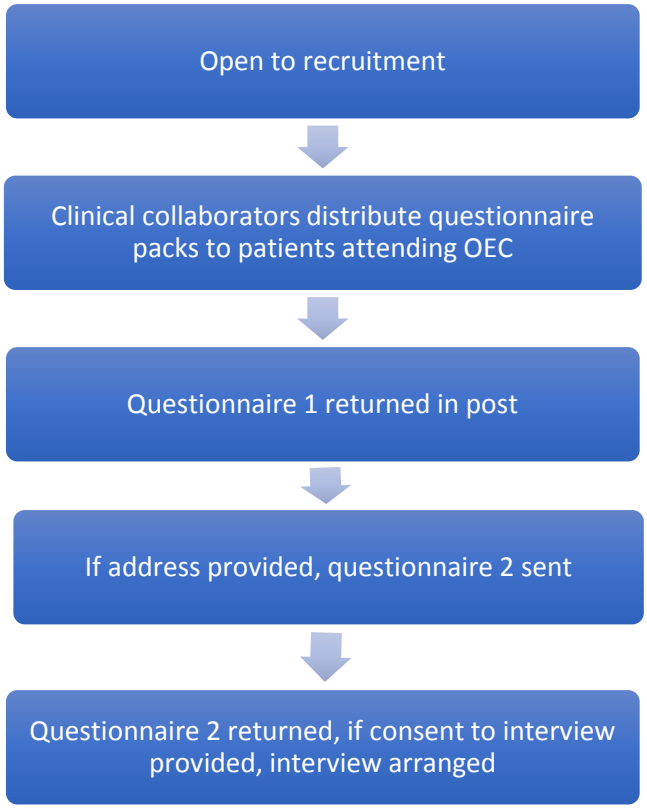

Figure 3.6 Process of recruitment of patient participants

I conducted interviews using an open conversational style, providing an opportunity for participants to speak freely about their perceptions and experiences, guided by an interview schedule (Appendix

10). The supervisory research team provided guidance and support in the conduct of interviews and a training course was attended at the University of Oxford.

Participants consented to interviews being digitally recorded and these recordings were subsequently transcribed verbatim by the research student. Recruitment to the study ceased after an 18-month period on 24th February 2018.

3.5.4c Questionnaire pilot

A questionnaire evaluation page (appendix 11) was added to questionnaire packs distributed to patients. The purpose of this was to further evaluate and pilot the questionnaire to ensure participants were completing the questionnaire accurately, to ensure it was understandable and to confirm the student had asked the right question in the right way. This page was removed from future questionnaire packs once 20 completed pilot response pages had been received.

Findings from pilot responses indicated the questionnaire was well received and completed correctly by study participants. Minimal written feedback was recorded but participants scored ease of completion of questionnaire as an average of 8.5/10. As a result, no changes were made to the questionnaire and the pilot evaluation page was removed from future prints of questionnaires.

3.5.4d Data management

Upon receipt of a completed questionnaire, participant identifiable data such as an address or contact details were removed and stored in a separate lockable drawer. Questionnaire content was stored in its paper format. All questionnaire data was entered into SPSS23© at a later date. Questionnaire data and identifiable data were stored separately in a locked filing cabinet, in a locked office at Oxford Brookes University. Paper copies of the interviews were created and stored in a locked filing cabinet in a lockable office at Oxford Brookes University. Electronic backups were also created and stored with paper copies. Audio recordings were deleted and transcript data imported into NVivo11© for analysis.

Interviews were recorded using an electronic digital recorder. They were transferred to a portable, password protected laptop before being transcribed verbatim into a word document. Word documents were locked with a password only accessible by the research student and supervisory team. Unique study IDs were applied to each participant based on the ID of the questionnaire. Three different transcribed interviews were both read and listened to by each member of the supervisory team to ensure accuracy in transcription, and appropriate interview style of the research student.

3.5.4e Analysis of questionnaire data

Questionnaire data was imported into SPSS23©. Responses to each question and potential answer were coded numerically. Once the complete data set had been electronically imported, the data set was examined in detail and 'cleaned' to ensure no false entries were made. Variables were recoded for analysis for example to create groups within a variable such as age, or to allow for calculations where recoding was indicated such as in the use of the MMAS-8 measure.

Categorical variables were presented using frequencies and percentages. An advantage of using SPSS23© was the ability to create cross tabulations through using the Custom Tables feature allowing comparisons of data and occasionally where appropriate the use of Pearson Chi Square Test (Kirkwood and Sterne, 2005) to test for significant associations.

For descriptive statistical analysis, no questionnaires were excluded based on incomplete data or missing responses due to low numbers of responses. When validated measures were calculated, responses were disqualified as indicated by official guidance from the authors of the measure e.g. for the CTSQ, should respondents have only completed 3 out of 5 required questions, their data would not be included in the analysis. Missing responses have been included in tables where appropriate to indicate the number of responses excluded.

Appropriate use of the SIMS tool required exclusion of any participants who did not fully complete all 17 responses. The 17 items constituting the SIMS tool are summed to provide an overall score, with 17 indicating highest levels of satisfaction. Where a participant had left one or more fields empty, their data was removed from analysis. The SIMS tool was used in both questionnaire 1 and 2 in the same format, enabling a comparison of scores over time. This was compared using a non-parametric Wilcoxon Signed Rank Test (Kirkwood and Sterne, 2005). Following consultation with a statistician at the University of Ulster, advice was taken to also complete a matched paired T test due to the small sample size of the data.

3.5.4f Analysis of interview data and development of typologies

The process of qualitative data analysis has been described in detail in section 3.5.3d. The same process was used for both HP interviews and PWC interviews.

An advantage of qualitative data, is the development of typologies where 'types' of characteristics or people can be identified within a sample of sufficient size. To aid the process of developing typologies, summaries produced from the development of matrices were extracted and inserted into a large characteristics table. Matrix fields were participant ID; gender; age; cancer; oral SACT; view of oral SACT; reported adherence; experience of OEC; preference for nurse or pharmacist; received

telephone or face to face education; views on telephone or face to face education; views on telephone follow-up; family situation; polypharmacy; coping strategies; side effects; health seeking behaviours; routine; relationship with GP; clinical nurse specialist; other personal characteristics. By creating this large matrix in Microsoft Excel© comparisons could be made between cases. Through repeated review of the matrix, regularly revisiting the original data source, participants could be grouped by different characteristics for example, identifying any common characteristics between participants who report adherence, or those who report non-adherence. Results from analysis this data for typologies will be presented in Chapter 5.

3.6 Data integration

Findings from health professional interviews and from patient questionnaire and interview were analysed individually using the methods detailed previously. As previously discussed, authors Adamson et al. (2009) used a theme derived from qualitative data to test within their quantitative data. Unfortunately, due to the small sample size of quantitative data in this study, no statistical tests or inferential interpretation was feasible, therefore each of the five research questions was used to drive the enquiry and integration of data sets. Once analysis of the respective data sets was completed, each data set was mapped out visually using paper by summarising the data using a specific subject heading. Using each research question as a thread, the written subject heading was physically moved to sit under each research question – in essence following a thread (the research question) through each data set resulting in a large visual representation of key findings from all data sets related to the research question. Where a subject heading related to more than one research question, a duplicate piece of paper was created to ensure all aspects of data were aligned with the respective research question. By following such a process, I was able to visually understand what sections of qualitative or quantitative data related to the question and easily move forward to interpretation of the findings leading to a detailed answer of the question. Interpretation of findings was guided by this visual map where key themes could be identified. These themes were repeatedly reviewed by the research student and confirmed through rigorous discussion with the supervisory team.

Within the reported literature on using mixed methods, researchers will often place weight on a data set within their data set either on qualitative, or quantitative data dependent on the study (O'Cathain *et al.,* 2010; Moran-Ellis *et al.,* 2006; Sandelowski, 2000). However in this study, as all data sets are essential to answering the research questions, equal weight was placed on all data sets.

3.7 Chapter summary

This chapter has presented both the methodology and methods of this study. The rationale and philosophical underpinnings of mixed methods research has been presented and methods used to conduct the study have been described. While health professional interviews were conducted first, these findings will be presented as the final data chapter with the next chapter presenting findings from the patient questionnaire. Findings have been presented in this way as the first 4 research questions relate to patient experience.

Chapter Four: Questionnaire Findings

4.1 Chapter outline

The following chapter presents analysis of responses from patients that received education through the oral education clinic (OEC), to questionnaires issued at baseline and 6 weeks later. Questionnaire data collection methods are described in the previous chapter. As no changes were made to the questionnaires following pilot, pilot responses are included in the presented findings.

The findings are organised into eight sections that include: participant characteristics; experience of the OEC; satisfaction with information; beliefs about medicines; experience of taking an oral SACT; side effects; and satisfaction with oral SACT. Analysis of free-text responses is discussed in section 10 and the chapter closes with a summary of questionnaire findings in section 11.

This chapter addresses the following research questions:

- What are the experiences of patients receiving oral SACT?
- How satisfied are patients with the clinical care they have received?
- How useful is the oral education clinic (OEC) for patients?
- What strategies do patients use to manage both their oral SACT and treatment related toxicity?

4.2 Response rate

From 11/2016 to 02/2018, an estimated 350 (84%) of 417 people with cancer (PWC) who received education from the OEC were invited to participate in the study. 84 (24%) of the 350-questionnaire time-point 1 (Q1) were returned. Of those 84 respondents, 81 consented to be posted a questionnaire at time-point 2 (Q2); 70 (83%) of 84 respondents completed and returned Q2. In total, 70 of 350 people invited to participate returned both Q1 and Q2 (20%).

Due to a low response rate, the level of statistical analysis was limited. Throughout this chapter and reported results it has been difficult to determine causality or statistically significant findings. Where small numbers of respondents are indicated, sensitivity analysis (Thabane *et al.,* 2013) has been considered, but reported in the relevant appendix due to an inability to assess significance.

4.3 Participant characteristics

The following section describes the characteristics of respondents including socio-demographic data, types of cancer and type of treatment received.

4.3.1 Socio-demographic characteristics

Participant demographics are presented in Table 4.12. 47 of the 83 respondents indicated their gender was male (56%). The mean age of respondents (n=75) was 52.5 years; five (6%) respondents were aged between 31 – 49 years; 69 (82%) respondents were aged 50-89 years; and the median age was 67 years. 64 (76%) respondents were 'married or living as married', 70 (83%) had no dependents and 50 (60%) were retired from paid work. 75 (89%) identified themselves as White British with one individual identifying as Asian and another mixed background. The level of education attained by respondents varied: the proportion of respondents that had completed further education and above was 71.5% (n=81) and of those, 7% (n=6) had PhDs.

Table 4.12 Socio-demographic characteristics

Socio-demographic characteristics		N	%
Gender	Male	47	**57.0**
	Female	36	**43.0**
	Total	83	**100.00**
	Missing	1	**-**
Age	31-49	5	**6.7**
	50-69	30	**40.0**
	70-89	39	**52.0**
	90+	1	**1.3**
	Total	75	**100.00**
	Missing	9	**-**
	Mean age	52.54	**-**
	Median age	67.00	**-**
Marital status	Married or living as married	64	**79.0**
	Divorced or separated	6	**7.4**
	Widowed	9	**11.1**
	Single	2	**2.5**
	Total	81	**100.00**
	Missing	3	**-**
Dependents	No	70	**86.4**
	Yes	11	**13.6**
	Total	81	**100.00**
	Missing	3	**-**
Employment	Paid work	18	**22.2**
	Temporarily off sick	7	**8.5**
	Unemployed	2	**2.4**
	Retired from paid work	50	**61.0**
	Unable to work	4	**4.9**
	Other	1	**1.2**
	Total	82	**100.00**
	Missing	2	**-**
Ethnicity	White – British	75	**90.4**
	White - Eastern Europe	3	**3.6**
	White - other groups	3	**3.6**
	Asian - Middle East	1	**1.2**
	Mixed Background	1	**1.2**
	Total	83	**100.00**
	Missing	1	**-**
Education	Secondary school	23	**28.4**
	Further education/college	26	**32.1**
	University degree	19	**23.5**
	Postgraduate degree	7	**8.6**
	PhD	6	**7.4**
	Total	81	**100.00**
	Missing	3	**-**

4.3.2 Clinical Characteristics

56 (67%) respondents had solid tumours, classified as oncological cancers, and 27 (33%) had either lymphoma, leukaemia or myeloma, classified as haematological cancers. There was a total of 20 different types of cancer diagnoses (Table 4.13): 15 participants (18%) had breast cancer; 14 (17%) had renal cancer; and 12 (14%) had prostate cancer. Other cancer diagnoses included: adrenocortical carcinoma, B cell prolymphocytic leukaemia, gastrointestinal stromal tumour (GIST), glioma, lymphocytic leukemia and lymphoplasmocytic lymphoma.

Table 4.13 Clinical characteristics

Cancer type		
Cancer type	**N**	**%**
Breast	15	**17.9**
Renal	14	**16.7**
Prostate	12	**14.3**
Chronic lymphocytic leukaemia (CLL)	8	**9.5**
Colorectal	7	**8.3**
Multiple myeloma (MM)	6	**6.0**
Lung	5	**6.0**
Melanoma	3	**3.6**
Chronic myeloid leukaemia (CML)	2	**2.4**
Myelofibrosis	2	**2.4**
Mantle cell lymphoma (MCL)	2	**2.4**
Other	7	**8.3**

Respondents were asked to record any co-morbidities, phrased as 'long-standing conditions'. 50 (59%) respondents reported one or more co-morbidity (Table 4.14). Most common co-morbidities included: high blood pressure (n=19, 23%), arthritis (n=15, 18%) and a neurological condition (n=10, 12%). In relation to management of co-morbidities, 68 (81%) respondents reported taking daily medicines other than their oral SACT with only 15 (18%) respondents having no other regular medicines.

Table 4.14 Long standing conditions and polypharmacy

Number of long standing conditions		
	N	**%**
No chronic conditions	34	**40.5**
1 other chronic condition	26	**31.0**
2 other chronic conditions	11	**13.1**
3 or more chronic conditions	13	**15.5**
Total	84	**100.0**

4.3.3 Treatment information

Participants were prescribed one of 34 different oral SACT regimens (Table 4.15) that included either a single SACT drug e.g. capecitabine or a combination of two SACT drugs e.g. bicalutamide and enzalutamide. 12 (14%) respondents were prescribed capecitabine, which is used to treat breast and colorectal cancers, 11 (13%) were prescribed ibrutinib to treat B-cell malignancies and 11 (13%) were prescribed sunitinib to treat renal cell carcinoma.

Table 4.15 Types of oral SACT

Type of oral SACT		
	N	**%**
Capecitabine	12	**14.3**
Ibrutinib	11	**13.1**
Sunitinib	11	**13.1**
Enzalutamide	6	**7.1**
Cyclophosphamide and thalidomide	3	**3.6**
Exemestane and everolimus	2	**2.4**
Ruxolitinib	2	**2.4**
Abiraterone	2	**2.4**
Bicalutamide and enzalutamide	2	**2.4**
Dabrafenib and trametinib	2	**2.4**
Lenalidomide	2	**2.4**
Other targeted oral SACT	23	**27.6**
Total	78	**92.9**
Missing	6	**7.1**

61 (73%) respondents indicated that they were not offered a choice between oral or IV SACT. Reasons for choosing an oral treatment were described in the free-text box with most indicating their oncologist/haematologist had advised oral SACT was their best treatment option (Table 4.16). 49 (58%) respondents received previous treatments with a different oral SACT (n=15, 18%) or an IV treatment (n=9, 11%).

Table 4.16 Reasons for choosing an oral SACT

Reason for choosing oral SACT in preference to IV SACT	N
Recommended by doctor	16
Oral SACT less burdensome	4
Could not tolerate other treatment options	3
Oral SACT appeared to have more positive factors	2
Conducted own research and went private to get oral SACT	1

72 (86%) respondents provided information about date of diagnosis and date of attendance at OEC. Oral SACT was commenced more than 2 years from diagnosis in 26 (31%) respondents but ranged

from starting treatment within the same month of diagnosis (patients with chronic myeloid leukaemia (CML), myeloma, renal cell carcinoma (RCC), lung, breast, melanoma and mantle cell lymphoma (MCL)) to 25 years after their first diagnosis (breast cancer) (Table 4.17).

Table 4.17 Time since diagnosis to commencing oral SACT

Time since diagnosis to commencing oral SACT		
	N	**%**
< 1 month	12	**14.3**
2-3 months	10	**11.9**
4-6 months	5	**6.0**
More than 6 months but less than 1 year	6	**7.1**
1-2 years	13	**15.5**
More than 2 years	26	**31.0**
Total	72	**85.7**
Missing	12	**14.3**

4.3.4 Sample summary

More than half of the participants were male; the median age was 67 years. Most participants were married or living as married with no dependents and retired. The sample lacks ethnic diversity and was mostly white British respondents. The level of education across the sample was relatively high with varying degrees of education. Most individuals were living with one or more chronic condition(s) and were taking one or more daily medicines.

The most common type of cancers that participants had were breast, renal or prostate and they were prescribed one of 34 oral SACT regimens. Most respondents did not have the option to choose between oral SACT or IV SACT, but where there was choice, selection of oral SACT in preference to IV SACT was influenced by oncologist/haematologist recommendation. Over half of the respondents had received prior anti-cancer therapy before commencing their oral SACT.

4.4 Experience of the Oral Education Clinic (OEC)

The following section addresses aspects of each of the following research questions:

- How satisfied are patients with the clinical care they have received?
- How useful is the oral education clinic for patients?
- What strategies do patients use to manage both their oral SACT and treatment related toxicity?

4.4.1 Experience of receiving an OEC appointment

82 (98%) participants received OEC appointments within 3 weeks of agreeing to commence oral SACT. 31 (37%) participants received OEC appointments within 1-2 weeks; 29 (34%) within 4 – 7 days; 12 (14%) within 1-3 days and 10 (12%) within 2-3 weeks. The majority of participants (n = 60, 71%) did not receive their oral SACT before their appointment; although 20 (24%) did and 6 (7%) participants had started their medication prior to the OEC.

PWC were offered their education appointment either face-to-face at the hospital or by telephone, with two (3%) participants reporting being offered either a telephone or face–to-face appointment. When asked in the questionnaire, more than half of respondents (n= 45, 62%) indicated a preference for a face-to-face appointment rather than a telephone appointment (Table 4.18).

Table 4.18 Face to face vs telephone appointments

Type of appointment offered and preferred			
		N	%
Appointment type offered	Appointment at cancer centre	35	**60.3%**
	Telephone appointment	21	**36.2%**
	Both	2	**3.4%**
Preference for appointment type	Appointment at cancer centre	45	**61.6%**
	Telephone appointment	26	**35.6%**
	No preference	2	**2.7%**

For patients offered an appointment at the cancer centre, 25 (47%) preferred a face to face appointment, with only 4 (8%) indicating a preference for a telephone appointment [six missing responses]. For individuals who received a telephone appointment, only 3 (6%) would have preferred a face to face meeting with 17 (32%) maintaining a preference for a telephone appointment [one missing response].

4.4.2 Experience with the OEC facilitator

Of 80 respondents, 78 (98%) recorded that the health professional they met at the OEC told them their name. 46 (58%) respondents received their education from a pharmacist and 26 (33%) received education from a nurse; 6 (8%) were unsure of which health professional they saw; one respondent indicated seeing both a nurse and a pharmacist; and one participant indicated they received education from a doctor.

77 respondents indicated if they had a preference about which type of health professional provided their education. 51 (66%) stated they did not mind who they saw; 13 (17%) preferred a pharmacist; 9 (12%) a nurse; and 4 (5%) a doctor. No associations were identified amongst those indicating a preference for a specific type of health professional when considered by cancer type, SACT type, gender or who they received their education from initially.

Confidence in the health professional facilitating the OEC overall was high with the majority of participants reporting feeling 'very confident' (n=45, 56%) or 'confident' (n=29, 36%). Minimal differences were observed between confidence in those who saw a nurse, or a pharmacist and the findings have been summarised in Table 4.19.

Table 4.19 Confidence in health professionals who deliver education in the OEC

Confidence in health professionals									
	Very confident		Confident		Not confident		Not at all confident		Total
	N	%	N	%	N	%	N	%	N
Nurse	17	**65.4%**	9	**34.6%**	0	**0.0%**	0	**0.0%**	26
Pharmacist	25	**54.3%**	16	**34.8%**	4	**8.7%**	1	**2.2%**	46
Don't know	3	**50.0%**	2	**33.3%**	1	**16.7%**	0	**0.0%**	6
Nurse and Pharmacist	0	**0.0%**	1	**100%**	0	**0.0%**	0	**0.0%**	1
Doctor	0	**0.0%**	1	**100%**	0	**0.0%**	0	**0.0%**	1
Total	45	-	29	-	5	-	1	-	80

Confidence in health professionals (summed)					
	Confident		Unconfident		Total
	N	%	N	%	N
Nurse	26	**100%**	0	**0.0%**	26
Pharmacist	41	**89%**	5	**11%**	46
Don't know	5	**83%**	1	**17%**	6
Nurse and Pharmacist	1	**100%**	0	**0.0%**	1
Doctor	1	**100%**	0	**0.0%**	1
Total	74	-	6	-	80

Slight differences were observed between men and women regarding confidence in health professionals, with more male respondents reporting 'very confident' compared to female respondents (n=27, 34% vs n=17, 22%); however this was not found to be statistically significant using a Pearson Chi squared test (p=0.473, df=3). No significant differences were observed considering age (p=0.023, df=9) or haematological vs oncological diagnosis (p=0.468, df=3) using Pearson Chi squared.

4.4.3 Experience of attending the OEC

Of the 62 participants that recorded a response, 41 (66%) attended the OEC appointment alone. With 22 missing responses, a total of 21 (25%) respondents were accompanied by someone with the majority bringing their partner (n=32, 68%) and some bringing their child (n=8, 17%). For participants who attended alone (n=41), 41% (9/22) said they would have liked someone to come with them, most often their partner (n=7, 88%).

Participants' views on the content of the OEC are summarised in Table 4.20

Table 4.20 Findings on content of the OEC

Findings on content of OEC				Summed positive and negative scores	
		N	%	N	%
Did you feel you had the chance to discuss your concerns and feelings about taking the oral anti-cancer medicine? [Q1B26]	Yes	64	**77.1%**	80	**96.4%**
	Yes, a little	16	**19.3%**		
	No, not really	1	**1.2%**	3	**3.6%**
	No, not at all	2	**2.4%**		
Did you feel that you received a clear explanation of how to take your oral anti-cancer medicines? [Q1B27]	Yes	77	**92.8%**	82	**98.8%**
	Yes, a little	5	**6.0%**		
	No, not really	1	**1.2%**	1	**1.2%**
	No, not at all	0	**0.0%**		
Were you given written information about your oral anti-cancer medicine? [Q1B28]	Yes	81	**97.6%**	83	**100%**
	Yes, a little	2	**2.4%**		
	No, not really	0	**0.0%**	0	**0.0%**
	No, not at all	0	**0.0%**		
Did you feel that all your questions were answered at the appointment? [Q1B29]	Yes	72	**86.7%**	78	**93.9%**
	Yes, a little	6	**7.2%**		
	No, not really	5	**6.0%**	5	**6.0%**
	No, not at all	0	**0.0%**		
Do you know at which point you should seek help or advice? [Q1B30]	Yes	76	**91.6%**	82	**98.8**
	Yes, a little	6	**7.2%**		
	No, not really	1	**1.2%**	1	**1.2%**
	No, not at all	0	**0.0%**		

Positive scores ('yes' or 'yes, a little') were the majority response in all questions (Q1B26 through Q1B30) but a small number (n=3) of respondents did not feel that they had the opportunity to discuss concerns or feelings about their oral SACT or receive a clear explanation about how to take their oral SACT. Demographic and clinical characteristics of these respondents were considered further (Appendix 18). All negative responses were from female participants, and validated

measures were often found below the mean score of the sample with BMQ concern mostly found above.

Most respondents (n=67, 81%) were given the option of contacting someone after the OEC if they had any questions. All respondents (n=83) knew who to contact if they became unwell. 47 of 76 (62%) respondents were told when their next appointment at the hospital would be.

Three questions were asked about respondents' perception of their own confidence in relation to their oral SACT [Q1B42-44]: confidence in starting oral SACT; confidence in managing any side effects; and confidence in managing oral SACT at home. High levels of confidence were reported for each question (77.1% - 90.2%); however almost 16 (20%) participants reported not feeling confident when they started their oral SACT, and 19 (23%) were not confident about managing any side effects (Table 4.21). No free text data was supplied to offer further explanation regarding low levels of confidence for some participants.

Table 4.21 Confidence after the OEC appointment

Findings of confidence post OEC appointment				Summed positive and negative frequencies	
		N	%	N	%
How confident did you/do you feel starting your oral anti-cancer medicine? [Q1B42]	Very confident	26	**31.3%**	67	**80.7%**
	Confident	41	**49.4%**		
	Not confident	15	**18.1%**	16	**19.3%**
	Very unconfident	1	**1.2%**		
How confident did you feel about managing any side effects? [Q1B43]	Very confident	17	**20.5%**	64	**77.1%**
	Confident	47	**56.6%**		
	Not confident	18	**21.7%**	19	**22.9%**
	Very unconfident	1	**1.2%**		
Overall, how confident did you feel managing to take your oral anti-cancer medicine at home: [Q1B44]	Very confident	31	**38.3%**	73	**90.2%**
	Confident	42	**51.9%**		
	Not confident	8	**9.9%**	8	**9.9%**
	Very unconfident	0	**0.0%**		

Subgroup analysis of confidence by gender, co-morbidities, age and diagnosis identified no statistically significant differences (Appendix 19).

Respondents were asked how well they could remember the information from the OEC. A large majority of respondents recorded 'very well' or 'quite well' (n=60, 89.5%) [of 67 respondents]). In the event of vomiting after taking a dose, most were educated on what action to take (n=54, 66%), however the majority of patients were not instructed what to do if they dropped a tablet on the floor (n=60, 73%). Most participants were not offered a red SACT diary (n=56, 68%).

Where participants had someone accompanying them (55 respondents, 29 missing responses) 98% reported a positive response in their experience of the OEC ('very satisfied' or 'satisfied') with only one respondent reporting dissatisfaction. This individual reporting dissatisfaction did not include additional information. A large majority of respondents indicated that overall, they were either 'very satisfied' or 'satisfied' (n=79, 97.5%) with the OEC appointment, with two (3%) respondents reporting being 'dissatisfied'. Both respondents reporting dissatisfaction were female, between the ages of 31-49 with no further free text information supplied.

4.4.4 Summary of patient experience of the OEC

Overall within this sample, appointments at the OEC took place promptly after the decision to take oral SACT with most having their education within 1-2 weeks. Most participants started their oral SACT after their OEC appointment, of which most were delivered face-to-face. Participants were mostly satisfied with their OEC appointment, regardless of the mode of delivery. OEC facilitators were mostly pharmacists and respondents did not indicate a preference to see either a nurse or pharmacist. Confidence in the OEC facilitators was high, but for men, whilst not statistically significant, higher confidence was reported.

Most respondents attended the OEC alone and indicated they would be comfortable repeating the experience although 41% would have liked someone to be with them. If an individual was accompanied, this was often by a family member such as a partner or adult child. Experience of the OEC was mostly positive, but a minority of respondents reported not being given sufficient opportunity to discuss concerns or ask questions. Following the OEC, the majority of PWC were clear who they could contact if they had an issue and most report being able to remember the information they received. Before commencing oral SACT, most PWC reported high levels of confidence, but where there was concern this was often related to managing side effects.

4.5 Satisfaction with Information

This section addresses the research questions:

- How satisfied are patients with the clinical care they have received?
- How useful is the oral education clinic (OEC) for patients?

The Satisfaction with Information about Medicines Scale (SIMS) is a validated tool used to measure patient satisfaction with provision of information on a medicine. SIMS was measured at baseline in questionnaire 1 and 6 weeks later in questionnaire 2. Potential scores range from 1 – 17, with 17 representing the highest level of satisfaction with information. Where there was missing data, the respondents' scores were removed from analysis. In this study the tool has three purposes:

- To measure the levels of satisfaction with information received about oral SACT
- To identify topic areas where patients had most and least satisfaction
- To identify if there is a difference in satisfaction after a 6-week period

4.5.1 SIMS scores at baseline (Questionnaire 1)

73 participants gave complete SIMS responses in questionnaire 1: with a positive distribution of data -the median score was 14. Complete satisfaction with information (score of 17) was reported by 10 respondents, with the highest number of respondents (n=12) reporting a score of 16. Figure 4.7 demonstrates a simple line count of responses.

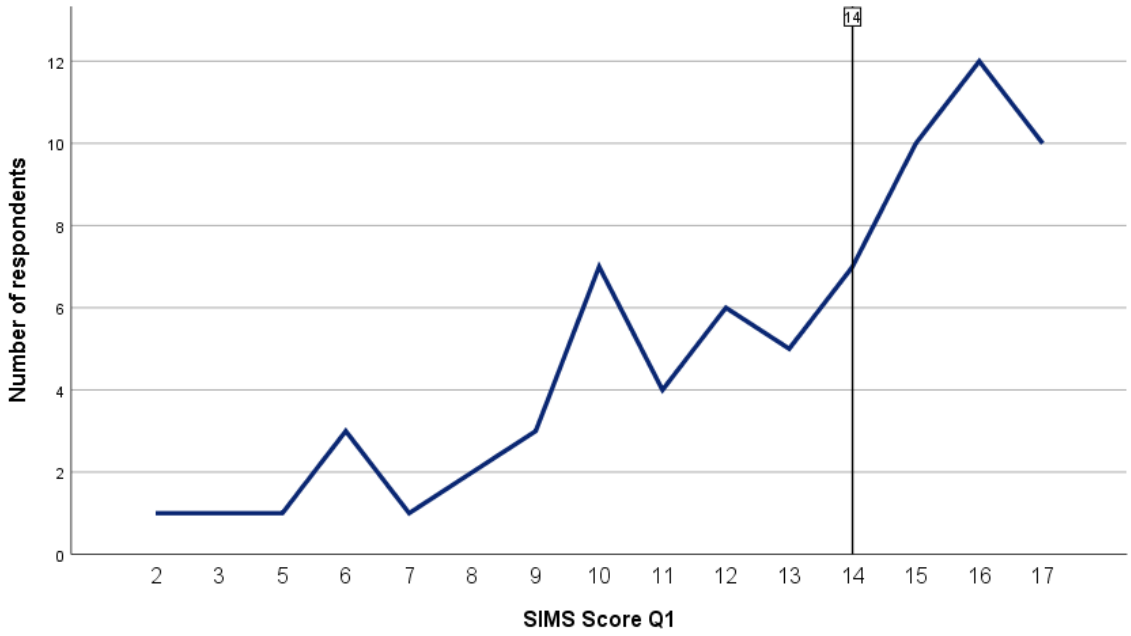

Figure 4.7 Line count of total SIMS score for Q1

Sub-group analysis identified no statistically significant differences in SIMS score by gender (p=0.794, df=14), long standing conditions (p=0.729, df=42), age (p=0.843, df=42) or oncological vs haematological diagnosis (p=0.839, df=14). Referring to Figure 4.8, respondents were most satisfied [answering 'about right'] with the amount of information regarding how to take their oral SACT (98%, n=79) and least satisfied with the amount of information on how to tell if their oral SACT was working (39%, n=31) and effect on sex life (40%, n=32).

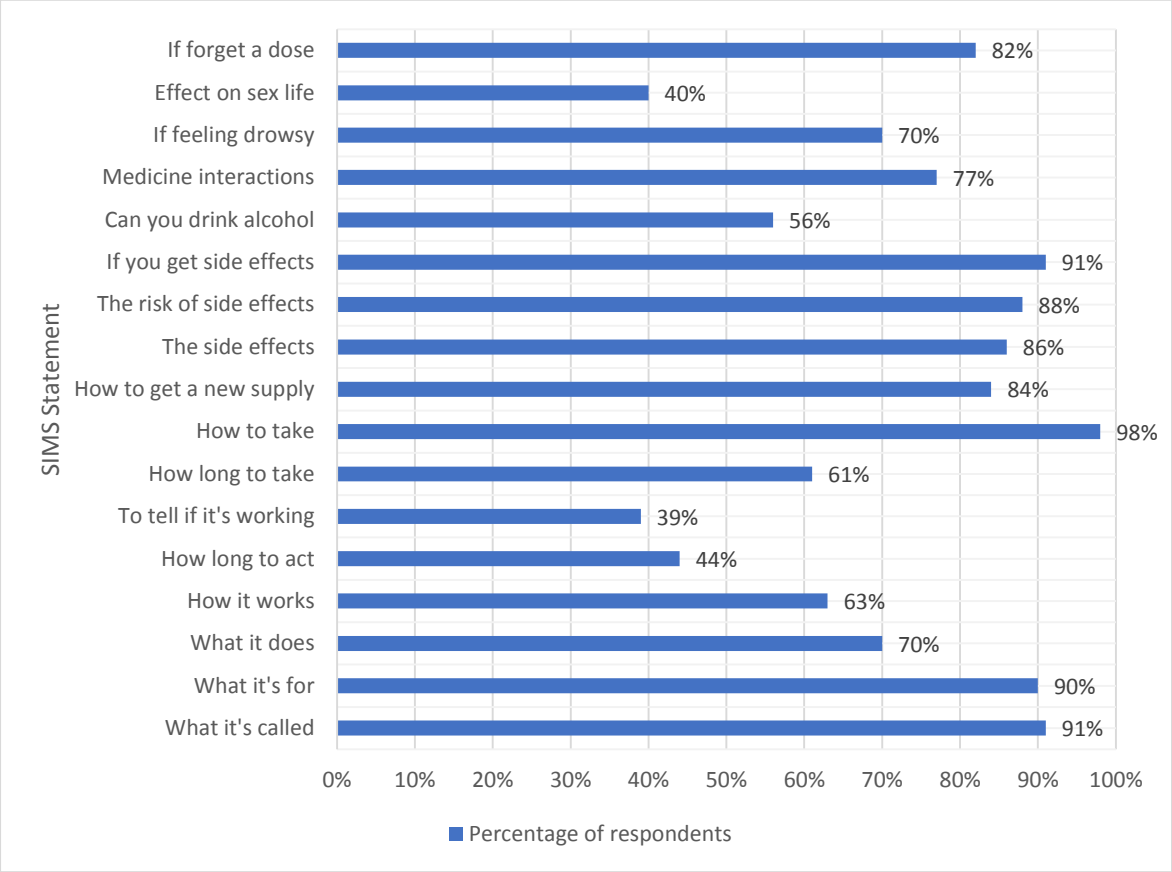

Figure 4.8 Bar chart detailing percentage of respondents reporting complete satisfaction to SIMS items

Proportions and frequencies for each of the SIMS statements has been summarised in Table 4.22 with key findings emphasised in bold text. 8 (10%) respondents reported too much information received on the side effects of their oral SACT. Reports of 'too little' or 'none received' are clinically significant as most subject areas covered by SIMS are essential for safe oral SACT administration, however, the highest proportions of 'too little' information received were found in: what their oral SACT does (15%, n=12), how it works (17%, n=14), how long it will take to act (19%, n=15), how to tell if it's working (21%, n=17) and information of interaction with other medications (14%, n=11). The highest proportions of 'none received' were: how their oral SACT works (17%, n=14), how long it will take to act (35%, n=28), how to tell if it's working (36%, n=29), how long to take their medication

(20%, n=16), whether they can drink alcohol (35%, n=28), what to do if feeling drowsy (21%, n=17) and finally the effect of medication on the individuals sex life (41%, n=32).

Table 4.22 Individual proportions and frequencies for all 17 SIMS items

Questionnaire 1 C45 through C61 Frequencies for each SIMS question %(n)							
Question	Too much	About right	Too little	None received	None needed	Total	Missing
1 What it's called	3%(2)	91%(74)	1%(1)	5%(4)	0%(0)	81	3
2 What it's for	-	90%(73)	6%(5)	-	4%(3)	81	3
3 What it does	-	70%(57)	**15%(12)**	**10%(8)**	5%(4)	81	3
4 How it works	-	63%(51)	**17%(14)**	**17%(14)**	3%(2)	81	3
5 How long to act	-	44%(36)	**19%(15)**	**35%(28)**	3%(2)	81	3
6 To tell if it's working	-	39%(31)	**21%(17)**	**36%(29)**	4%(3)	80	4
7 How long to take	-	61%(48)	**14%(11)**	**20%(16)**	5%(4)	79	5
8 How to take	1%(1)	98%(79)	1%(1)	-	-	81	3
9 How to get a new supply	1%(1)	84%(67)	5%(4)	10%(8)	-	80	4
10 The side effects	**10%(8)**	86%(70)	4%(3)	-	-	81	3
11 The risks of side effects	5%(4)	88%(71)	5%(4)	3%(2)	-	81	3
12 If you get side effects	3%(2)	91%(74)	6%(5)	-	-	81	3
13 Can drink alcohol	-	56%(45)	3%(2)	**35%(28)**	7%(6)	81	3
14 Medicine interactions	-	77%(61)	**10%(8)**	11%(9)	1%(1)	79	5
15 If feeling drowsy	1%(1)	70%(56)	4%(3)	**21%(17)**	4%(3)	80	4
16 Effect on sex life	-	40%(31)	8%(6)	**41%(32)**	13%(10)	79	5
17 If forget a dose	3%(2)	82%(65)	4%(3)	10%(8)	1%(1)	79	5

4.5.2 Change in SIMS scores between baseline and 6 weeks

59 participants gave complete SIMS responses in questionnaire 2, with a positive distribution of data: the median score was 13. Complete satisfaction with information (score of 17) was reported by 8 respondents, with the highest number of respondents (n=10) reporting a score of 16. Figure 4.9 demonstrates a simple line count of responses.

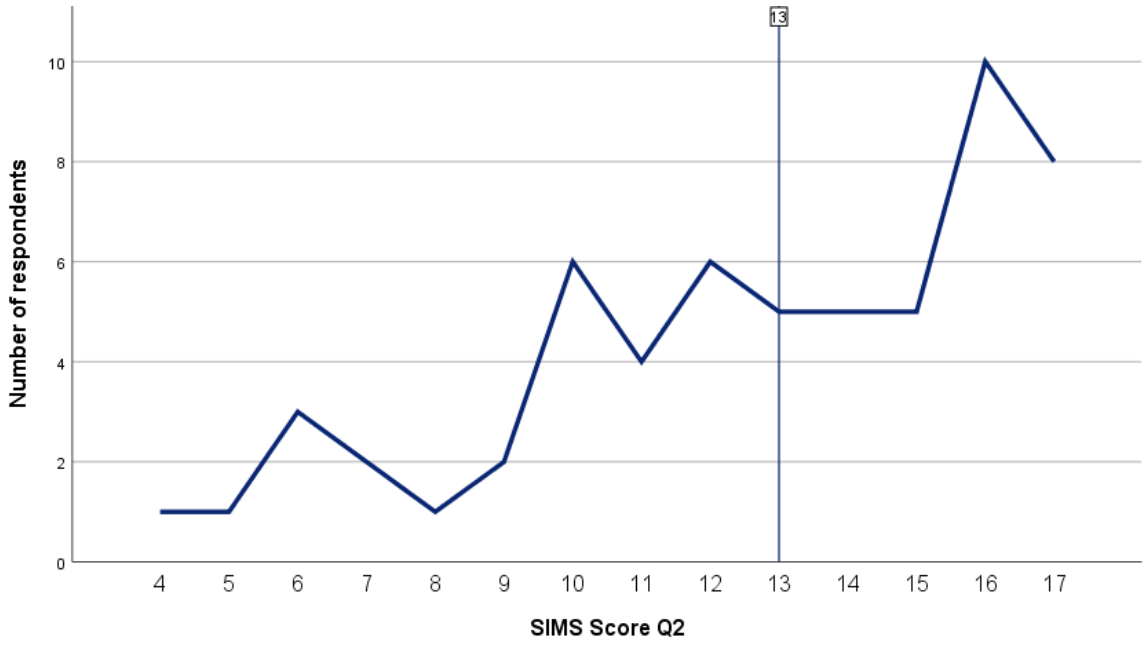

Figure 4.9 Line count of total SIMS score for Q2

As sub-group analysis was conducted on questionnaire 1 data and there were no significant findings this was not repeated for questionnaire 2.

51 individuals had completed SIMS both at Q1 and Q2 and were therefore eligible for comparative analysis. The median score in Q1 was 14 and in Q2, 13. No significant difference in scores was observed between the two-time points, using either the non-parametric Wilcoxon Signed Rank Test (p=0.679) or a matched paired T test (p=0.572). Proportion and frequency of responses to each of the 17 items were tabulated for both questionnaire 1 and questionnaire 2 as illustrated in Appendix 20 with key differences of a greater than 10% change highlighted.

Using comparison percentages as depicted in Figure 4.10, complete satisfaction was higher in questionnaire 1 for 9 items, unchanged in 3 and lower in 5. While these differences are relatively small, and not statistically significant, the findings suggest that for some participants, over a 6 week period, on reflection an increased level of information might be desired around: information on medicine interactions, alcohol consumption, how long to take treatment, what it does and how it works.

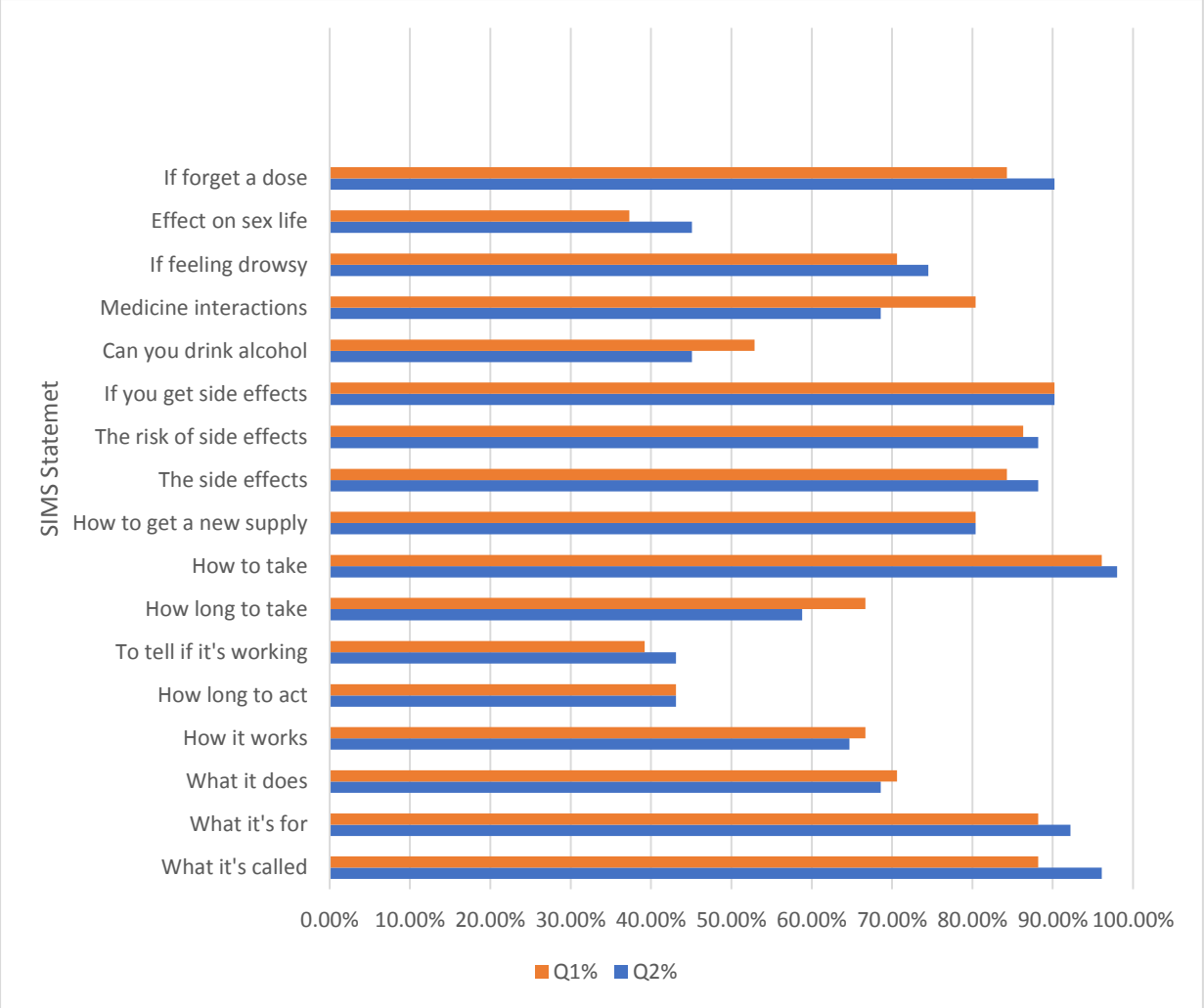

Figure 4.10 Comparing complete satisfaction with SIMS scores in Q1 and Q2 for all SIMS items

4.5.3 Summary of SIMS data

Satisfaction with information was generally high at Q1, with no differences in satisfaction observed by gender, age, co-morbidities and oncological vs haematological diagnosis. Median satisfaction was higher for men (14.5) than women (13), although the difference was not statistically significant. Complete satisfaction with information was highest regarding how to take an oral SACT, but lowest concerning information on how to tell if oral SACT was working. Several topic areas were identified where some respondents felt they received too little information including information on how to tell if oral SACT is working, how long it will take to act, and what oral SACT does. Satisfaction scores generally remained high in Q2. For the few individuals who were less satisfied in Q2 this was in relation to medicine interactions, duration of treatment, how oral SACT works and what it does.

4.6 Beliefs about Medicines

This section addresses the research question:

- What are the experiences of patients receiving oral SACT?

The BMQ is a validated tool used to assess and identify patient beliefs regarding concerns about their medication versus perceived necessity of the medication. The BMQ is split into two sub-scales for necessity (BMQ-N) and concerns (BMQ-C). Each sub-scale presents a statement with responses on a Likert-type scale scoring 1-5. Final scores will range between 5 and 25, with scores above 12.5 indicating strong beliefs. A necessity-concerns differential can also be calculated with the difference between necessity and concerns resulting in a potential range of -20 to 20. A positive score indicates perception that the benefits of the medication outweigh the cost, whilst a negative score indicates a personal belief that the medicine incurs greater cost than benefit.

4.6.1 BMQ Necessity and Concerns

The mean score for BMQ Necessity was 21.1 (SD 3.03) and for BMQ Concerns 14.7 (SD 4.28). As the maximum score is 25, it is common in reported literature to consider any scores below 12.5 as weaker beliefs, and scores 12.5 and above as stronger beliefs. In this sample, respondents had a mean score of 21.1 indicating strongest beliefs about the Necessity of their medication.

A positive mean BMQ differential score of 6.42 (SD=5.63) indicates that on average, respondent's beliefs in necessity of their oral SACT outweighed concerns. Individual scores ranged from -7 through to 20. A total of 11 individuals had negative scores with the remaining 68 having scores of greater than or equal to 0. Demographic and clinical characteristics of these respondents were considered further (Appendix 21). Due to the small size of this sub-sample and a mix of characteristics, no further level of analysis was conducted.

4.6.2 Summary on beliefs about medicines

Strong beliefs about medicines were found in both domains of Necessity and Concern, but strongest beliefs were found in Necessity. For all BMQ-N statements the highest proportion of respondents selected strongly agree. Across BMQ-C statements, the highest proportions of respondents selected agree or disagree accounting for a lower, but still 'strong' BMQ-C score. With a positive mean BMQ differential score the findings overall indicate PWC have strong beliefs in the need to be receiving their oral SACT.

4.7 Experience of taking an oral SACT

This section addresses the following research questions:

- What are the experiences of patients receiving oral SACT?
- What strategies do patients use to manage both their oral SACT and treatment related toxicity?

4.7.1 Medication adherence

Patients reports of adhering to their medication were measured using the MMAS-8, a standardised measure of self-reported adherence where a maximum score of 8 equates to high adherence, 6 to <8 medium adherence and <6 low adherence. MMAS-8 has been used to investigate adherence to an oral SACT, as effective and safe treatment is dependent on appropriate adherence.

The median MMAS-8 score from 70 respondents was 8.00 (Table 4.23). 40 (57%) of the respondents had high adherence, scoring 8; 27 (39%) had medium adherence scoring 6 or 7; and 3 (4%) respondents had low adherence, scoring between 3.75 and 5.25.

Table 4.23 MMAS-8 scores

MMAS-8 scores		
Median	8.00	
Adherence classification	**N**	**%**
Low adherence (<6)	3	**4%**
Medium adherence (7 - <8)	27	**39%**
High adherence (8)	40	**57%**
Total	70	**-**
Missing	14	**-**

A slight difference was observed in adherence scores between genders, with male respondents scoring 7.55 and female respondents 7.33; however this was not found to be statistically significant ($p = 0.515$, $df=8$). Using the MMAS-8 adherence classification (low, medium and high), responses were compared by gender, age, co-morbidities, marital status, oncological vs haematological diagnosis and by number of side effects experienced (Table 4.24). Respondents who reported low adherence were 2 females and 1 male, aged between 31-69, with 0-1 co-morbidities, two were married (one participant had not recording marital status) and they all experienced 5 or more side effects. Of the 3 respondents reporting low adherence, two had a positive mean BMQ differential score (where belief in necessity outweighed concern). Adherence to oral SACT was highest in men, individuals between the ages of 70-89, those with no co-morbidities, an oncological diagnosis, those

living as married, those without dependents and those experiencing 5 or more side effects, however no differences were statistically significant.

Table 4.24 Adherence classification against gender, age, co-morbidities, marital status, dependents and diagnosis

MMAS-8 adherence scores by gender, age, co-morbidities and marital status							
		MMAS-8 Adherence classification					
		Low adherence		Medium adherence		High adherence	
		N	%	N	%	N	%
Gender	Male	1	**2.6%**	14	**35.9%**	**24**	**61.5%**
	Female	2	**6.5%**	13	**41.9%**	16	**51.6%**
Age	18-30	0	**0.0%**	0	**0.0%**	0	**0.0%**
	31-49	1	**20.0%**	2	**40.0%**	2	**40.0%**
	50-69	2	**7.5%**	11	**40.7%**	14	**51.9%**
	70-89	0	**0.0%**	12	**38.7%**	**19**	**61.3%**
	90+	0	**0.0%**	0	**0.0%**	1	**100.0%**
Co-Morbidities	No co-morbidities	1	**3.0%**	12	**36.4%**	**20**	**60.6%**
	One co-morbidity	2	**11.1%**	6	**33.3%**	10	**55.6%**
	Two co-morbidities	0	**0.0%**	5	**50.0%**	5	**50.0%**
	3 or more co-morbidities	0	**0.0%**	4	**44.4%**	5	**55.6%**
Diagnosis	Oncological	2	**4.5%**	16	**36.4%**	**26**	**59.1%**
	Haematological	1	**4.0%**	10	**40.0%**	14	**56.0%**
Marital status	Married or living as married	2	**3.8%**	21	**39.6%**	**30**	**56.7%**
	Divorced or separated	0	**0.0%**	2	**40.0%**	3	**60.0%**
	Widowed	0	**0.0%**	4	**44.4%**	5	**55.6%**
	Single	0	**0.0%**	0	**0.0%**	1	**100.0%**
	Other	0	**0.0%**	0	**0.0%**	0	**0.0%**
Dependents	Yes	2	**22.2%**	4	**44.4%**	3	**33.3%**
	No	1	**1.7%**	23	**39.0%**	**35**	**59.3%**
Number of recorded side effects from oral SACT	No side effects	0	**0.0%**	2	**18.2%**	**9**	**81.8%**
	1-2 side effects	0	**0.0%**	2	**40.0%**	**3**	**60.0%**
	3-4 side effects	0	**0.0%**	3	**30.0%**	**7**	**70.0%**
	5 or more side effects	3	**6.8%**	20	**45.5%**	**21**	**47.7%**

4.7.2 Taking an oral SACT

Respondents were asked about how they usually remember to take their medication, 54 (77%) indicated they established a medication-taking routine. Five (7%) of the respondents reported using a diary; three (4%) reminders; and four (6%) a combination of these factors (see Table 4.25).

Table 4.25 Strategies to manage adherence at home

Strategies to manage adherence		
	N	**%**
Part of daily routine	54	**77.1%**
Diary	5	**7.1%**
Reminders	3	**4.3%**
Combination of above	4	**5.7%**
Other	2	**2.9%**
Total	70	**100.0%**
Missing	14	**-**

Some additional free text comments were also provided with four individuals writing about their use of a dosette box to help organise and manage their medications and others describing the type of routine they had established, "*I take them after breakfast, before cleaning my teeth*" (P060). The majority of patients had no difficulty swallowing their oral SACT (n=67, 97%). One participant indicated that difficulty in swallowing tablets was attributable to the number of tablets. In addition to the MMAS-8, further questions on adherence and convenience in taking an oral SACT were also included (see Table 4.26). Findings are similar to MMAS-8 scores with 51 (75%) of the respondents indicating they have never had trouble remembering to take their medication, 13 (19%) indicating rarely having trouble, 3 (4%) reporting sometimes, and one answered always, but did not provide a free-text response to explain why. When asked if oral SACT was taken exactly as directed, 55 (81%) of the respondents reported always, but 12 (17.9%) were not taking it as directed, four of whom reported forgetfulness as the reason.

With regard to convenience, 42 (63%) of respondents indicated they found oral SACT 'very convenient' or 'convenient', 20 (30%) reporting neither and 5 (8%) reporting 'inconvenient' or 'very inconvenient'. Finally, 61 (91%) of respondents were not bothered by the time it took to take their oral SACT.

Table 4.26 Further questions of adherence

Further adherence questions			
		N	%
How often have you had trouble remembering to take your oral anti-cancer medication? [Q2D91]	Never	51	**75.0%**
	Rarely	13	**19.1%**
	Sometimes	3	**4.4%**
	Always	1	**1.5%**
	Total	68	**100.0%**
	Missing	16	-
How often have you taken your oral anti-cancer medication exactly as directed? [Q2D92]	Never	4	**6.0%**
	Most of the time	8	**11.9%**
	Always	55	**82.1%**
	Total	67	**100.0%**
	Missing	17	-
If you didn't always take as directed, why was this? [Q2D93]	I forgot	4	**57.1%**
	Side effects	1	**14.3%**
	Other	2	**28.6%**
	Total	7	**100.0%**
	Missing	77	-
How inconvenient was it for you to take your oral anti-cancer medicine? [Q2D94]	Very convenient	21	**31.3%**
	Convenient	21	**31.3%**
	Neither	20	**29.9%**
	Inconvenient	2	**3.0%**
	Very inconvenient	3	**4.5%**
	Total	67	**100.0%**
	Missing	17	-
How bothered were you by the amount of time it took to take your oral anti-cancer medicine? [Q2D95]	Not bothered at all	61	**91.0%**
	A little bothered	5	**7.5%**
	Very bothered	1	**1.5%**
	Total	67	**100.0%**
	Missing	17	-

4.7.3 Summary of taking an oral SACT

Overall respondents reported 'high adherence' to taking their oral SACT. Highest adherence rates were found in those who were male, between the ages of 70-89, with no co-morbidities, an oncological diagnosis, individuals who were married or living as married, those with no dependents and those experiencing 5 or more side effects. Adherence was often promoted by establishing a routine. Finally, while there were fewer respondents to Q2, the majority of PWC report taking their oral SACT as directed with no difficulty in remembering.

4.8 Side effects

This section addresses the following research questions:

- What are the experiences of patients receiving oral SACT?
- What strategies do patients use to manage both their oral SACT and treatment related toxicity?

Collecting data on experience of side effects is vital to inform future models of care and identify how individuals manage experience of a side effect when distanced from the hospital.

4.8.1 Experience of side effects

Table 4.27 summarises the time within which respondents first experienced side effects. 11 of 68 respondents (16%) reported having no side effects. The most common time other respondents experienced their first side effect was within days of starting treatment, with four (6%) respondents experiencing their first side effects after 3 weeks. Notably, approximately 10% of respondents were experiencing the first onset of side effects between days 8-10 (11.8%, n=8) and days 11-14 (10.3%, n=7).

Table 4.27 Times of onset of side effects

Onset of side effects					
Timeframe	**N**	**%**	**Timeframe**	**N**	**%**
1-2 days	17	**25.0%**	Within a week	38	**55.9%**
3-5 days	15	**22.1%**			
6-7 days	6	**8.8%**			
8-10	**8**	**11.8%**	Within 2 weeks	15	**22.1%**
11-14	**7**	**10.3%**			
After 3 weeks	2	**2.9%**	Within 4 weeks	4	**5.8%**
After 4 weeks	2	**2.9%**			
No side effects	11	**16.2%**			
Total	68	-			
Missing	16	-			

A list of the 28 most common side effects experienced by people receiving anti-cancer treatments was included for respondents to tick if they had experienced that side effect and if so to indicate the severity of their side effect. 57 (84%) respondents experienced one or more side effects. The incidence and severity of five side effects reported by more than half of the respondents are shown in Table 4.28. The most common side effect was fatigue (n=45, 79%) followed by dry lips or mouth (n=31, 54%) and physical weakness (n=31, 54%). Experience of severity was grouped as: 'manageable' or 'requires intervention' such as advice, supportive medicines, medical review or

urgent treatment. The most common side effects requiring intervention were physical weakness (n=9, 29%) and fatigue (n=9, 20%).

Table 4.28 Most common side effects and experienced severity

Most common side effects and severity								
Side effect	**N**	**%**	**Severity**	**N**	**%**	**Classification**	**N**	**%**
Fatigue	45	**79.0%**	Mild	4	**8.9%**	Manageable	36	**80%**
			Tolerable	32	**71.1%**			
			Bothersome	6	**13.3%**	**Required intervention**	**9**	**20.0%**
			Quite severe	3	**6.7%**			
			Very severe	0	**0.0%**			
Dry lips or mouth	31	**54.4%**	Mild	8	**25.8%**	Manageable	26	**83.9%**
			Tolerable	18	**58.1%**			
			Bothersome	5	**16.1%**	**Required intervention**	**5**	**16.1%**
			Quite severe	0	**0.0%**			
			Very severe	0	**0.0%**			
Physical weakness	31	**54.4%**	Mild	2	**6.5%**	Manageable	22	**71.0%**
			Tolerable	20	**64.5%**			
			Bothersome	6	**19.4%**	**Required intervention**	**9**	**29.1%**
			Quite severe	3	**9.7%**			
			Very severe	0	**0.0%**			
Nausea	29	**50.9%**	Mild	11	**37.9%**	Manageable	25	**86.2%**
			Tolerable	14	**48.3%**			
			Bothersome	3	**10.3%**	Required intervention	4	**13.7%**
			Quite severe	1	**3.4%**			
			Very severe	0	**0.0%**			
Skin dryness	29	**50.9%**	Mild	5	**17.2%**	Manageable	27	**93.1%**
			Tolerable	22	**75.9%**			
			Bothersome	2	**6.9%**	Required intervention	2	**6.9%**
			Quite severe	0	**0.0%**			
			Very severe	0	**0.0%**			

4.8.2 Managing side effects

The majority of respondents reported discussing their side effects with their doctor at their next appointment (n=57, 86%). Less than half (n=29, 44%) reported they made phone contact prior to their next appointment. Nearly half (n = 30, 47%) of respondents had contacted triage. Other health professionals contacted by phone were (n=12 total responses): GP (n=5, 42%), local pharmacist (n=3, 25%), NHS out of hours (n=1, 8%), chemotherapy nurse (n=1, 8%), clinical nurse specialist (n=1, 8%) and contact through the use of a digital application (n=1, 8%). 45 (54% of complete sample) respondents were not given additional medicines to help manage side effects. 39 of 51 (64%) respondents did not keep a record of their side effects; however, 8 (16%) made use of a SACT diary.

Table 4.29 illustrates findings from six questions regarding patient actions in response to experience of a side effect. Of 35 respondents who made contact by telephone, 15 did so within a day of experiencing a side effect; however, 13 respondents reported delaying seeking telephone advice for 4 or more days. Phone calls were most often made either by the patient participant (n=31, 80%) or sometimes by family members (n=8, 21%). 14 respondents reported the reason for not seeking advice about a side effect was that they did not deem the side effect as serious. Where individuals made telephone contact with triage, the majority of concerns were addressed (n=26, 93%). Three respondents reported contacting their GP for advice as the first point of contact. Overall, individuals reported high levels of confidence (very confident n=20, 56%; quite confident n=11, 31%) in the health professional they contacted in managing their side effect; however, five respondents (13.9%) did not feel confident in the health professional, a clinically significant finding.

Table 4.29 Actions taken while managing a side effect

Actions taken while managing a side effect			
		N	%
How soon did you phone for advice?	Within an hour	3	**8.6%**
	Within 3-4 hours	6	**17.1%**
	Within a day	6	**17.1%**
	Within 2 days	7	**20.0%**
	4 days or more	**13**	**37.1%**
Who called for advice about your side effect?	You	31	**79.5%**
	Family member you live with	6	**15.4%**
	Family member you do not live with	2	**5.1%**
If you had a side effect, but didn't call for advice, why was this?	I didn't think it was serious enough	**14**	**45.2%**
	It passed by itself in a few hours	5	**16.1%**
	I didn't want to bother anyone	1	**3.2%**
	I thought I could manage myself	**6**	**19.4%**
	Combination of all	3	**9.8%**
	Other	2	**6.5%**
If you didn't call triage first, who were you referred to?	Triage	2	**40.0%**
	GP	**3**	**60.0%**
Did triage address your concerns?	No	2	**7.1%**
	Yes	26	**92.9%**
How confident were you in the health professional managing your side effect?	Very confident	20	**55.6%**
	Quite confident	11	**30.6%**
	Not confident	**5**	**13.9%**

4.8.3 Summary of patient experiences of side effects

The majority of side effects were first experienced within one week of commencing treatment. Most common side effects were fatigue, physical weakness and dry lips/mouth. The most common side effects requiring an intervention were fatigue and physical weakness. Some respondents did not report or seek advice about their side effect, but most discussed with their doctor at their next appointment. Contact was not made at the time as most respondents deemed the side effect to not be serious enough to need medical intervention. For respondents who sought advice regarding a side effect, this was initiated in most cases by the patient and a call placed within one day of experiencing the side effect.

4.9 Satisfaction with oral SACT

The following section will address the following research question:

- How satisfied are patients with the clinical care they have received?

Identifying and measuring patient experience is pivotal to driving forward improvements to healthcare delivery services. For this reason, satisfaction of patients receiving oral SACT was included as a research question.

4.9.1 Cancer Therapy Satisfaction Questionnaire

The CTSQ is a standardised tool to evaluate patient satisfaction with cancer treatment. It includes 16 questions across three domains (Expectations of Therapy (ET), Feelings about Side Effects (FSE) and Satisfaction with Therapy (SWT)) with a maximum score of 100, where 100 indicates complete satisfaction.

Table 4.30 illustrates the number of responses, mean score, standard deviation and median scores for each of three domains. SWT had the highest mean domain score of 81 indicating high levels of respondent satisfaction with their oral SACT. ET had the lowest mean domain score of 53.68. The FSE domain mean was 66.37. These scores indicate respondents had highest levels of satisfaction regarding questions of satisfaction with oral SACT with domain questions referring to cost-benefit and overall satisfaction with oral SACT. Whilst ET received the lowest mean score, these questions focussed on oral SACT efficacy and treatment outcomes. This study has not been designed to identify treatment goals and thus cannot identify if a respondent is taking oral SACT with curative intent. It is likely many respondents will be taking oral SACT to control their cancer, rather than cure and thus some questions found within the ET domain may have affected the lower mean.

Table 4.30 Summary of CTSQ scores

Summary of CTSQ domain scores			
Domain	**Responses**	**Mean (SD)**	**Median**
Expectations of Therapy	68	53.68 (21.29)	50.00
Feelings about Side Effects	63	66.37 (21.75)	68.75
Satisfaction With Therapy	65	81.08 (18.01)	85.71

Analysing mean scores by different sample characteristics using Pearson Chi Square test, mean scores for male respondents were higher than female in each domain, but this was not found to be

statistically significant for both ET and SWT domains (see Table 4.31). A statistically significant difference was identified between gender within the FSE domain (p=0.029, df=14) with the mean for male respondents 74.65 (SD14.63) and female respondents 55.32 (SD24.86). Mean scores were highest for people over the age of 70 in each domain, but no statistical significance was identified. Concerning marital status, individuals who were married, or living as married reported the highest satisfaction across each domain. Individuals with no co-morbidities reported a highest mean score of 58.20 (SD20.40) for ET, but for FSE individuals with two co-morbidities had the highest mean of 68.75 (SD19.76) and those with one co-morbidity had the highest mean of 84.80 (SD14.37) for SWT. Finally, cancer type was categorised by oncological or haematological. Respondents with a haematological diagnosis reported higher levels of satisfaction within FSE (71.31, SD19.73 vs 62.81, SD22.06) and SWT (85.18, SD13.95 vs 78.87, SD19.89), but oncological diagnosis respondents had higher satisfaction in ET (53.75, SD20.65 vs 52.24, SD22.28) – none of these differences were found to be statistically significant.

Table 4.31 Subgroup analysis of CTSQ domain scores by gender, age, marital status, co-morbidities and diagnosis

Comparing mean scores by gender, age, marital status, co-morbidities and diagnosis								
		n	ET	Chi2 symbol (df)	FSE		SWT	
			Mean (SD)		Mean (SD)		Mean (SD)	
Gender	Male	47	**55.20 (22.87)**	.430 (17)	**74.65 (14.63)**	*.029 (14)*	**86.88 (13.19)**	.462 (22)
	Female	36	51.75 (19.31)		55.32 (24.86)		73.88 (20.65)	
Age	31-69	35	52.42 (17.65)	.233 (16)	64.01 (22.64)	.151 (14)	79.17 (17.28)	.228 (21)
	70+	40	**54.35 (25.15)**		**67.41 (20.72)**		**82.53 (19.34)**	
Marital status	Married or living as married	64	**54.38 (21.93)**	.360 (17)	**67.95 (20.47)**	.866 (13)	**82.17 (17.60)**	.596 (21)
	Lives alone	17	51.61 (20.61)		65.18 (23.22)		79.51 (17.92)	
Co-morbidities	No co-morbidities	41	**58.20 (20.40)**	.058 (51)	64.66 (23.93)	.754 (42)	78.87 (20.91)	.768 (66)
	One co-morbidity	21	52.94 (22.29)		68.38 (19.57)		**84.80 (14.37)**	
	Two co-morbidities	13	52.00 (26.37)		**68.75 (19.76)**		79.89 (12.44)	
	3 or more co-morbidities	9	40.83 (11.59)		65.63 (23.39)		82.62 (19.71)	
Diagnosis	Oncological	56	**53.75 (20.65)**	.501 (16)	62.81 (22.06)	.704 (14)	78.87 (19.89)	.557 (22)
	Haematological	27	52.24 (22.28)		**71.31 (19.73)**		**85.18 (13.95)**	

Referring to Table 4.31, the mean score for ET was lowest and therefore scores were examined individually for each statement. For most respondents (n=56, 78%), oral SACT would at times help the individual get back to a normal life with only 15 respondents (22%) recording rarely or never. The majority of respondents (n=36, 53%) reported never or rarely feeling like the oral SACT would cure their cancer, however this might be due to treatment types being non-curative, information which was not asked on the questionnaire. For most people, oral SACT was not viewed as a way to help prevent cancer returning with only 4 respondents (6%) selecting 'always'. For the majority of participants (n=52, 75%), oral SACT was viewed as a means to stop cancer from spreading with only 4 (6%) selecting 'rarely' or 'never'. Finally for ET, there was a clear majority of people thinking oral SACT would help them live longer (n=52, 75%).

Similarly, individual scores for FSE domain was examined. For a slight majority of respondents (n=38, 55%) oral SACT had some degree of limitation on their daily life with 30 respondents (45%) commenting rarely or never. No respondent recorded an 'always' response to feeling upset about their side effects, but most experienced this at least sometimes (39%, n=26) or for a few, most of the time (n=6, 9%). For most people, taking an oral SACT was much easier than expected (n=37, 54%) with only 6 (9%) recording a 'somewhat more difficult' response. Finally, the majority (n=37, 55%) of respondents' experience of side effects were much better or somewhat better than expected with 17 respondents (25%) finding side effects worse.

4.9.2 CTSQ summary

Within the 3 domains of the CTSQ, Satisfaction with Therapy (SWT) scored the highest with Expectations of Treatment (ET) lowest. Within the SWT domain, mean scores were highest for male respondents, above the age of 70, married or living as married, with one co-morbidity and a haematological diagnosis.

Overall, the results for the CTSQ demonstrate high levels of satisfaction with no mean scores in any domain falling below 50 demonstrating oral SACT as an acceptable treatment.

4.10 Free text comments

Questionnaire 1 and Questionnaire 2 free-text comments were analysed within NVIVO11© software using the thematic framework developed from analysing patient interviews. All reported comments aligned to the coding framework including a positive view of oral SACT, the frustration and challenge of obtaining repeat oral SACT prescriptions, and poor reported administration of care, such as

disorganised appointments and challenges in acquiring a repeat prescription. All findings reported in free text on the questionnaires were addressed in patient interviews and thus are not further reported here.

4.11 Chapter summary

Overall, the findings from this questionnaire study suggest that the OEC is an effective way to prepare PWC who are commencing an oral SACT. Satisfaction with the appointment was high and respondents had high levels of confidence in the OEC facilitator, regardless of their professional background. Most reported no preference for a nurse or a pharmacist. Areas where greater information was required include information on treatment efficacy and lifestyle advice.

Adherence to treatment was high across the sample with only a small number of respondents reporting not taking their treatment as directed or missing a dose. Where non-adherent incidences were reported this was due to forgetfulness or a change in routine. Oral SACT was reportedly easy to take and rarely an inconvenience to an individual's lifestyle, with establishment of routine being seen to promote adherence. Strong beliefs are held by individuals taking an oral SACT, but particularly regarding necessity of the treatment, where for most the perceived benefits of taking the treatment outweighs the risks.

Where PWC experienced side effects, these would often occur within a week of starting treatment and most did not report or discuss their side effect until their next medical appointment. This was usually because there was a sense the side effect was not serious enough to report, or a perception it could be managed independently at home. For individuals who reported their side effect, this was often done within a day of first experiencing it and confidence was high in the health professionals they spoke with. The most common side effects were fatigue, weakness and dry lips/mouth.

Measured within a standardised satisfaction tool, CTSQ scores revealed that patients were most satisfied with receiving an oral SACT, but satisfaction was lowest regarding expectations of treatment. ET domain questions were focussed on the outcome of cancer treatment including disease progression or prognosis, these findings might be misinterpreted if PWC were receiving a palliative course of oral SACT, or an oral SACT to manage cancer as a long term chronic condition. Satisfaction with treatment and experience of taking an oral SACT were high.

Chapter Five: Patient Interviews

5.1 Chapter outline

The following chapter will present findings from 28 semi-structured interviews with patients receiving an oral SACT. The aim of this study has been to explore the perceptions and experiences of patients receiving oral SACT; therefore this chapter will address the following research questions:

- What is the experience of patients receiving or who have received oral SACT?
- How satisfied are patients with the clinical care they have received?
- How useful is the OEC for patients receiving oral SACT?
- What strategies do patients use to manage their oral SACT at home and treatment related toxicity?

The methods have been presented in chapter 3. Interview data was analysed using Framework (Ritchie and Spencer, 2004). Over-arching themes will be presented. Following presentation of thematic findings, specific case characteristics will be discussed alongside presentation of an identified typology.

5.2 Sample and demographics

The patient participants had one of 13 different cancer diagnoses; breast (n=5), renal (n-5) and prostate (n=4) cancer were the most common. Oral SACT prescribed included cytotoxic drugs, such as capecitabine (n=5), the anti-androgen therapy enzalutamide (n=4), and small molecule inhibitors, such as sunitinib (n=4) and ibrutinib (n=4).

Of those interview participants who could recall, they reported having been diagnosed between one year and more than three years before commencing oral SACT, but nearly half were 'treatment naïve' not having received anti-cancer therapy before. 19 participants received oral SACT education from a pharmacist and nine from a nurse. The majority of participants received face-to-face oral SACT education (n=22, 73%), but some had telephone appointments (n=6, 27%), which was reflective of participants completing the questionnaire where 64 (76%) received telephone education, and 20 (24%) received face to face education.

Sixteen men and twelve women, aged 35 – 92 years, of whom most were married without dependents, participated in the semi-structured interview. Most participants identified as white British (all were white), educational attainment ranged from secondary education to PhD level, and most were retired. Recruitment to interview was open to anyone who indicated a willingness to be

interviewed due to low recruitment numbers; therefore a specific sample characteristic was not determined. However, considering the demographics presented in chapter 4, *P.* 110-114, interview participants were representative of the questionnaire respondent population.

5.3 Thematic analysis

Nine themes were derived from indexing transcript data. Appendix 12 demonstrates the sub-themes and original index attached to the data. At the stage of abstraction, three over-arching themes were identified: a person's experience of cancer is challenging, and how they cope depends on the individual; patient perceptions and experiences of oral SACT; and models of care should be tailored towards the needs of the individual (Table 5.32).

Table 5.32 Nine themes identified from coding, leading to three final themes

Themes derived from coding	Themes derived from abstraction
Cancer and its treatment needs to be 'coped with'	A person's experience of cancer is challenging, and how they cope depends on the individual
The experience of the healthcare system could be improved	
How a person copes with cancer and its treatment is dependent on their personal traits	
Oral SACT compares favourably to intravenous SACT	Patient perceptions and experiences of oral SACT
Participants experience of side effects	
Different health professionals are viewed as giving information differently and all should provide person-focused information	Models of care should be tailored towards the needs of the individual
Interactions with health professionals	
Written information was beneficial, but sharing it should be paced	
The option of telephone follow up review would be beneficial	

5.3.1 A person's experience of cancer is challenging and how they cope depends on the individual

5.3.1a Cancer and its treatment needs to be 'coped with'

For all participants, the impact of having cancer was emotionally challenging. Feelings of shock at diagnosis were common; one individual described how their *"whole world fell apart" (PT_INT28).* The 'stress' caused by a cancer diagnosis also generated negative feelings about individuals' self-identity and rumination about dying:

> *"I was always quite a bubbly character, and I still am a little bit, but I certainly don't enjoy going out as much […] it's the emotional side of thinking what might happen next […] and you always think the worst don't you?" (PT_INT07)*

> *"[…] every night I go to bed and think am I going to die tonight? It's just in your head." (PT_INT09).*

In addition, to verbalising an altered identity of self, one participant commented on *"other people's attitudes […] if you say you've got cancer to someone they really try and avoid you like they might catch it" (PT_INT23).* The sense that having cancer was emotionally difficult arose collectively from the stress caused by a cancer diagnosis, fear of dying from cancer and the stigma associated with a cancer diagnosis.

Attending the cancer centre for appointments was also a stressful and overwhelming process, because of the "*reality of [the] situation" (PT_INT02).* Depending on the type of appointment, for example if an individual was receiving 'bad news' of cancer progression, the ability to assimilate information was considerably reduced:

> *"[…] if you just have results or you've just been told the chemo you were on is not working and you have to go on something else, I think you're not always thinking about okay how do I take the next one, you're just thinking oh shit, bad news" (PT_INT02).*

One participant talked about leaving an appointment with a consultant oncologist believing they were unsuitable for oral SACT, only to be later told that they were eligible. Being given conflicting information resulted in anxiety, frustration and worry for participants:

> *"The problem is […] three oncologists told me three different stories. One said the tablet will last for a year and then we have to do immunotherapy; the other oncologist in next meeting told me, not a year, maybe 3 months […] and then the other one said no, I've got a patient that's lasted 5 years on this thing. Jesus guys when do you want me to die? You know what,*

why don't you all get into a room, so I can get one story from you, you know? So in my opinion, none of them really know 'how long is a piece of string?', because none of them are giving you the same fact […]. I think for patients, you really just want the right information" (PT_INT09).

Confusion was also experienced by some participants when commencing their oral SACT due to inconsistencies in the information provided, e.g. when verbal information was delivered about how and when to take oral SACT and it was different from written information. Inconsistent information caused worry about whether the oral SACT was being taken correctly:

"What the nurse had told me was then slightly different from what was on the box of tablets from the pharmacy […] so that was slightly confusing" (PT_INT02).

Many participants dreaded the thought of chemotherapy and a lack of certainty about their treatment duration caused anxiety.

"[…] I wasn't told when, how, whether I'd know, […] if it was working or not […] you don't know until the next CT scan […] that was hard" (PT_INT25).

All participants reported difficulty in identifying if their treatment was working. There seemed to be an expectation that this would be discussed, or that health professionals should relay information on signs that the treatment is having its desired effect.

"I feel everybody is a little bit unsure of how it will work […] I did ask one of the doctors how long it would be effective for and he said years and years (laughs), which is very vague" (PT_INT01).

Cytotoxic treatments were viewed as "*bloody awful" (PT_INT20)* and "*the pits" (PT_INT23).* The treatment was associated with thoughts of looking unwell, baldness, and having nausea and vomiting, "*because you hear so many people with chemo and the side effects that they have, I just don't want to go down that road" (PT_INT11).*

Finding out about the potential side effects of oral SACT was associated with fear and viewed as highly stressful, disturbing and '*off-putting'* (PT_INT02). One individual described feeling, "*petrified, absolutely petrified" (PT_INT24)* leaving their appointment with a, "*really negative feeling" (PT_INT24).*

"That was very disturbing […] there must be a better way to explain to someone" (PT_INT09).

Reactions to hearing about side effects varied across participants. One participant described '*becoming numb' (PT_INT21)* to the information and '*not assimilating it' (PT_INT21)*, with another participant feeling like they would get every side effect discussed:

"It's probably quite bad because after a while you get like deadened to that and you're kind of going (eye roll gesture) yeah, okay, yeah, uh-huh" (PT_INT02)

"The word chemo does frighten you […] I don't know you just feel you're going to get them all" (PT_INT16).

While learning about side effects caused fear and stress, one participant reflected, "*if I got it [the side effect] and I didn't know about it then I'd be complaining, so I suppose in one way it's gotta be said […] I can't see any better way of putting it really to be quite honest" (PT_INT15).* One participant suggested that while discussing side effects, an emphasis should be placed on the probability or chance of experiencing that side effect. By presenting the likelihood as "*1 in 10 people experience X, 1 in 100 people experience Y and 1 in 1,000 people experience Z*" (PT_INT09) would reduce stress and improve the delivery of this essential information:

"The likelihood of having it […] that was where I found my comfort" (PT_INT09).

Whilst some participants felt they would get every side effect possible, others felt they might be okay and not have any side effects, *"you get told some side effects […] they explain it as this could happen, so you don't really, you think I'll be alright" (PT_INT0*3).

While education on side effects is essential, it was hard for the participants to hear. Participants employed a variety of coping strategies, which were dependent on their usual, individual styles of coping. The type and level of support required also varied dependent on the individual, which meant the health professionals needed to assess individual needs. One participant described themselves as "*anally retentive" (PT_INT01)* and as someone who was well accustomed to routine with a strong sense of personal discipline, in this scenario no additional support was required for them to take their oral SACT as prescribed. Another participant described themselves as a *"strong person" (PT_INT23)* and did not require additional counselling or psychosocial support.

5.3.1b The experience of the healthcare system could be improved

The OEC service was viewed by all participants as a "*very effective way of starting people off" (PT_INT01)* on their oral SACT. The appointment itself was described as straight forward, receiving a thorough explanation about the oral SACT, what the tablets were, how they were to be taken and what potential side effects might be experienced. The location of the appointment (a private room) was viewed as comfortable and appropriate, allowing for family members to also attend. Some participants took their own regular medicines with them allowing the OEC facilitator to check through and ensure there were no adverse drug interactions.

Attending the OEC appointment, however, required participants to attend the cancer centre, which was a challenge for many participants. Car parking caused stress due to local traffic and difficulty accessing the hospital car park. It was common to have more than a one-hour wait to get into the car park with an individual commenting, *"[I've] parked in the suburbs and walked down, in the middle of winter, now, I'm supposed to be sick here" (PT_INT09).* Being given a free parking pass was *"helpful […] and such a relief not to have to pay every time" (PT_INT16).*

One participant was offered the option of having a face to face, or telephone appointment. The telephone appointment was deemed as acceptable, but having had the appointment the individual reflected that they would have felt more confident if their appointment had been face to face:

> **P:** "*I would say that actually speaking to somebody face to face is better than a phone call, but the phone call as I say as far as I was concerned was quite adequate. […] At the time I said no don't worry about it [attending study site for OEC appointment], because I never really thought it through properly when they said it […] and I said no, telephone will do.*
> ***I**: Do you think if you knew then, what you know now, would you have opted to go in for the appointment?*
> ***P**: Yeah*
> ***I**: You would have?*
> ***P**: Yeah*
> ***I**: Okay, and why is that?*
> ***P**: Just more confident that's all" (PT_INT19).*

Although some participants preferred the convenience of telephone appointments, face to face appointments were highlighted as crucial by several participants

> *"[…] this kind of thing you need it to be with real people, I know they're real, but I think you need to be face to face, that's pretty important I think" (PT_INT24).*

The OEC appointment aimed to prepare someone to safely manage oral SACT and focused on practical details

> "A*ctually seeing people is very important, because you pick up a lot of stuff about people by the way they speak and move and stuff, but I mean in these sort of practical things then just telephone is fine I think*" *(PT_INT26).*

There was, however, a sense that OEC appointments appeared disorganised both in content and logistics. Several participants reported an experience where they arrived to the outpatient

department for their appointment to find health professionals not expecting them, which led to confusion, worry and a sense of disorganisation.

> *"Someone phoned me and was like can you come in, come in at this time, ask for me at the DTU desk, which I did and then they were like well we don't know where you need to go, go and see them in the oncology, so I went in there and then they were like no you need to meet her out here and then someone had to go and find her and it was all a bit like wooow" (PT_INT02).*

Participants sensed that health professionals were over-stretched and over-worked. Appointments were often delayed, and waiting would be involved, whether this was to have blood samples taken, or to commence treatment. Observing delays and (at times) an appearance of staff under pressure, led patients to sense the NHS was *"at maximum capacity" (PT_INT09).* One participant described the overworked nature of the NHS:

> *"I know the national health is overworked […], but actually when you get there people are really very nice" (PT_INT04)*.

One of the main inconveniences of having oral SACT was obtaining a new supply. The process was unclear, *"always a difficulty" (PT_INT13)* and often required initiation and follow-up by the patient themselves. Several instances were reported where the prescription was not signed by relevant staff and thus delayed, or it had not been ordered and thus not delivered in time or where the patient would come to collect their medication only to find it unavailable. The impact of this was a sense of disorganisation and 'clumsiness' resulting in it being challenging to get a new prescription:

> *"It's a matter of making sure that one the doctor has sent the prescription in for it and that the pharmacy have got the prescription and that […] it'll actually be ready when I call in for it. Doesn't run like clockwork really […] I feel it does ask the patient to be on the alert to know when the next supply of drugs is coming up, make sure it's in the right place and it's been prescribed properly." (PT_INT01).*

It was accepted that while the system may be under the strain *"[…] the positives [of the NHS] outweigh the negatives [delays]" (PT_INT02).* Patient participants described NHS staff as, "*absolutely marvellous" (PT_INT05),* "*amazing" (PT_INT10)* and "*just brilliant" (PT_INT26.)*. There was an overall perception that staff were caring, hard-working, patient and reassuring.

5.3.1c How a person copes with cancer and its treatment is dependent on their personal traits

Some participants described ways in which they coped with managing their cancer and its treatment. The sense of needing to accept the diagnosis and treatment and '"*just get on with it*" *(PT_INT16)* was commonly described. Having a time point for the end of treatment also helped some participants to cope as, *"these are only blips that are going to be just for 6 months, so that's what I keep hanging onto" (PT_INT05).* Positivity, or trying to remain positive, was another mechanism used to protect the emotional fragility of several participants and assist them coping with their diagnosis and treatment. For some participants positivity was essential:

> "*What you need to try and give a patient when he walks out through the door, because he or she is in absolute panic mode, literally if there's a weak person they'll commit suicide, I promise you […]. I think they need to walk out with a positive attitude, that's what you need to try and achieve" (PT_INT09).*

While participants described their own coping mechanisms, family was a key source of support. Family members were described as *"helping out everywhere" (PT_INT15)* and "*their own pharmacist" (PT_INT18).* Participants thought that there was a need for extra support for some patients, particularly older people or those without supportive family members.

> *"It depends on the individual; if you're an old guy sitting at home by yourself with no support, you probably need that [telephone follow-up]; you know I've got a wife and hopefully a bit of normality about the house" (PT_INT07).*

When reflecting on challenges, it was common for people to speak to others to have a query answered, which was perceived as difficult for less assertive participants.

> *"I've got good support of family and friends. If you were on your own, or, em, yeah, and also see I'm used to being in hospital and dealing with hospitals, so that's not intimidating, but for someone who's not used to being in hospital for whatever reason, I mean I'm not used to being on the receiving end [it could be difficult]" (PT_INT05).*

Several participants attended the OEC with a family member or carer, which they found helpful. Having a third person present enabled the participant to assimilate information better with family members picking up on different pieces of information, extending discussions with the health professional, and asking questions that the participant hadn't thought of. Participants that had a third person present at their appointment recommended that PWC bring someone along:

> *"We remember different things when we come away, so you do need someone with you […] I would definitely recommend that people take someone with them" (PT_INT05).*

One individual who attended the OEC alone, and often attended other appointments at the hospital alone, felt that due to the volume of information being delivered at the OEC, a third person would be helpful.

> *"I mean I don't normally have anybody with me in appointments, but actually the information, that information was such a lot I probably could've done with somebody" (PT_INT21).*

How participants' families were affected by their cancer diagnosis was also recognised, which generated concern and worry for family members:

> "*Worse for [the family] I think […] it's easier to deal with it when it's you" (PT_INT24).*

> "*I think my wife suffered a lot […] she's the one I think about most really to be honest with you, rather than myself" (PT_INT08*).

Participants talked about their family needing support, "[*My partner] is like a little lost soul" (PT_INT28).* There was a sense, however, that support for family members was lacking and family also appeared to be "*just kind of in the background" (PT_INT16)*.

> *"I think they should not just look at me as the patient, it's the carer as well, I say carer because she's there all day most of the time […] it would be useful if they could talk to my [partner], or anybody's wife or husband." (PT_INT27).*

Several participants commented that their family members, "*probably do need some support" (PT_INT16),* but that they "*wouldn't admit that [they] needed help even if you asked" (PT_INT14)*. The offer of family support was not always desired, as it was perceived as indicating the serious nature of the participant's illness.

> *"I don't know it's a funny one isn't it, because I think if you get the hospital involved [in supporting family members] does it up the anti on its seriousness? I'd prefer to keep them away from that" (PT_INT07) {individual with partner and 3 children}.*

Another area where participants found support was in discussions and contact with peers who had cancer and specifically those with experience of taking oral SACT:

> *"it was a real good relief to meet somebody going through it, because although you're told things by the professionals, and they're very good, it's only then I think when you meet*

someone who isn't within the profession you can open up a bit more and share things […] it really is helpful learning from other people" (PT_INT16).

Another participant who sought peer advice from an online forum commented:

"I messaged on there, ohhh I'm not sure I'm doing it right and they were all like we take ours with food […] and that seems to make less nausea […] I kind of was reassured okay I can change and take it this way" (PT_INT02).

Where individuals had not accessed peer support, there was a desire for this:

"*If there was a forum of people that had, that are on the tablet and saying this is my experience" (PT_INT18*)

"Whether some 3 or 4 line case histories of what people had felt, or something would help […] this is what I felt like on the first one and this what I felt like on the 3rd, but now I'm a year past it and you can get through" (PT_ INT05).

Consultations often focussed on medical aspects of care. Participants spoke about little information being provided on holistic aspects of care, or on adapting oral SACT to their individual needs. Fitness was viewed as a key aspect for an individual in managing their cancer and treatments, and physical activity was both a distraction and helped in trying to 'cure their cancer'.

"We're not really busy, which I try and keep myself, then I don't think about it, like I've just joined one of those leisure gyms" (PT_INT09).

Health professionals did not discuss fitness, getting fit or promoting healthy activities, resulting in one participant losing faith in the hospital staff and a reluctance to attend appointments:

"I don't even want to go to hospital anymore […] not one NHS person has told me to get fit. I've said can I go back to the gym […] oh yeah you can go and exercise, they aren't prompting, I want the doctor to say yeah, yeah, yes, that's good for you, go and do it […] why don't you tell me that as a doctor? […] Go and do your exercise, go and drink lots of water, you know, all those type of things" (PT_INT09).

Several participants talked about receiving emotional support from health professionals they trusted, perceiving them as clinically competent and 'experts':

"you put yourself in their hands don't you […] I have absolutely no qualms about trusting them." (PT_INT26).

There were, however, barriers to receiving support from health professionals. A challenge for many participants was the frustration in *"never seeing the same person twice" (PT_INT11)* with several commenting they'd been seen by *"4 or 5 different people" (PT_INT13)*. For those feeling or coping well, there was no issue or negativity to seeing different doctors, but for others it was more challenging. It was felt that by seeing a new doctor each time, formalities had to be gone through for the doctor to be updated on the patient's progress reducing the time available for medical consultation.

> *[Seeing the same person] gets rid of the formalities before, so it means more of the consultation can be happen with […] secondly […] seeing the same person, they usually do remember a little bit as they look up on the computer" (PT_INT13).*

A lack of continuity of health professional also restricted the development of a therapeutic relationship, which was perceived as vitally important:

> *"It would just be good if you could have that same consultant perhaps and build up some sort of relationship, because you walk in and it's somebody else; you really start at the beginning, oh here we go again" (PT_INT27).*

In addition to the strategies described above, participants also talked about devices they used to exercise control, which helped them cope. The patient diary allowed one participant to feel:

> *"a bit more in the driving seat […] it's been my crutch really" (PT_INT25); another felt it important to drive their car to appointments "I do drive, [my partner] can obviously drive [their] own car, but I drive to these appointments because I feel I'm in control*" (PT_INT28).

Other participants referred to written literature providing informational support:

> *"I just didn't know what was happening […] I couldn't sleep for about 3 days […] you just don't know what's happening, so I referred back to that [written information] […] and em then sort of calmed myself down" (PT_INT03).*

Overall, participants described a variety of strategies to help them cope with the challenges of having cancer and being treated with oral SACT including: acceptance, positivity, trust, control, family support and activity. Some participants described attributes they had that meant they were more activated towards self-management, and other indicated areas where they needed additional support to self-manage their care in relation to taking oral SACT.

5.3.2 Patient perceptions and experiences of oral SACT

5.3.2a Oral SACT compares favourably to intravenous SACT

There was a view expressed during some interviews of oral SACT being akin to poison. This was held both by participants when taking the tablets, *"I do look at them some days and think oh well another dose of poison" (PT_INT23*), but also reported to be expressed by health professionals with participant PT_INT16 commenting, *"my GP keeps saying 'you know you're taking poison'?" (PT_INT16).* One participant reflected on a concern shared with peers that the oral SACT might not be having an effect on their cancer, and just be causing harmful effects on their body:

> *"A number of people I've met in a similar situation […] wonder whether or not they're just filling their body with chemicals and nothing's really happening, and all they're doing is just destroying other organs along the way to manage the cancer" (PT_INT28).*

The majority of participants described oral SACT treatment as a relief (in comparison to the prospect of IV SACT). Taking an oral SACT provided participants with a sense of independence, control and freedom that enabled them to, *"maintain the illusion of normality" (PT_INT02)* and 'carry on life as normal', which were all regarded as positive factors.

> *"I feel more autonomous, because I can just do them […]. I felt relieved that I could do them at home" (PT_INT05).*

One participant commented on the length of time associated with receiving an IV SACT, including travel, pre-treatment tests and administration of treatment, in comparison to taking a tablet at home; oral SACT eliminated these treatment-related burdens - it saved time and was more convenient.

> *"Somehow it [oral SACT] hasn't got the medical paraphernalia around it […], but taking tablets, just taking tablets has a different feel about it" (PT_INT01).*

Oral SACT was also perceived as 'less fuss' to receive than IV SACT, with fewer high-grade side effects, avoiding feeling ill and spending significant time in hospital. The process of receiving an intravenous treatment was viewed by many as time intensive "*sitting endlessly" (PT_INT18),* invasive and a burden.

> *"I don't want to sit there for 8 hours and then feel rubbish, so I think I felt a bit of relief" (PT_INT24)*

> *"[It's] quite an event […] there's such a fuss about having it intravenously" (PT_INT01).*

Being attached to an infusion was also viewed as restrictive causing feelings of claustrophobia: "*It's not because I'm enclosed, but it's because I can't go anywhere, which I found quite difficult*" *(PT_INT26).* While IV SACT was described as claustrophobic, oral SACT enabled individuals to participate fully in activities like working, going out for a meal and going on holiday. The portability and freedom attributed to oral SACT led to one participant feeling, "*quite happy in a way, it sounded like something I could manage myself" (PT_INT06).*

A few participants received education about their oral SACT by telephone, which was effective, convenient and removed the need to attend the cancer centre.

> *"Phone was better because it involved half an hour or so on the phone where otherwise it involves an afternoon of getting the bus to (place) and waiting around until people are ready, etc, so I preferred it" (PT_INT13).*

Whilst receiving telephone education, there was still opportunity for the OEC facilitator to check the patient's level of understanding:

> *"They went through each thing and said, 'Is that fine? Do you understand?' They explain it so clearly you don't have to question, you know" (PT_INT19).*

Oral SACT was viewed as "*way more manageable" (PT_INT02)* when compared to IV SACT. There was a view that once a routine of taking the tablets was established, the process was easy and enabled a normal lifestyle. One participant referred to the physical act of taking the tablet as:

> *"Easy peasy, because it's twice a day with breakfast and with dinner, that's easy […] there's no issue of forgetting […] I have been known to swig them down with wine!" (PT_INT05).*

Keeping oral SACT in the home and self-administration were viewed as an easy process:

> *"I'm totally amazed, and as long as it carries on going the way it is, I'll be happy as a pig in what's it? (laughter) […] it hasn't stopped me, you just carry it with you [if travelling]" (PT_INT28).*

Participants reported that oral SACT gave the opportunity to carry on life as normal, reflected in the view of comparing oral SACT to, *"just another tablet" (PT_INT19).* A sense of normality, routine and lack of time at the hospital limited the perception of negative impact of the treatment:

> *"I felt relatively more normal and able to carry out a normal life" (PT_INT02*).

A common finding was the need to establish a routine to ensure adherence. Having the responsibility of taking a tablet that was believed to be the cure for their cancer, or a means to control their cancer, was the motivating factor for reportedly high levels of adherence:

> "*How could you forget to take something that important?" (PT_INT23)*

> "*The routine of having medication that's going to keep you alive is a very positive routine […] it's well established, it's the need to do it" (PT_INT28).*

Several participants described interventions they use at home to maintain an adherent routine, such as setting alarms on their mobile phones: "*I didn't have that problem because I set an alarm on my phone*" (*PT*_INT02).

Another participant used physical reminders alongside electronic alarms to promote adherence describing:

> "*I've got an alarm on my phone, on my wife's phone […] I've got reminders everywhere […] one on the fridge […] one on top of the fridge" (PT_INT09).*

The best time to remember taking their oral SACT was in the morning or in the evening:

> *"I just thought like when am I going to be at home, first thing in the morning seemed like a good idea, you almost have it with your coffee in the morning you know!" (PT_INT07).*

Where the oral SACT required more than once daily administration, the best option was in the morning and with the evening meal, or before going to bed; all times that would enable a routine to prevent forgetting to take the medication. Established routines varied between participants, but all described routines carrying the same characteristics: a daily activity at the same time(s) of day. Examples of routines included leaving the oral SACT box sitting on top of the individual's dosette box where the oral SACT joined an already established routine or completing a daily treatment diary and reviewing each day the progress or side effect experience – all daily activities that facilitated remembering to take the oral SACT.

> *"There's nothing saying you should take it first thing in the morning, but in a routine, that I've set up it's perfect, then the rest of the day I just carry on, fill all this out [gestures toward treatment diary] about 7 or 8 o'clock and just carry on" (PT_INT25).*

Where patients had an existing established routine with their other regular medication, adding in oral SACT was not a challenge, other than perhaps the first couple of days which took some time to adjust to a change in their established routine:

> *"I've been taking a couple of pills every day for ages now, and then it grew and grew […] so I already had a routine that I could carry on, I think if you hadn't got a good routine, I think it's hopeless actually, really tricky, so a good routine required" (PT_INT21).*

No set routine was advised by health professionals; rather the individual taking the oral SACT identified what would work best for them in their daily life and established the repetitive activity:

> *"I wake up normally around 04:00 or 05:00 […] so now when I wake up I take my tablet […] so I found my own way round it, it works for me" (PT_INT14).*

Family assisting with adherence was also common with the participants, "*[they] can help you just to remember not to forget to get on with it and take it" (PT_INT10).* Family members were recognised to have a significant role in assisting with reminders to adherence with one participant describing their partner as, "*my own pharmacist" (PT_INT18)* and another describing their partner checking in, *"my [partner] was pretty good at saying you know have you had your tablet?" (PT_INT24)*

Although dosette boxes were a helpful visual aid, some of the drugs are cytotoxic and therefore carry administration risks, so the use of a dosette box is not recommended; to counter this, participant PT_INT21 left the oral SACT in its packet, but sets this on top of their dosette box they use to manage other medications:

> *"I didn't take the main pill out of its packet because it said no not take out of its packet until the last minute, so I would always put it out every night so it was next to my box so I knew where I was everyday" (PT_INT21).*

The use of a medication record card (MRC) was used by several participants, particularly at the commencement of oral SACT or for regimens that have many associated medications:

> "*I did tend to forget, you know, which ones I had to take, that's why they give you this [MRC]" (PT_INT03*) and *"they give you a sheet with the pills, what to take on day 1, day 2, day 3 and that's all very clear […] really helpful […] I don't now [refer to MRC] I did for the first 3 or 4 days because you know you're making sure you're doing it, but because mine's so easy" (PT_INT05).*

A challenging aspect of oral SACT was the supportive medications that often supplemented the oral SACT itself. One individual reported:

> "*The one thing they don't explain is that you're going to have additional medication to go with it, now I think they should state that at the beginning" (PT_INT08).*

With another highlighting that managing many medications carries, "*an awful lot of responsibility […] it just adds to the confusion" (PT_INT06).*

A few participants described incidents of nonadherence. These were attributed to a change in routine or forgetting.

> "*Inevitably I did forget and I was an hour late […] on another day we went down to (place) and I hadn't taken the tablets with me and we got held up for some reason or we had something else to do so I couldn't do that, so I came back took the tablets and then we went back to (place) […] I am disciplined" (PT_INT11).*

While routine promoted adherence for most, one participant reflected on an incident where established routine resulted in nonadherence:

> *"It's a funny thing to say actually, because it becomes routine, and it was one of those things that you almost do without thinking […] I wasn't sure if I'd taken it, which is ridiculous because I remembered about 10am and I could've still taken it but I wasn't sure if I'd taken it because I think, you know, I just go to the pot and off it goes" (PT_INT07).*

There was a sense of frustration and seriousness attached to forgetting to take the oral SACT at the correct time with PT_INT28 commenting:

> "*I've almost slapped myself for doing it, come on, get back home and do this, so you do have an added responsibility, but you are in control of the whole thing*" *(PT_INT28).*

Oral SACT was described as providing PWC with the opportunity to achieve a sense of normality. One participant described an encounter with their consultant who advised them:

> *"To try to live as normally as possible so I was trying to live as normally as possible, and I did" (PT_INT26).*

Another participant reflected that while taking their oral SACT they, *"felt relatively more normal and able to carry out a normal life" (PT_INT02).*

Oral SACT was not only regarded as easier to manage than an IV treatment, but it was also viewed as 'milder'. There was a perception that taking a tablet would be easier on the body, with fewer side effects. This sense of mildness compared to the perception of an IV treatment contributed to the sense of ease in taking a tablet.

> *"Do you want to get pumped full of shit for, you know, 8 hours every 2 weeks and feel pretty awful, or do you want to take a tablet […] ultimately at the moment it's a nice option" (PT_INT07)*

> *"I'll take the tablet, it seems like the drip side really kills quite a bit off, where this is very mild" (PT_INT18).*

Oral SACT was perceived as less toxic because of peers' experiences, "*I'd heard from other people who had tried it that in terms of side effects it was quite minimal, it was one of the nicer ones" (PT_INT02).*

A large majority of participants reported a preference for being treated with an oral SACT rather than IV SACT. When asked to explain this participants referred to, *"a better quality of life" (PT_INT23),* increased convenience (*"It's more convenient […] I certainly prefer the tablets" (PT_INT01))* and a treatment that was not as invasive *("I would choose the tablet because it's easy […] having an intravenous thing is also quite invasive" (PT_INT06)).* Some participants were also aware of the effectiveness of the oral SACT:

> *"I also did research and then I realised yes it does work and that it seemed to be quite effective on that scale" (PT_INT08).*

While there were clear advantages and benefits to taking an oral SACT, a negative aspect of treatment was the lack of clarity on treatment course and duration. An advantage of receiving a course of IV SACT was the finite nature of treatment, with a clear timeline and end point. There was a sense that for IV SACT participants could, "*get it over and done with" (PT_INT08*) or "*just go and get the bone marrow done [cytotoxic IV treatment] and then I'd be fine for the rest of my life" (PT_INT18).*

In addition, side effects from IV SACT were perceived to have a treatment course-related duration and, therefore, provided hope that feeling ill would end:

> *"if you were on systemic chemo, you have a horrible 3 months or whatever it is […] and you're feeling dreadful, but after that you hope you'll be feeling better, but I think if you know it's going on forever [as with oral SACT] it's hopeless" (PT_INT21).*

5.3.2b Participants experience of side effects

A participant's experience of the amount and severity of side effects had a direct influence on their view of oral SACT. Individuals who experienced minimal side effects referred to their treatment as easier and preferable. One individual noticed an improvement in baseline symptoms from their cancer within one day of starting their oral SACT and commented, *"you know it's doing you good; therefore you keep taking it" (PT_INT07).*

Where side effects had been experienced, participants were then less inclined to take the treatment, and in some cases they agreed with their consultant to cease treatment due to high-grade toxicity:

> *"Well the ulcers cleared up, but because my mouth had been so bad, I just haven't felt like going back on and I have told them [oncologist] that" (PT_INT04)*

> *"There were a few times when I didn't want to take it, didn't like what it was doing to me" (PT_INT24).*

Experience of fatigue and tiredness was reported by a large majority of participants. It was described as, "*constant tiredness and lack of energy" (PT_INT26)* by some and its persistence was common, "*I'm tired most of the time, that's what the tablets done" (PT_INT25*).

When describing the experience of fatigue, it was referred to in a negative and persistent way, which had a significant impact on an individual's daily life:

> "A*wful actually […] that's a side effect I think of these more than anything, but of course actually I've always been a fairly sort of busy person and I like to get on and do things and I found it very frustrating" (PT_INT05).*

Tiredness had a negative effect on their daily life and created a sense of social isolation:

> "*Hardly been out, I've missed out on so many things I should've done and that's the worst thing about it, not the actual side effects but the fact I think, oh God, I just about go down the garden or put the dustbins out; I think this is ridiculous as I've always been a very fit person in spite of all the things I've had wrong with me" (PT_INT23).*

Participants were surprised about the severity of the tiredness:

> "*Couldn't possibly believe that I could be affected by this […] from the first day I took them I felt as if my get up and go had gone" (PT_INT05).*

When asked if any advice had been given on how to manage fatigue one participant was unaware of any guidance, but recognised they might have missed it, but another participant was able to recall advice on taking some exercise:

> *"I don't think they did, but they might have done and I might have sort of dismissed it, no this isn't going to be me, so I don't think they did […] not specifically" (PT_INT05)*

> *"I didn't even have the energy to take a 5-minute walk; they do tell you to take some exercise" (PT_INT23).*

There was an option in most regimens to reduce or interrupt the dosage of the drug due to treatment-related toxicity. While often an effective strategy in managing acute side effects, this had a negative connotation and some participants did not wish to report side effects for fear of dose reduction, interruption or cessation.

> *"The nurse did say maybe go down to 37.5mg, because of the side effects in the 3rd and 4th week, which are not good, but I think no I'm going to stick to 50mg to give it it's full thing … in your mind you think no, take more, take more to stop the cancer" (PT_INT16).*

There was a concern that if their oral SACT was reduced, the reduction of dose would have a negative impact on their treatment effectiveness and they wouldn't be giving themselves the best chance of a cure or prolonging their lives.

Since distinguishing symptoms of cancer and co-morbidities from the side effects of cancer treatment was difficult, there was also a challenge in deciding at which point the symptom was a side effect that needed medical intervention. While some participants, *"lean towards the idea if there's something obviously wrong I'll go and talk to somebody" (PT_INT01*) it was not clear when to do this in written information:

> "*It does seem a bit nonsensical with that leaflet they give you about what to do if anything's wrong, temperature, have you got fever, all sorts of things, but you could have a lot of that stuff, nearly all the month […] the first month I phoned about 4 times because I was so unsure about what was going on I thought this is terrible. I mean I could have sepsis, I don't know?" (PT_INT23).*

Medical help seeking behaviours were always triggered by physical feeling, which could potentially be quantified e.g. by taking a temperature:

> *"if I thought there was anything I would take my temperature and then that would indicate to me if it was over the 37 or whatever I would have to just call to check" (PT_INT05)* or as one participant deemed, "*I would tend to ring triage if I thought I needed some treatment of some kind" (PT_INT26).*

Participants reported a sense of knowing their own bodies and when to seek help:

> *"Again it's very personal, it's how seriously I take whatever reaction I'm having and whether I think that's something I need to worry about or not" (PT_INT06)*
>
> "*I know my [own] body" (PT_INT14*)
>
> *"If I felt I was getting out of control, phone triage immediately" (PT_INT28).*

5.3.3 Models of care should be tailored toward needs of the individual

5.3.3a Different health professionals are viewed as giving information differently and all should provide person-focused information

The content of the education was also viewed as disorganised by one participant who compared their education on oral SACT to education they received when being taught how to self-inject another medication, which had been delivered by a nurse in a day treatment unit.

> *"I had a nurse do that with me, it was much easier to cope with all that and she was having to show me how to inject myself, so she had it, I think she had it better organised, it was all a bit disorganised, there were all these boxes of pills all over the place" (PT_INT21).*

Delivery of education was described by several participants as structured and rigid. Several references were made to an authoritarian view of the hospital with the education described as, "*fairly regimental" (PT_INT17)* and the facilitator, "*like a school teacher with a syllabus" (PT_INT09).* There was also a sense that the education had been done many times before with the health professional following an established routine that lacked empathy:

> *"[They've] done it so many times before I think, so it wasn't again empathetic" (PT_INT17).*

One participant observed the facilitator literally ticking off a list of what they needed to cover once they had spoken about it. This systematic delivery had a negative impact on effective communication skills, resulting in patients sensing a lack of empathy:

> *"[OEC facilitator was] focussed on making sure they got through their list of things, and wasn't really interacting with me" (PT_INT14)*

Several participants felt that education was not tailored to the individual. Many people were given information about their oral SACT before attending their OEC appointment. For those who had read this information in detail, repeating this information was viewed as pointless, or in some cases stressful when the adverse effects of treatment were repeated:

> *"I think he could have said now have you read all the side effects bit, if not, I'll go through some of them with you […]. I think going through all those side effects was awful really and I'd already read them" (PT_INT21).*

The process of receiving education was also viewed as stressful because of *"trying to assimilate information that's coming at you quickly" (PT_INT28).*

> *"The thought of it was a bit stressful and you know they go through all these things you must do and mustn't do and what happens if you miss one […]. They did go through most of the stuff […], maybe a little bit fast, because I'm not stupid, but there's a lot of information" (PT_INT21).*

A strong emphasis was placed on the importance of communication skills of each health professional running the OEC, with the skill of the health professional directly affecting the patient's experience of the OEC appointment. Participant PT_INT03 described the appointment as, "*straight forward" and* that the appointment went well as, *"I think it's down to the individual*" *(PT_INT03).*

One health professional was described as not convincing enough, but "*systematic" (PT_INT09)* and a lack of sincerity attributable to, "*the volume of people coming through that place, I think that's where your sincerity is lost" (PT_INT09).* Similar feelings were experienced by participants where they sensed the health professional was under pressure to complete a task due to the volume of people waiting to be seen:

> *"I mean [they] seemed in a big rush somehow, I mean [they] probably weren't, but that's how it seemed […] in a bit of a rush and a bit flustered over it, and I was already a bit flustered, so yea a little bit calmer" (PT_INT21).*

Compassion, sincerity and communication skills were closely linked, as one individual reflected on their negative experience of attending the OEC, attributable to poor communication skills of the health professional:

> *"I don't think you can ever underestimate communication skills, they are so important, I mean the last person who told me about my em, tablets, didn't have any communication skills bless [them]. They have a task. (Name) is not terribly good at communicating, but you know, it's listening and communicating and having eye contact and engaging," (PT_INT14).*

Another participant would have liked more interactive dialogue and deemed their appointment as *"clinical" (PT_INT27)* feeling that the OEC could be:

> *"A little bit more friendly, a bit more engaging, as opposed to take this, take this, take this, it would be more, and I don't know if that's the individual" (PT_INT27).*

The OEC could have been more engaging if the OEC facilitator had related the information to the individual's own lifestyle and needs. One participant felt that if there was a pause during the appointment and a discussion held about how oral SACT might affect their own life, it would have been more helpful in preparation for managing oral SACT:

> *"I think it would have been ideal if they'd stopped and said now what do you think about this so far, how is this going to affect your life, what if your trousers fall off in the middle of the shops or you get bad diarrhoea and so just that effect, which you do get and you think what the hell do I do now?" (PT_INT28).*

Participants received information about their cancer and oral SACT from doctors during the treatment allocation and consenting process, and from nurses and pharmacists at the OEC appointment. The format and focus of information giving varied depending on the professional's background. When information was received from a doctor this was viewed as explanatory, where the rationale and reason for interventions were described:

> *"Hearing it from the doctor is slightly different […] the doctor is being more specific, he's being, describing it more […]. Every time he told me something he told me the reason why I needed to do this" (PT_INT19*).

Education received from a nurse focused on the day to day impact and management of medication on the individual's life, with one participant feeling that nurses, "*are more well versed on the practicalities of day to day care with regards to cancer patients" (PT_INT02).* From a pharmacist, the education was seen to be more focused on management of the drug itself, presenting the pharmacist as having most knowledge on the science of oral SACT where *"maybe you could ask more detailed questions of a pharmacist" (PT_INT24).* Considering the style of delivery and content from doctors, nurses and pharmacists, there was a clear sense that different health professional disciplines provided different types of information and support.

5.3.3b Interactions with health professionals

Participants identified different health professionals they would contact should they experience worries or have concerns. The type of health professional contacted included general practitioners (GP), clinical nurse specialists (CNS) and the hospital triage team. There was a clear sense that these health professionals were viewed as a 'back-up' and that the individual would contact a professional in whom they placed their trust. Often patients trusted health professionals at the cancer centre because they could *"put [themselves] in their hands" (PT_INT26*) and a perception *"that back up is there" (PT_INT27).* PT_INT02 trusted their CNS who they viewed as having enhanced cancer knowledge compared to their GP, "*if I was worried about anything that I thought could be related to my cancer I would contact my breast care nurse, I wouldn't go to my GP" (PT_INT02)*. The GP was viewed as a first point of contact for some participants who had a well-established relationship with

their GP and found a GP appointment more convenient than a hospital appointment, "*they're easier to see [GP] than it is to get into a hospital appointment" (PT_INT10).*

Participants compared communication with staff in the OEC to oncologists, where one oncologist asked a participant about their holiday and was regarded as 'incredible' and 'really caring' (PT_INT28) and another oncologist talking to the participant 'like they were a human being'. In contrast, participants described instances where communication was poor, which led to feelings of task-orientated care that lacked compassion. There was a desire to feel heard and for health professionals to communicate with empathy and compassion:

> *"It's something they have to do rather than something they want to do […] I think you look for compassion in their eyes […] and I've only seen it twice, the others are like robots" (PT_INT09).*

While some participants reported not having a CNS, those that had access to a CNS held them in high regard with one participant commenting, *"I couldn't praise them [breast CNS team] highly enough, I think they're brilliant, they're fab" (PT_INT02).* The CNS was viewed as having a role in relation to their oral SACT: monitoring treatment toxicity, escalating problems, trouble-shooting, providing information and navigating the hospital system. For example, the CNS often contacted participants when they were at home to monitor progress with treatments and discuss any concerns or side effects. On occasion this contact led to participants having dose reductions or interruptions, demonstrating the CNS role in safe oral SACT management:

> *"We lowered the dosage […] this was all sort of over the phone with the specialist nurse because I don't think I was due to go back to clinic for 2 weeks" (PT_INT08).*

The CNS also investigated a participant's swollen legs and referred the individual for a scan, which identified progression of cancer:

> "*It was one of those nurses who actually referred me for a scan […] phoned her on the Friday […] they [hospital] phoned on the Monday and then I was in there on the Tuesday […] I can't fault that, in terms of that support, it really, they've been faultless" (PT_INT11).*

In addition to providing information, the CNS explained the content of medical conversations "*clarifying what was heard*" *(PT_INT14).* Participants were also advised that even if they were on holiday they should contact their CNS who could discuss any concerns with them and if required, identify the nearest hospital [within a UK setting] where the individual could attend:

> "*I said if anything happens to me up there what do I do? She said ring us, then if we think it's necessary we will then get in touch with the nearest place for you" (PT_INT19).*

Navigating the hospital system was challenging, particularly when trying to identify the correct person to contact. One participant reflected that the CNS reduced this burden and worry:

> *"I ring [CNS name] and she sorts it, whereas before I've had endless phone calls […] I've had up to 14 phone calls just trying to sort an appointment that hasn't come in the post or something, so you know [they're] brilliant, there is always somebody on that phone, even if it's not [them] there is always someone so that's excellent" (PT_INT21).*

Even when patients didn't initially recognise the need for a CNS and there were some issues about the accessibility of the CNS, overall their role was viewed as invaluable in complementing the OEC service:

> *"initially I thought it was a bit silly, but she's super actually […] a real help, I mean she really was" (PT_INT21).*

Participants acknowledged that their GP's had a general knowledge and were not viewed as experts on cancer. This view was not held in criticism of the service offered by GPs, but rather awareness that a GP could not be an expert in every area of medicine and healthcare. When asked if an individual would contact their GP regarding a cancer specific issue, participant PT_INT13 responded:

> "*No […] because he's a general practitioner, and they're, and this is not demeaning anything about him, he's a general practitioner, a very experienced one, and they are the cancer experts so I'd rather" (PT_INT13)*.

Hospital staff being viewed as experts was also reflected by PT_INT19 who commented, *"they're the experts and they would be the ones I would go to first" (PT_INT19).*

The role of the GP was, however, unclear:

> *"I hadn't actually made the connection that when you're seeing an oncologist you've still got your GP to go back to […] I was a bit confused I think as to who was responsible for what" (PT_INT06).*

All participants referred to their GP as a generalist who was limited in how they could support a person with cancer:

> "*When I go to the practice for anything it's always a case of what's the hospital say, what are you doing, what are they doing, what's going on, the only times it's not that type of reaction is if it's something, oh I don't know, I had pain in my shoulder and things like that" (PT_INT08)*.

The role of the GP in cancer care was not just unclear in the participant's minds, but also in their own general practitioners with one GP purporting no further role in the individuals care:

> "*They [GP] basically said we're handing you over to the [study site] now. We'll have nothing to do with you anymore; that was his exact words […] like wash your hands type of thing" (PT_INT27*).

The challenge for patients, acknowledging the hospital as a place of expertise and the GP as a generalist, was in knowing when to contact the hospital, or when to contact their GP:

> *"It's that difficulty of knowing whether […] the problem is that you've got is unconnected to the cancer and therefore it's reasonable to go to your GP to have it sorted or not" (PT_INT26*).

Overall, patients held the view that GPs had a role in providing support for general health, such as *"a chest infection" (PT_INT07*) or to provide "*psychological support" (PT_INT08)* and day to day needs, such as assisting with applying for a blue disabled badge:

> *"A doctor can only specialise in one thing, and a GP can't specialise in a lot of things, but he can give advice which is a different thing altogether" (PT_INT12).*

The triage service was regarded as an invaluable service, "*they are enormously friendly […] it's like a little helpline that's for your personal use" (PT_INT28).* It provided a sense of, *"connection" (PT_INT16)* and the service was viewed as reliable where if they cannot take your call straight away, "*they'll phone you back in 5 minutes and they always do" (PT_INT23).*

> *"They've been very good […] when I got to the hospital they knew I was coming because triage had rung so that was good […] even if it's a small thing like having forgotten to take the pill you don't get any sense of this guy doesn't need us sort of thing, they're very positive about it" (PT_INT26).*

The service was viewed as responsive, reliable and an invaluable source of support and connection, "e*verything was dealt with straight away" (PT_INT24)* and the follow-up to information requested:

> *"I'm utterly chuffed someone has taken the trouble to ring me and say Hi, we've got the information; what we suggest you do is blah, blah, blah or get back in here for a review" (PT_INT28).*

Other participants, however, referred to triage as an emergency service and did not want to contact them for something personally deemed to be trivial. This resulted in some delaying seeking answers to questions or queries until next attending the hospital.

"*I felt triage was too important, I didn't want to bother them too much" (PT_INT25).*

Ultimately, while participants recognised roles of health professionals in both primary and secondary care, the motivation for their choice of health professional to contact first was based on trust. Participants placed trust in clinical nurse specialists, triage staff, GPs and online support groups.

5.3.3c Written information was beneficial, but sharing it should be paced

Written information was overall viewed as easy to read and accessible, being a helpful reminder of what had been discussed at the OEC as *"you can't take it in all in one go" (PT_INT05).* However, all participants talked about the large volume of information they received, both verbal and written with one individual saying, *"it feels like you're bombarded with it" (PT_INT03).* When receiving large amounts of information, many reflected on the challenge of assimilation and how time is needed to digest information. Making notes on conversations was helpful for some participants, *"I write notes and try and remember to ask all the right questions" (PT_INT06).*

Due to large amounts of information, some participants questioned whether it was all necessary or relevant? One participant reflected on the challenge of not even realising they wanted to know the information:

"*I mean I came away with so much literature […] I had about 6 booklets […] I suppose I wanted to know, but I didn't know I wanted to know it!" (PT_INT14).*

Physical wellbeing also impacted on the cognitive function and participants' ability to recall information. Several participants described experiences where they had felt so unwell from side effects or symptoms from their cancer, that they were unable to process and act upon information they had been given:

"I'd forgotten about the list [traffic light system] because I was feeling pretty, I was feeling really ill actually, so I didn't really remember that I […] I just wasn't thinking what I needed to do really" (PT_INT21).

There was a view suggested that a way to overcome feeling overloaded with information was to deliver information in stages, such as separating by priority or topic and going through it at a slower pace to aid understanding:

"It was a bit too much information actually, I mean I think you needed it all, but you needed it […] somehow cutting it down into blocks and going through it more slowly might be really good" (PT_INT21).

Written information was enhanced when it had been personalised and discussed in collaboration between the participant and health professional. Detailing written information and working through this together was seen to make the information more meaningful and assist in assimilating key points:

> *"[it was] a big wedge of paper but she didn't just sort of plonk it on my lap […] she went through the detail. I found that really useful, so I had some kind of visual aid, which helps me, without being handed a pile of bumph which can be a bit overwhelming […] to have someone go through it point by point, and then she wrote some notes […] made it very easy to understand and follow" (PT_INT05).*

Another advantage of written information was the ability to share it with family and friends who were interested or involved in the patient's care. Several participants commented on how their family had taken the written information and gone through it themselves. A resource also used by family, and a resource complimenting written information was YouTube where a health professional had advised a patient to access videos about their treatment online. These videos were subsequently shared with family members and were reportedly useful, complimenting written information.

One participant was very hard of hearing, and unable to hear a conversation by telephone. This had been addressed by the study site, so the participant regularly used email to contact people. So whilst some individuals relied heavily on the support of their families, not all were able to share a lot of information with their family, because the relationship was not one where illness was discussed – suggestive of an increased need for emotional support for these types of individual.

It was very common for participants to leave appointments, both OEC and consultant reviews, and realise they have unanswered questions. Participants often reported, "*when you're in the moment you do forget what you want to ask" (PT_INT16).* Anxiety regarding the content of the consultation, feelings of shock, forgetfulness and being in the presence of senior health professionals, were all contributing factors.

While there might be barriers to asking questions, it was often difficult for patient participants to know exactly what to ask, given all the new information and unfamiliar content, *"[…] when you don't know something, you don't always know the questions to ask really" (PT_INT16).* Questions were often triggered by friends or family asking questions to the individual afterward:

> *"It wasn't until people asked me questions, I thought oh maybe I should have asked that?" (PT_INT24).*

The opportunity to ask questions was often viewed as limited due to the speed of delivery of new, unfamiliar information. Participants required time to process information and in turn formulate questions, often unable to do so hospital environment:

> *"There's a settling time; you're in your own environment, this is my castle, this is where I can think, I wonder what if, what if, what if? Whereas in a hospital with thousands of people running around in a hub of noise, you're just not in that frame of mind to be able to adjust to the information you've just been given." (PT_INT28).*

One participant suggested that a possible means to counter this would be to provide information prior to attending an appointment. In doing so, the individual would have an opportunity to read the information and consider it in the context of their own daily life, allowing time to formulate a response: "*it prepares me for it and then I can get the questions coming out" (PT_INT27).*

It was challenging to know who to contact for help when addressing queries or concerns:

> *"I don't know which nurse to contact because there seems to be so many of them, and if you do phone in they're never there and you never know if you're phoning the right one" (PT_INT23).*

Other individuals who had proactively contacted medical secretaries described the challenge in this, reflecting it might be difficult for other people to navigate the system: *"I guess a lot of people would not cope with it very well." (PT_INT11).* The same individual later commented on the challenge in contacting a CNS and described the impact of not receiving a response:

> *"almost without exception, and you know, in the early days you get concerned, I was phoning and it was always an answer phone, there was never anybody available and you would wait […] you'd sit here all day waiting for a response, and on one occasion nobody came back to me" (PT_INT11).*

Contacting health professionals using email was viewed as a, *"a more efficient way to speak to people" (PT_INT02),* but also quicker to receive a response, *"if I wanted to get a quick response* [the main way] *was to send an email" (PT_INT06).* There was a sense that health professionals are busy, and voicemails would not be picked up until the end of the day, whereas email could be accessed intermittently throughout the day.

When asked if participants had used a treatment diary or any personal type of record whilst taking oral SACT, there was a mixed response. For some, the diary provided a strong sense of control, was beneficial and had become part of a daily routine.

> *"It's the dailyness of it […] the fact you can't miss taking the tablet because you're filling it out" (PT_INT25).*

Benefits of using a diary were described as promoting adherence, maintaining a sense of control, facilitating conversations with health professionals, monitoring side effects and recalling past side effects. One participant described the diary as "*my crutch" (PT_INT25).*

> *"I don't think the treatment diary is something that people, pharmacists perhaps, or even the specialist oncologists even stress enough, it was so much easier in that meeting [referring back to diary during a consultation] and for me it's easier" (PT_INT25).*

For others, the diary was viewed as *"a waste of time" (PT_INT09)* or something that couldn't be coped with on a daily basis, generating more burden than benefit. In addition, side effects were clearly recorded and the diary assisted in establishing a routine, but once a routine was established and as confidence in taking oral SACT grew, the diaries were used less often:

> *"Then I didn't write so much stuff, just odd bits and in fact I've got up to the 13th and stopped […] then it becomes routine" (PT_INT06).*

Overall, for those who use diaries, they were seen as beneficial and valuable.

One participant had concerns that they were not encouraged to drink more water, having realised they should drink a lot of water from reading information about their drug. This was perceived to be a concern for older patients who might have nocturnal enuresis, be taking diuretics, have lower urinary tract symptoms, or have urinary incontinence and, therefore, might be nervous about drinking fluids during the day.

> *"they ought to mention a little bit more about drinking water […] It's not until you read up in other places that it tells you, you should drink a lot of water […] if you've somebody in their late seventies, they do not drink because they're too worried about going to the loo" (PT_INT08).*

Sexual function was viewed as important for several individuals, yet most participants reported that it was not discussed in any consultations at the hospital, and if discussed sexual function was only touched on briefly. Sexual function was viewed as an area that health professionals were reluctant to speak about, or didn't feel was important with one participant commenting, "*why is it, you know, I can't get an erection anymore? […] No one has bothered to ask me" (PT_INT28).* One individual felt that health professionals might be "*embarrassed" (PT_INT15)* by this, but another participant recognised that patients might also "*not ask that […] and for some people it is important"*

(PT_INT16). Discussions about sex and sexuality were recognised as not necessarily a topic area that everyone will want to talk about, or be deemed as a priority area for some; however there would be value in identifying if patients wanted to discuss this topic:

> *"Let's just take this sexuality bit of it; It's not everyone, every human being has to cope with it in their head, and I think it can be just identified and not to be afraid to ask. Get your patients to ask you as a consultant, whether you're male or female or otherwise […] we're still human beings, come on, my hands are exactly the same as they were yesterday; the rest of me looks the same as it was yesterday, but help me, you know," (PT_INT28)*

Collectively with information needs regarding healthy living, holistic aspects of care, sexual function and sexuality, there was a clear sense that patients had a desire for information to stay well and live well.

5.3.3d The option of telephone follow up review would be beneficial

Participants were asked about their views about the prospect of telephone follow-up (TFU). Overall, this was welcomed, but viewed as non-essential by most individuals. Receiving a TFU call was viewed as a means to improve support, making patients feel they were within the system and being cared for.

> *"For me it would just be nice to know, oh I'm in the system, they're taking care of me" (PT_INT03)*

> *"It's stretching the caring which you do, we all know that, full blown appreciated, but taking it a stage further, and that would be important […] this is about our wellbeing and that would help" (PT_INT28).*

While TFU was viewed as a way to enhance the care experience, it was recognised that for some people receiving an oral SACT that the TFU would be needed to ensure safe care. There was a perception that individuals who live alone, who are older or frail, or do not have well established support systems would need a TFU soon after commencing treatment.

> *"I think you know, if it was me without (wife) being about, I would really really struggle, I wouldn't have a clue what was going on other than be there at a certain time and do this, I wouldn't have a clue […] if you know if you're talking to a single person who's like me then they would definitely need that support" (PT_INT22).*

Individuals who felt TFU was required, reported that taking an oral SACT was *"such a new experience" (PT_INT05)* and full of unknowns, such as potential side effects, that a TFU would offer reassurance and an opportunity to refresh the education received:

> *"I think it's a good idea because people are just getting used to the side effects, because again I didn't know which ones I would be affected by" (PT_INT17).*

The timing of a TFU was perceived to be most valuable just over a week after commencement of treatment. A couple of days would be too soon due to unknown potential side effects. Further, it was felt that once the treatment regimen was established a TFU would not be required.

> *"Couple of days is too soon I think, a week is okay, a week to 10 days is okay" (PT_INT28)*

> *"I should think you know the first time and so forth, but afterwards you know when you're on a long stint or not I shouldn't think it's any use at all" (PT_INT20).*

Where TFU was viewed positively, the biggest advantage would be to ask questions that arise once the patient has started their oral SACT regimen: *"you could ask questions you didn't think about, when you've had time to think about it really" (PT_INT15).* Several participants reflected how, *"other questions come up later" (PT_INT27),* but as they were not viewed as an emergency, they would not contact triage and rather wait until their next medical review to ask. For individuals who didn't have a CNS, there was confusion as to who to contact to resolve their questions.

> *"I noted down things I hadn't thought to ask at the time and then when you actually start on the course you have questions and I know you can phone the triage team, but that's for emergencies you don't expect them to waste their time on routine little questions, so I could've done with yeah, a backup […]. I was in contact with one of the nurses who sat in on one of the initial appointments and I could phone her up, and she said but I'm not actually on the team you're being [cared for] by, so I haven't really got a nurse I could ask anything" (PT_INT23).*

5.4 Development of typologies

5.4.1 Typology by adherence behaviour

When analysing the characteristics and traits of adherers versus partial-adherers, the only finding that differed between these groups of patients was that partial-adherers sometimes forgot to take their oral SACT due to a change of routine or forgetfulness. This finding is useful, but did not constitute a typology.

5.4.2 Typology by ability to self-manage

Across participants and analysed findings, there was a clear difference between those who felt confident to manage their oral SACT and associated side effects, and those who perceived a need for enhanced support. To consider this in more depth, a typology of activation to self-manage was explored.

5.4.2a Individuals activated to self-manage

Amidst individuals who expressed a confidence in managing their oral SACT, a variety of coping strategies were reported including acceptance, positivity, focusing on an end goal, maintaining a sense of control and finally trust in health professionals. Implementation of these coping strategies enabled the participants to self-manage their care by using a strategy that would help sustain them in their routine of medicine taking. One participant reflected on their daily routine and use of a patient held diary which led them to feel, *"[…] a bit more in the driving seat […] it's been my crutch really" (PT_INT25).*

Having a third party (family member or carer) present during the OEC assisted in assimilating and retaining the different types of (often complex and distressing) information provided. It was notable across several participants that presence of the third party enabled conversation following the OEC visit, where through debrief, gaps in respective knowledge bases could be discussed. This appeared to lead to increased feelings of confidence, and knowledge about what to do when encountering potential problematic scenarios:

> *"[my wife could] remember lots of things that I couldn't remember, and it is easier with somebody else there" (PT_INT03)*

Some participants attended their OEC appointment with an already established knowledge base about their oral SACT. Some discussed researching their medication to ascertain its effectiveness and potential side effects, whilst other participants had spent dedicated time periods reading the information previously supplied to them by the study site. This enabled the participant to approach the appointment pre-prepared and in a position to discuss their medication in more detail, already having imagined the impact the medication might have on their life:

> *"I think he could have said now have you read all the side effects bit, if not, I'll go through some of them with you […] I'd already read them [the patient information about side effects]" (PT_INT21).*

The sense of activation to self-manage was represented practically where participants described a heavy reliance on the establishment of routine. Various mechanisms were used to establish this routine, such as the use of a diary to record administration times and experience of side effects; the use of alarm reminders, dosette boxes and eliciting family members support to prevent forgetfulness and non-adherence. One individual described their reliance on routine:

> *" […] the routine of having medication that's going to keep you alive is a very positive routine, so you establish one has to do this at certain times during the day, it almost becomes automatic, I can get through a day without looking at my watch knowing the routine, its well established, it's the need to do it" (PT_INT28)*

Early establishment of routine and effective mechanisms to minimise non-adherence resulted in high levels of adherence, with many participants reporting no episodes of non-adherence.

Following the OEC visit and establishment of an initial routine, participants who demonstrated an ability to self-manage described proactive approaches to managing their care at home. Several participants reported instances of seeking further information through the use of the internet, peer support and contacting a health professional if required. One participant described the benefits of using an App that assisted in managing their fatigue, acting on advice prompted by the App. Further, utilising a toxicity grading scale provided by the OEC enabled some participants to quantify the severity of their side effect and identify at which point to seek help:

> *"the answers they've got there [on the App], well they give me [the] answer, so they say either do this, like for instance the first few times I told them I was tired, they turned round and said make sure you're active […] what was the other one, something else happened, oh I know, I had a sore mouth, it said use the mouthwash […] oh its telling me to get in touch with the hospital so that's what I do" (PT_INT19)*

Some participants were able to find out about adapting their medicine routine to minimise the risk of side effects, for example taking it at night as opposed to the morning, taking it shortly after a meal, or by changing the time of their other regular medications to prevent interactions.

Patients who made contact with a health professional (hospital triage, CNS if they had one, or a GP) did so based on a sense of trust, *"I have to say the staff are just brilliant, I have absolutely no qualms about trusting them and they've all been amazing" (PT_INT26*). Most patients contacted their CNS or triage if they had a question regarding their oral SACT or an issue requiring advice. These health professionals were contacted, because they were viewed to have expert knowledge and understanding secondary to the specialist nature of their role. Some participants made contact with

their GP, because they trusted their GP or because they were viewed as physically more accessible (in relation to patient's home location).

5.4.2b Individuals requiring additional support to be activated to self-manage

For individuals appearing to require additional support, a common reported finding was anxiety caused by the lack of clarity about their oral SACT, particularly with regard to treatment efficacy and duration. The sense of the unknown contributed to a heightened anxiety state. Fears of treatment efficacy being compromised were heightened with prospect of a dose-reduction, 'drug holiday' or a change in treatment, which led to under-reporting of side effects in some participants.

> *"[discussing reason for not reporting a new side effect] The other thing … I don't want to feel that I need to change treatments again … it's very important for me … to put things into remission again, I don't want to think of what the possibilities are if I don't go into remission" (PT_INT08)*

Within the sample of participants interviewed, female participants generally had a higher anxiety level than men. The causality for this gender difference is unknown and was not explored through questioning.

As demonstrated by participants activated to self-manage, sources of support were sought based on trust. Several participants described poor relationships with their GP, often attributable to delays in diagnosis or lack of knowledge regarding their cancer or oral SACT with one participant reflecting, *"I don't feel, and I will be very honest, that I have any back up with them [their GP]" (PT_INT08).* Poor relationships with a GP resulted in the loss of a possible source of support in the primary care setting.

During descriptions of receiving education through the OEC, many participants described a lack of person-centred information where provision of information was often drug-focused or scripted, *"She read a long list and she'd ticked off what she said what to do if you drop them, all these, and I didn't seem to have any time to ask her things" (PT_INT23).* A biomedically-focussed approach to information delivery caused stress to several individuals, particularly when information about side effects was repeatedly given. These participants reflected on a desire for the OEC facilitator to establish the participant's baseline knowledge of oral SACT and identify questions of how the oral SACT could fit into their own daily life.

Several participants within the interview sample received their education appointment via telephone. One participant reflected on the challenges of processing information that was delivered

over the telephone, highlighting a preference for a face to face appointment secondary to the volume of information being delivered.

There was a clear view that patients who did not have familial support, or who were frail due to older age, or social isolation were regarded as needing more care and perhaps ongoing telephone support. Several participants reflected that while they could successfully manage their oral SACT at home that this was not without challenges, and if they were older, without social support, they would not have managed, *"It depends on the individual, if you're an old guy sitting at home by yourself with no support you probably need that [telephone follow-up]" (PT_INT07).* Further, several participants described the challenge in attending the OEC alone with the challenge of a vast amount of information requiring assimilation. The idea of an ongoing telephone support to these individuals was viewed as essential for safe care.

Some participants described the challenge in identifying the time at which point to seek support from a healthcare professional. When not informed about the severity of a side effect it was difficult to decide at which point they should call for help. One participant reflected that due to their age and diagnosis, they would feel "*Generally unwell" (PT_INT24)* every day and, therefore, it wouldn't be appropriate to contact triage when they felt unwell.

5.4.2c Comparing those activated to self-manage and those requiring additional support

Individuals who were activated to self-manage had clearly identified coping strategies, were often accompanied by a third party, approached the OEC pre-prepared with information and were quick to establish a routine in oral SACT administration. They displayed successful behaviours in accessing further support as required, such as identifying sources of peer support, utilising Apps and use of the toxicity grading scale. Comparatively, those who required enhanced support described anxiety regarding unclear information, were often female, and several described poor relationships with their GP. The lack of person-centred information delivered by the OEC led to increased levels of anxiety and stress, and when this was delivered via the telephone it was more challenging to assimilate. Several participants did not have access, or recall receiving a toxicity grading scale, leading to a challenge in knowing at which stage they should seek help from the relevant health professional.

Comparing these two groups, there is a clear distinction between those who have 'coped' with their oral SACT, promptly establishing a routine and knowing where from and when to seek help; and those requiring enhanced support. Those requiring additional support often experienced anxiety regarding information received and demonstrated a lack of awareness of where from and when to seek support.

5.5 Chapter summary

This chapter has presented the findings from semi-structured interviews with 28 participants organised into three over-arching themes.

The first theme, 'a person's experience of cancer is challenging and how they cope depends on the individual' described participants personal experiences with having cancer. A diagnosis of cancer was viewed as emotionally difficult and psychological and physical effects from diagnosis often had an impact on patient interactions at the hospital. The NHS was viewed in a positive light, but several references were made to the challenge in accessing a strained healthcare system and an often time poor appearance of staff. A key desire for patients was the ability to develop a therapeutic relationship with health professionals they encountered, but for some this was challenging. Overall, it was clear that within the interview participants, experiences varied depending on the person with multiple coping strategies and experiences discussed.

A sense of information overload was common within the participants and the OEC often felt scripted. Several areas were identified where patients desired more information, but a lack of clarity and a sense of the unknown induced anxiety in stress. While patients had a desire for information on how to live well with their cancer and oral SACT, it was often difficult to know what questions to ask if and when given the opportunity due to the volume of information received. Overall the OEC was well received, but several areas for improvement were identified including communication skills in the OEC facilitators and tailoring education toward the individual's preferences.

The second theme, 'patient perceptions and experiences of oral SACT' explored in detail participants perceptions and experiences of oral SACT itself. The treatment was viewed by some as poison, but was overwhelmingly viewed as a relief, with IV treatments dreaded and viewed as time consuming, invasive and restrictive. With a clear preference for oral SACT it was common to perceive the treatment to be easier than IV and have fewer, or less severe side effects, but some participants discussed the length of treatment and how less severe side effects, for a prolonged period of time would be off-putting.

The third and final theme, 'models of care should be tailored towards the needs of the individual' explored how individuals managed their oral SACT at home. It was clear that high quality experiences of care focussed on development of relationship and a sense of trust was implicit in feeling cared for and supported. Patients contacted a variety of health professionals for support, but this was often directed toward the hospital, with only a few patients involving their GP. The GP was viewed as having a role in supportive care, but some participants described difficult relationships

and a lack of trust due to the generalist nature of GPs. Families were described as welcome at appointments, but no participants discussed their families being given any direct support and recognised this was required for many. Oral SACT was not troublesome to manage at home, and side effects were often manageable, but all participants described tiredness and fatigue as their main side effect and one that had a significant impact on their daily life.

The final section of this chapter explored the development of typologies. Characteristics of those reporting adherence and non-adherence were compared but the differences did not constitute a typology. Activation of an individual to self-manage their care was, however, identified as a typology. Analysis demonstrated that one group of individuals were activated to self-manage and thus confident in managing their oral SACT, while a second group of individuals required additional support, and thus were not activated to self-manage their care and oral SACT.

Chapter Six: Health professional interviews

6.1 Chapter outline

The following chapter will present findings from 23 semi-structured interviews with health professionals (doctors, pharmacists, pharmacy technicians and nurses across scheduled and unscheduled care) involved in the management of care of patients receiving an oral SACT. The aim of this PhD has been to identify both the experience of patients and the health professional perspective; therefore the research question being addressed in this chapter is:

- What are the perceptions and experiences of health professionals involved in the management of care of patients receiving oral SACT?

The methods used to conduct this stage of the PhD study have been presented in chapter 3. Interview data was analysed using Framework (Ritchie and Spencer, 2004). Over-arching themes will be presented.

6.2 Sample characteristics

23 participants provided informed consent to be interviewed. The convenience sample included five specialist cancer pharmacists with a direct role in the OEC, one pharmacy technician who had a direct role in dispensing oral SACT, five nurses who practice within unscheduled care, six nurses who practice within scheduled care, five consultant oncologists and one consultant haematologist. Unscheduled care refers to areas of the hospital where emergency, 24-hour care is provided, nurses from this area of practice included in-patient ward level nurses (n=2) and nursing staff from the acute oncology (n=1) and triage service (n=2). Scheduled care consequently refers to areas of practice delivering planned care interventions, nurses recruited from this area included oncology and haematology clinical nurse specialists (n=4) and nursing staff with a direct role in delivering the OEC (n=2). All health professionals recruited had a role in the care of patients taking an oral SACT and met the inclusion criteria for the study, no participant demographic detail was collected.

6.3 Thematic analysis

Eight emergent themes were identified. Appendix 17 demonstrates the sub-themes and original index attached to the data. At the stage of abstraction, three over-arching themes were identified, with a degree of overlap: comparing the benefits and limitations of oral SACT to intravenous SACT; perceptions and experiences of delivery of care; and perceptions and experiences of safe management of care (Table 6.33).

Table 6.33 Seven themes identified from coding, leading to three final themes

Themes derived from coding	Themes derived from abstraction
Health professional training and experience	Comparing the benefits and limitations of oral SACT to intravenous SACT
Oral SACT	
Patient experience	Perceptions and experiences of delivery of care
Oral education clinic	
Families and carers	Perceptions and experiences of safe management of care
Clinical role	
Healthcare provision	

6.3.1 Comparing the benefits and limitations of oral SACT to intravenous SACT

Several perceived advantages of an oral SACT versus IV SACT were reported. All participants described patients needing to attend hospital less frequently, avoiding repeated cannulation, and enabling patients to have more independence and autonomy:

> *"it's something that patients don't have to have a cannula for, they don't have to spend time in day treatment unit] […] the idea is to try and make them, or help patients, get on with their lives as much as possible" (HP_INT03).*

While describing perceived advantages of an oral SACT, participants also highlighted several perceived disadvantages to oral SACT. Participants talked about some patients having difficulty getting oral SACT out of their packaging or that they might find tablets difficult to swallow, particularly very large tablets. One outcome of this administration issue was changing a patient's oral SACT to another drug given by subcutaneous injection:

> *"We've had to change from oral to Velcade (subcutaneous injection) for the fact they [the patient] just couldn't pop the thalidomide (tablet) out of the packet"* (*HP_INT15).*

As an oral SACT is ingested, there is a greater risk that the bioavailability might be reduced due to interaction with other medications the patient is taking. One participant, a prescriber of oral SACT, described their experience:

> "*There seems to be more interactions with them [oral SACT] than a lot of intravenous […] because of the whole issue of absorption" (HP_INT22).*

While oral SACT were perceived to provide advantages to patients, there were some perceived disadvantages. Health professionals talked about patients viewing oral SACT as different to IV SACT, and many discussed the erroneous perception that oral SACT are less toxic than IV treatments. Participants thought that this perception could lead to patients not acknowledging the risks associated with oral SACT, *"I think they don't always take on the risk associated with them, oh it's a tablet, it's not as dangerous I suppose" (HP_INT01*) or impacting on how patients view the seriousness of their side effects:

> *"Patients kinda take these symptoms as less important, because they're on a tablet rather than IV" (HP_INT10).*

It was reported by many participants that by taking an oral SACT patients retained control and autonomy. Some health professionals viewed this as a major psychological benefit for the patient, as they were in control of taking their own treatment:

> *"I think that just psychologically something that you can hold in your hand and take yourself there's control over it … you're in control, I think people like that" (HP_INT07).*

Having the responsibility associated with control, however, was considered potentially challenging for some patients, *"would prefer not to have that responsibility [of taking an oral SACT] …" (HP_INT13*) and instead they might prefer a nurse to manage their care and medication, avoiding the associated stresses or pressures of managing their own treatment.

Participants thought that reasons why patients might have a sense of increased responsibility could be related to the challenge of managing multiple medications, often referred to as polypharmacy: *"[polypharmacy] can get very overwhelming and sometimes it's easier to just stop everything" (HP_INT20).*

Patients might be prescribed multiple oral SACT supportive co-medications or drugs for other conditions resulting in a potential risk of confusion or the inability to differentiate between their medications and the associated implications:

> *"Because they're taking anti-sickness and other things they don't always recognise that the capecitabine's a chemotherapy" (HP_INT08).*

Most health professionals referred to oral SACT as an anti-cancer treatment that wasn't always cytotoxic by nature, describing a shift from cytotoxic treatments to targeted anti-cancer treatments.

Some participants reported that patients, *"don't really like the term chemotherapy because a lot of things we use technically aren't" (HP_INT04).* Another participant, however, discussed the origins of the term chemotherapy and recognised that drugs used to treat cancer could technically be classed as chemotherapy:

> *"Any agent that's given to a patient, it doesn't mean to say a cytotoxic […] but these drugs do count as chemotherapy, because they're agents we give to patients" (HP_INT23).*

Participants, therefore, recommended the use of appropriate terminology to explain oral SACT.

6.3.2 Perceptions and experiences of delivery of care

The oral education clinic was well-received and regarded as an effective model of care by health professionals of all disciplines, particularly for people receiving treatments that were well-tolerated:

> *"For oncology treatments that are well tolerated, then I see that [OEC] as a reasonable model" (HP_INT18).*

Participants believed that patients need to be informed about their treatments and how to manage them, and the OEC was viewed as a useful vehicle to inform patients about their SACT. The clinic was viewed as a *"progressive and innovative development" (HP_INT22)* and was described as something to be envious of, a model that could be replicated in other settings.

Participants recognised that, *"there will be more and more oral chemotherapies coming" (HP_INT13)* and, therefore, the model was a good idea without which patients "*wouldn't be taking it [oral SACT] safely" (HP_INT17).*

Some health professionals discussed the impact of the OEC on the wider hospital setting. It was reported to reduce the volume of calls to the acute oncology triage service, with patients having a greater understanding of how to manage their medication. A nurse working within acute oncology commented the OEC, "*keeps a lot of our calls to a bit of a minimum if I'm honest" (HP_INT09).* Further, patient feedback to health professionals indicates that following the OEC individuals have a greater understanding on how to take their oral SACT and find the appointment helpful:

> *"We know because of triage admissions before having oral education clinics, some patients were really confused as to how to take their chemotherapy or what to expect … they [patients] do say those sessions are very, very helpful" (HP_INT01).*

The OEC was also reported to have a positive impact on the day treatment unit (DTU) in terms of resource and capacity:

"It gives them more space for patients who need IV treatments … it's very helpful for them [DTU staff]" (HP_INT12).

While the clinic was held in a positive view, many participants perceived that for patients there was a burden of attendance at the OEC. It required patients to come to the hospital for another appointment, resulting in personal time and costs:

"Taking up the patients' time and they have to travel in for that so you get all the associated costs and such forth with that" (HP_INT03).

A suggestion to overcome these difficulties was to consider implementing the OEC model at another hospital site having more than one clinic running, *"there's no reason why we can't set up an education clinic at (hospital name)" (HP_INT03).* The distance and time required for travel might be greatly reduced should patients have access to a local hospital, closer to home.

One health professional who works within the OEC as a facilitator commented that the clinic at present wasn't, *"a very efficient use of time" (HP_INT16),* later referring to the administration required on the facilitators behalf prior to the appointment. Health professionals regularly commented that due to staff issues they were unable to see, *"all the patients that perhaps [they] should be seeing" (HP_INT01)* with another individual reporting, *"we just don't have enough people to cover it [the OEC]" (HP_INT02).* There was also a view that the OEC could have a negative impact on the functioning of the outpatient unit where patients are reviewed by consultants secondary to capacity and length of appointments:

"I can imagine [the OEC] slowing it [DTU] down a lot" (HP_INT20).

All health professionals directly involved in patient education reported increased effectiveness when education was delivered face-to-face. Telephone education was viewed as, *"much more difficult" (HP_INT16)* and less effective, because of the lack of visual cues and challenges in interpreting patient responses.

Participants also reported difficulties in initially making contact with patients and maintaining communication as, *"people at home are very distracted" (HP_INT04).* Once contact had been made, awkward gaps in communication, an inability to assess the patient's level of understanding and being unable to talk through and explain written information were reported:

"You don't really know if they've understood" (HP_INT17).

However, telephone education was seen to be better than no education. Group education had previously been tried, however, health professionals found this ineffective as patients were inhibited

about disclosing personal information and asking questions in a group setting, resulting in multiple patient-initiated contacts after the session to resolve queries, which was not an effective use of resources as it duplicated patient contact time.

Both nursing and pharmacy professions involved directly in the OEC were reported to be effective in their role in supporting patients receiving an oral SACT by most participants. The OEC staff were described as senior members of staff, implying competence and experience.

> *"As medics we're just not very good at talking through a lot of these practical details…it's good to have a dedicated, practically-focused session with either a pharmacist or a nurse" (HP_INT22).*

One participant commented that the majority of OEC staff were pharmacists, as it had proved challenging to recruit nurses to the role: no explanation to recruitment challenges were given. Nursing and pharmacy staff were perceived to be thorough in delivering education and care to patients, guided by the OEC service protocol:

> *"They adhere to a script and didn't leave things out and did it rigorously […] if you leave these things to medics they tend to decide to do it their own way and are less protocol driven" (HP_INT19).*

Some participants felt that nurses and pharmacists were better placed to deliver education than medical staff. Doctors were perceived to be task-orientated, and therefore, perhaps nurses or pharmacists were better placed to provide patient information regarding the use of oral SACT and managing side effects:

> *"Medical staff focus more on kind of symptoms […] they're very task oriented […] they don't necessarily think […] how am I going to keep this patient on treatment with these side effects?" (HP_INT08).*

When considering the roles of nursing and pharmacy, one participant described the experience nurses have in providing holistic care. It was reported that pharmacists have a greater experience with managing medication, but not the holistic, person-centred role that nursing staff could bring, suggesting that from this participant's perspective, nursing staff might be best placed to deliver education:

> "*[The nurses have experience] dealing with patients, managing patients, reviewing patients […]. [Pharmacists] are much more about the drugs, side effects, drug management, not the rest of the extended roles that the nurses bring" (HP_INT23)*.

Many participants referred to future health care requiring increased primary care service support. Participants reported that health professional communication with the GP was consistent and completed by doctors writing letters. Patient contact was, however, influenced by the patient's prior relationship with their GP, *"[…If] they have a good relationship […] they're more likely to go to the GP and contact the GP" (HP_INT13).*

Trust was often referred to when participants spoke about the relationship between a patient and their GP. A few participants, however, highlighted a loss of trust with the GP for patients whose GP had misdiagnosed or delayed diagnosis of a malignancy.

> *"[Recalling patient feedback] 'I don't like my GP, I didn't get diagnosed in time' […] If they don't trust their GP after their cancer diagnosis, they won't go back to them" (HP_INT08)*

> *"If there's been a delay in diagnosis, they're [patients'] often very anti the GPs and they're very angry that they took so long to get diagnosed and so lose a bit of faith" (HP_INT21).*

Medical staff generally felt that the GP had no role in directly managing cancer treatment-related care for patients receiving oral SACT, recognising that GPs were generalists, had over-stretched workloads, and primary care services were under-resourced:

> *"Cancers I deal with are quite rare, so I wouldn't expect much knowledge base in general practitioners […] I'm not quite sure how much we could rely on their regular input" (HP_INT22).*

Patients were perceived to be "*hard-wired" (HP_INT19)* to make contact with the GP if they felt unwell, so while a GPs knowledge of oral anti-cancer treatments might be limited, patients choose to seek help from their GP.

One participant identified a potential risk of involving the GP in the patient's cancer treatment with a view that if a higher proportion of people are involved in care decisions, there is a higher chance that changes to treatment may take place without communication or monitoring:

> *"If you have too many people involved […] too many chances for things getting missed […] too many chances of them playing around with doses without discussing" (HP_INT14).*

In contrast to participants from a medical background, some nursing and pharmacy staff perceived the role of the GP to be a significant care provider to ensure safe management of patients receiving oral SACT describing the role as, *"a collaboration […] a lot more things should be managed at home" (HP_INT11).*

A nurse working in unscheduled care referred to the crucial role of the GP in caring for people in their own home. In this respect, the participant advocated that the GP is the health professional

who can access and undertake assessment to potentially prevent an acute hospital attendance or admission:

> *"Our eyes in the field […] they're an extension of us essentially […] we do only have limited beds and you can't see every single patient and you do need to try and manage people at home" (HP_INT09).*

Overall, health professionals described a varied role of the GP, some recognising an essential and valuable input, others considering the management of this patient's group care is beyond the GP role. In light of this it was suggested that *"We [oncologists] could probably carry out more education sessions … [for GPs]" (HP_INT18*).

Patients were reported to have different levels of understanding, some may have had cancer treatments previously and, therefore, education did not necessarily need to be repeated to the same extent.

> *"You adapt it to [the] […] understanding level of your patients" (HP_INT20)*.

One participant, while reflecting on delivering education, reported some patients attending with a list of their own questions. This was viewed as positive, directing the health professional's attention to areas of concern or knowledge deficits for the patient:

> *"Patients come in with 5 or 6 questions straight away, which is […] helpful because it directs me to where they need advice or help" (HP_INT03).*

A large majority of health professionals perceived that information overload was often experienced and something OEC facilitators should be aware of, assess and try to prevent. One participant reported that the ability to process information wasn't to do with the patient or their family's level of cognition, but rather the context of diagnosis and treatment:

> *"I think there's perfectly intelligent people and perfectly intelligent carers who do not have a clue, because it's just all very overwhelming and there's not really much information on the bottle about what they're actually containing" (HP_INT19).*

Due to the risk of information overload, many participants reported the importance of repeating information at all patient encounters, "*reinforcing that education every time you see them [patients]" (HP_INT19).* A few participants recognised the challenge in retaining large amounts of new information during the context of a cancer journey and that reiteration was key to understanding with, *"[patients] only take in a small percentage of it usually" (HP_INT10).*

Further strategies to overcome information overload included: providing information in more than one form, giving the patient time to process information and formulate questions, use of a patient diary, assessing stress levels and asking the patient to repeat back information.

Multiple participants felt patients receiving an oral SACT would benefit from further support in the form of an ongoing care review. A few health professionals perceived a need to be, *"proactive and ring them [patient" (HP_INT03)* to identify any issues the patient may have encountered while starting their oral SACT. This was seen as something that would be positive for the patient, making them feel reassured and supported:

> *"If there is just a job there, that would follow up the patient after the oral education it would be really helpful for the patient" (HP_INT12).*

Two participants felt the clinic required a greater integration in that the service could be more streamlined or easily accessed with, *"some sort of rapid access scheme" (HP_INT16),* such as a means to deliver structured patient education on demand, but also a service that could be quickly accessed by patients.

> *"[The OEC needs to be] more streamlined […] you're not sort of taking up too much of their [patient] time" (HP_INT03).*

The use of technology in healthcare was referred to often by several participants, *"telemedicine is here and just not yet in oncology" (HP_INT19).* One participant discussed the potential of incorporating patient diaries into an electronic format accessible by the care team and being able to, *"see problems in real time" (HP_INT18*). Another medical participant viewed technology as a means to help compliance or reporting medical concerns as patients are reluctant to attend the hospital. The ability to remotely monitor a patient's vital signs including heart rate, blood pressure and temperature were viewed as a means to prevent unnecessary hospital attendance and considerations for future healthcare interventions:

> *"We could […] use technologies like you know a watch to monitor pulse, temperature, maybe even give people a blood pressure cuff to take at home" (HP_INT22*)

> *"Monitoring patients in real time […] Fitbits, phone monitors […] remote monitoring of patients" (HP_INT23).*

When considering the role of technology in caring for patients taking an oral SACT a suggestion was made to be creative, but what was ultimately required was contact with the patient, which could be completed by a phone call:

"We could be really creative here, but […] you just need to speak to them actually" (HP_INT07).

6.3.3 Perceptions and experiences of safe management of care

Participants reported several beneficial interventions in use to support patients taking an oral SACT, including the use of MRCs, patient diaries, and a treatment record book including records of treatments, blood results, appointments, and blank space to make notes as required.

MRC's were felt to be an essential guide for patients taking a SACT that has multiple medications within the regime. As the information is written, it is accessible for them to refer back to if in doubt or to clarify any confusion. A pharmacist described MRC as:

"A personalised chart for the patient with all the medicines that they are taking, when they should be taking them and how long they take them for and the dose […] we give [it] to patients in order to help them understand and remember when to take their medicines […] it's written information so they usually absorb it better […] they love it, they absolutely love it" (HP_INT01).

Patient diaries were reported to have mixed benefits and use of the patient diary was dependent on the individual patient. For some medical staff the diaries offered little benefit compared to conducting a clinical assessment, but for others they assisted in detailing a patient's history.

"I don't use it very much […] clinically I don't find it that useful, otherwise I think I would use it more" (HP_INT22)

"I love chemotherapy record books; I think they're very useful for the patients […] I've lost count of the times […] with patients and had to go through their book to find out what they've been on because they can't remember" (*HP_INT20*).

A common report regarding benefit of the patient diary was the toxicity grading scale, a coloured traffic light system highlighting to patients at which point they should contact a health professional for advice as, *"it prompts patients to call us, with side effects that they might not necessarily call us with" (HP_INT08).* For example, if a patient has more than 8 episodes of diarrhoea within 24 hours, this will be colour coded red, highlighting a patient should seek medical advice. The tool was seen to not only tell patients when to call regarding the severity of a side effect, but also to highlight side effects requiring reporting, which otherwise may have been viewed as insignificant.

One participant described how they refer to the traffic light system:

> *"you know you can use the traffic light system to give yourself a feeling of how bad your symptoms are […] this gives you a good indicator about whether to ring or not*" (*HP_INT05*).

The impact of experiencing continuous, low-grade side effects associated with many oral SACT was suggested to *"grind(s) the patient down" (HP_INT19)* and have a negative impact on treatment experience:

> *"What we see with the oral SACTs is that the side effects are not as severe, but they're always there, every day, day in, day out" (HP_INT19).*

A health professional involved in managing patients receiving an oral SACT reflected that a patient's experience of side effects might impact on their adherence and ultimately treatment outcome as, *"if patients start to experience side effects they're disincentivised to continue taking the tablets" (HP_INT20).*

Patients were graded into two different 'risk categories' dependent on the risk of side effects. Those in 'group 1' mostly experience fatigue with mild, but continuous side effects, which are easily managed, but usually want to stop taking medication. 'Group 2' patients tend to have high-grade (severe) toxicities and these patients don't want to call for help for fear of medication being stopped:

> *"It's kind of getting a balance between managing to keep people on their treatment […], but also managing their side effects so they have a good quality of life" (HP_INT08).*

An aspect of safe treatment with an oral SACT is the early identification and management of side effects. There was a sense that patients were reluctant to report side effects or unaware of the need to seek advice. Participants provided possible explanations why they thought patients either don't report side effects, or delay doing so; patients wanting treatments to be effective at controlling or curing their cancer, so are reluctant to risk the chance of their treatment being stopped:

> *"When you're giving them a treatment they they're taking themselves that they know could cure their cancer, you know, they don't want you to tell them to stop taking the tablets" (HP_INT08).*

A few participants also described that, *"some patients don't want to bother people […] or think it can wait or think it's not such a big issue" (HP_INT13).* The sense that patients feel that health professionals are under strain, they have a reluctance to add extra burden and thus do not seek medical help.

To encourage health-seeking behaviour, one participant suggested re-branding the hospital acute oncology triage system as an *"advice line" (HP_INT16),* as that might appear more accessible and be a less intimidating term for patients than 'triage'.

One participant raised the issue of the optimal timing for the OEC appointment. They felt that when patients attend the OEC to receive education, the delivery of information is often hypothetical, as the patients' may be naive to SACT and, therefore, have no experience. It appeared the participant felt that this was a limitation on how well they were able to convey information about side effects that the patient may not yet have, and may not ever experience:

> *"[Patients'] haven't experienced the drug at that point […] they haven't felt the issues […] we talk about the potential issues […] so that they're aware of them, but they won't have actually had diarrhoea, or thrown up" (HP_INT05).*

Another participant referred to a technique called visioning where by a person is asked to think through (imagine) what they would do in certain scenarios, so if they do happen the person would be more prepared to manage the situation correctly:

> *"I think it's about running through scenarios this might happen what are we going to do when it does happen because most of the scenarios are predictable […] what a sports person would call visioning, so when you encounter the scenario in real life it's not the first time" (HP_INT19).*

Patients' ability to problem-solve was a concern for a few participants describing examples where patients might not respond correctly to certain scenarios, such as, "*[…] patients throwing up and they've just had their tablet" (HP_INT17)* or *"[…] going abroad […] and they've run out and it's how do we get it to them?" (HP_INT04)*.

Participants identified several factors deemed to be associated with a higher risk of adverse outcomes from oral SACT, such as high-grade side effects, delayed reporting of side effects and/or non-adherence to oral SACT. Most participants recalled experiences with patients receiving capecitabine who became very unwell. One participant who had a clinical role in prescribing the drug capecitabine, referred to patients receiving this drug as people that needed to be *"actively manage[d]" (HP_INT21)*. Similarly, a health professional involved in managing treatment related toxicities reported, *"[patients taking capecitabine] are the ones that call the most for side effects" (HP_INT08).*

Patients deemed to be at highest risk of adverse outcomes were older as, *"older people don't always question what they're taking" (HP_INT08),* and those who have problems with cognition or memory

loss, such as dementia. Participants also identified that an impact on emotional function may also position the patient at higher risk. The emotional effect of a cancer diagnosis could affect the patient's ability to absorb or retain information:

> "*If it's the first time they're taking treatment; you give them their oral education, but the next day they might have forgotten"* (HP_INT17).

Finally, accessibility and environmental issues were also identified acknowledging patients may have difficulties with eyesight, opening medications, have young children in the house or distant carers and family members. One participant highlighted that if patients were non-compliant with other medication then they may be pre-disposed to non-adherent behaviours. Table 6.34 provides a summary of health professional perceptions of factors positioning patients at higher risk of adverse outcomes, who might be considered as needing additional support to be activated to self-manage their care while taking oral SACT.

Table 6.34 Summary of factors positioning patients at higher risk of adverse outcomes

Patient factors for high risk of adverse outcome
Receiving capecitabine
Older or frail patients
Patients with dementia or memory problems
Recent bad news/same day education or anxiety
Sight issues
Lack of understanding
Patient's with stomas
Young children in the house
Swallow difficulties
Those with history of non-compliance
Distant carers or lives alone

Suggested strategies to assist in managing patients perceived to be at 'high-risk' were follow-up and increased communication with colleagues:

> *"If I have a case like [perceived as high-risk] that I would follow them up after a few days just to see how they're doing […] I also update the consultant what happened in the clinic" (HP_INT12).*

While individual follow-up is carried out for high-risk patients, one clinician referred to the need for *"an accessible health platform that feeds back to the centre only when absolutely necessary"*

(HP_INT19). This participant viewed it unnecessary that a patient would be required to attend hospital to tweak the dose of an oral SACT describing current practices as a, *"hospital-centric model for being on SACT" (HP_INT19).* Another participant reflected that, *"the beauty of having orals is you can do it at home and they don't have to come to hospital so often" (HP_INT13);* thus attendance at the hospital should be minimised where possible.

To assist in maintaining patient safety out of the hospital, telephone follow-up was viewed as an appropriate way to monitor patients:

> *"So, I've thought about this, and I did wonder whether a telephone follow-up would be good?" (HP_INT06).*

One participant discussed a chemotherapy unit elsewhere in the UK that actively contacts patients receiving cancer treatments during their first cycle; reporting this to be well received by patients. Most participants felt patients would feel safer knowing they had contact with a health professional monitoring them.

Families and carers were viewed and described as being a key source of support and having a significant role in patients' lives and in assisting with care: *"[The family is] a package with the patient" (HP_INT08)*. Participants acknowledged that family members often had a key role in both helping patients take their medication and in seeking medical advice:

> *"Have situations when you think that [the patient is] going to be […] fine with the tablets and then the daughter says 'oh actually I manage the tablets and I give them each day'" (HP_INT21).*

Another participant reflected on patients referring to their partners as a personal doctor and pharmacist:

> *"[Patients often] refer to their partner as being their doctor and their pharmacist because they keep everything in check" (HP_INT14).*

In light of family members sometimes being *"informed more than the patient" (HP_INT10)* all participants reported they should be encouraged to attend all patient encounters and particularly the OEC appointment. The availability of a specialist nurse or keyworker specifically to support families was viewed by one participant, as a means to improve support to families and carers:

> *"Specialist nurse, a key worker should be on hand to support families and that ought to be proactively rather than reactively" (HP_INT07).*

While the support of a key worker may be suggested as a potential benefit to patients, two participants reported the valuable role psychological support can have on patients, highlighting the key role Maggie's Centre can play in supporting patients and their families with one participant reflecting, *"I always recommend Maggie's" (HP_INT15*).

6.4 Differences in views between health professions

Considering the sample characteristics, three types of health professionals were recruited to interview: pharmacy staff, nursing staff and medical staff. To examine for key differences in views across professions, themes derived from coding (Table 6.33) were used to create a table, and all summaries from respective participants summarised and grouped by profession to enable comparison across cases.

Despite revisiting and interrogating both raw data, and thematic summaries, no differences were observed in reported views by health profession. All health professionals recognised the advantages oral SACT offered to a patient, with pharmacists, doctors and nurses all discussing the benefits to quality of life and freedom of movement oral SACT provides. Where participants referred to their clinical role, the emphasis and impact of their role was in identifying and subsequently delivering individual support. It was widely recognised that medical staff had a direct role in the prescribing and allocation of treatment, with pharmacy and medical staff having a direct role in delivering safe treatment including education and ongoing support. One participant, a consultant oncologist expressed a view that nursing staff were better placed to deliver patient education due to their close workings with patients' day to day to experience of receiving cancer treatment, thus an enhanced knowledge in the day to day management of treatment toxicities. This view was not expressed by any further participants with a clear generalised view that both nursing and pharmacy staff were well positioned to deliver tailored education and ongoing support with oral SACT.

While it is logical to assume that doctors, nurses and pharmacists might have different views on the safe management and care of patients receiving an oral SACT, informed by their professions training and subsequent job descriptions, no key differences were identified within this data set. The overarching findings from interviews with health professionals identified that safe management of oral SACT, including its dispensing and subsequent support should be guided by the individual's needs, preferences and characteristics. The ability to assess this individual need was not reported to be affected by professional background.

6.5 Chapter Summary

This chapter has presented the results of semi-structured interviews with 23 health professionals involved in the management and care of patients receiving an oral SACT.

The oral education clinic is perceived by a range of health care professionals to be an effective model of care to provide patient education for those receiving oral SACT. Participants talked about education needing to be patient-centred, tailored to individual patient understanding and specific needs, and repeated at future encounters. Staff felt it was important to assess the potential for information overload and include the patient's family and/or carers in the oral SACT education appointment. Participants felt that patients and their carers should have easy access to support from health professionals, suggesting the use of proactive monitoring by a member of the tumour site MDT. Participants described factors they believed place patients at higher risk of adverse outcomes, highlighting the importance of risk-stratified approaches to treatment monitoring and patient review. This could be viewed as some participants begin less activated to self-manage and need additional support to do so. At home, it was felt that patients would benefit from interventions, such as a patient diary, that help them remember to take their medication, and also help them assess toxicity and when to seek medical support. The GP was thought to have a significant role in providing care in the community, but there was a sense that the level of support patients sought from the GP was dependent upon the level of trust between the patient and their GP. Participants suggested that future health care interventions should consider increased education for GPs about managing patients taking oral SACT, and the use of technology to maintain an ongoing indirect review of patients.

Chapter Seven: Data Integration

7.1 Chapter outline

This chapter, acknowledging the overall aim and research questions of this study, addresses each research question through integration of data sets. Data integration was achieved through the process 'Following a Thread' (Moran-Ellis et al., 2006). Threads used to facilitate this process will be presented alongside findings following integration. The chapter will conclude with an overall summary of results before leading to the final chapter of this thesis, Chapter 8: Discussion and Conclusions.

7.2 Aim and research questions

The aim of this study was to explore the perceptions and experiences of patients receiving oral SACT and the views of relevant health professionals to inform models of care.

In order to meet the aim, the following the research questions have been addressed:

- What are the experiences of patients receiving oral SACT?
- How satisfied are patients with the clinical care they have received?
- How useful is the oral education clinic (OEC) for patients?
- What strategies do patients use to manage both their oral SACT and treatment related toxicity?
- What are the perceptions and experiences of health professionals involved in managing patients receiving an oral SACT?

7.3 Identifying threads

As discussed in the methods section of this thesis (Chapter 3, Section 3.4.3, P. 96) the process of following a thread can be conducted either by selecting a question to follow through the respective data sets, or by selecting a theme. Three data sets have been presented in this thesis, the conduct of which was guided by the over-arching research questions. Of the five research questions guiding the study, only one relates directly to health professional experience with the remaining four focussing on patient experience. To achieve authentic integration of data across all data sets, a thread was required that could relate to all sets respectively. One approach to developing threads

would be to use to the research question as a thread, however in their current format, complete integration by following a thread would not be achieved. For example the research question, "How satisfied are patients with the clinical care they've received?" could not be easily integrated with health professional interview data. As a diagnosis of cancer and its associated treatment has a significant and widespread impact on a person's life, it was crucial in this study to remain focussed on the research questions, therefore threads were required that were based on the research question, but could be followed through all data sets respectively. Considering all five questions, three threads were developed to facilitate this process. Figure 7.11 demonstrates how the threads were developed from the guiding research questions explicitly depicting how each research question is addressed through the threads.

Thread one: What is the experience of people receiving an oral SACT?

Thread two: How satisfactory is the clinical care received for oral SACT provision?

Thread three: How is oral SACT managed safely?

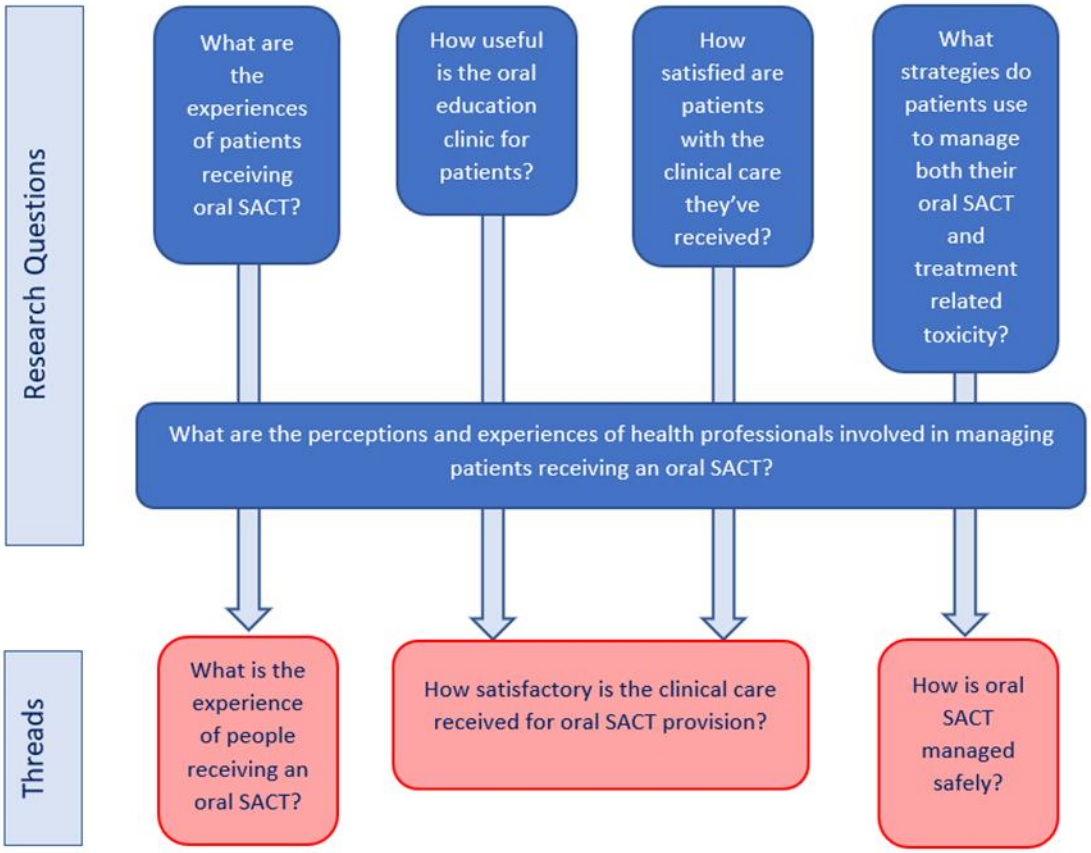

Figure 11 Developing three threads to achieve data integration

7.4 What is the experience of people receiving an oral SACT?

A diagnosis of cancer was viewed as generating a significant emotional burden. Feelings of shock, ruminations about dying, and negative alterations to self-identity, were commonly reported. The impact of a cancer diagnosis, such as the perceived stigma attached to their diagnosis, affected not only the individual, but also their families. When discussing delivering patient education and the risk of information overload, several health professionals reported that due to the context of a cancer diagnosis and treatment, cognition and processing was affected, having a negative impact on an individual's ability to assimilate new information. This experience is important to detail as it describes the often complex and emotional context of the patients' lives prior to commencing oral SACT.

Cancer treatments, specifically treatment with chemotherapy, were dreaded; oral SACT was referred to as poison by some patient participants. However, oral SACT enabled a person with cancer to largely continue with their usual lifestyle, reduced hospital attendance, and provided a sense of control and autonomy. Similarly, health professional participants reported the sense of control and autonomy associated with an oral SACT as having a significant psychological benefit to PWC. Oral SACT provided a freedom of movement enabling individuals to travel on holiday or take day trips, which would not be possible (or significantly more difficult to arrange) if they were receiving an intravenous treatment. Almost two thirds (63%) of questionnaire respondents reported that taking an oral SACT was convenient with a minority (8%) reporting inconvenience.

Overall, beliefs about oral SACT were positive. When assessed using the Beliefs about Medicines Questionnaire, participants were found to have 'strong' beliefs in the necessity of their medication. Whilst there was a clear preference toward oral SACT as opposed to IV SACT by patient participants, a disadvantage of oral SACT was uncertainty about the length of the treatment course by both patient and health professional participants. This finding was also reflected within SIMS data where respondents reported insufficient or no information on how long it will take oral SACT to act, how to tell if it is working or for how long to take the oral SACT. Patients however expressed strong beliefs about the necessity to take oral SACT and overall these beliefs outweighed the concerns they had.

Male respondents reported higher levels of satisfaction (higher CTSQ scores) than female respondents; for some female respondents oral SACT was more disruptive and more difficult to manage than expected. Within the Cancer Therapy Satisfaction Questionnaire (CTSQ) (P. 140) a statistically significant difference was identified in the 'Feelings about Side Effects' domain where male respondents had a higher mean score of satisfaction. Questions within the feelings about side effects domain focussed on the impact of oral SACT on daily life, emotional upset caused by side

effects, expectations of difficulty of taking oral SACT and whether the side effects were as expected. While no free-text comments were offered to support reasons why satisfaction might be higher in men than women, and no questions within patient interviews were geared towards exploring differences by gender, overall, male participants had higher levels of satisfaction than women. Health professional interviews did not explore or reference any potential differences in experiences based on gender.

In summary, the experience of PWC taking an oral SACT has been positive. While questionnaire findings point toward men being more satisfied than women with the treatment, for both genders, oral SACT was an acceptable treatment and one that promoted a sense of normality, with patients reporting a preference for oral SACT compared to IV treatments and health professionals recognising the psychological benefit of an oral treatment.

7.5 How satisfactory is the clinical care for oral SACT provision?

Health professionals and the NHS were held in high regard, with patient interviewees often highly commending the staff they encountered. There was, however, a clear sense that the NHS was overworked, with consultations sometimes feeling rushed or delayed which patients attributed to the volume of patients requiring attention. Health professionals similarly reported a lack of OEC facilitators being available to deliver the OEC and thus not all patients had access to the service.

An area of dissatisfaction for patients was discontinuity in their care, and they often reported seeing different health professionals at each appointment. Whilst the OEC was a stand-alone appointment, patients receiving an oral SACT would often return to the hospital intermittently for review, but encounter different doctors on each occasion. This reduced the opportunity to develop a therapeutic relationship and used precious time repeating discussions from previous consultations with other health professionals. A sense that the development of relationship was key to patient experience was clear throughout the patient interviews. When interactions with health professionals were individualised, person-centred, holistic and formed out of a therapeutic relationship, a sense of feeling cared for was generated. Many health professionals were commended for their caring nature and ability to empathise and display compassion. Where criticism of health professionals was reported, this was on account of poor communication skills preventing authentic interactions and relationships, or a perceived lack of compassion. A sense of feeling cared for and a desire for compassion was evident in interviews with PWC. Similarly, in questionnaire data, high confidence was reported for interactions with health professionals.

The OEC was viewed by both patients and health professionals as an appropriate model for promoting the delivery of safe care for patients commencing an oral SACT. Positive aspects of the OEC for patients included an opportunity to receive information on the purpose of their oral SACT, how to take the oral SACT and information on potential side effects they might encounter. Health professionals viewed the OEC as being innovative and progressive, providing patients with a dedicated opportunity to be informed about safe aspects of oral SACT administration. This innovation was seen in a positive light, where one participant felt the OEC should be replicated at other local district general hospitals to minimise the burden of attendance for patients. There was a sense from health professionals that following implementation of the OEC, patient calls to the hospital triage service were reduced and the volume of patients requiring hospital attendances minimised. Patient experience of the OEC was, however, negatively affected by the appointment appearing to be disorganised with one health professional participant reflecting that improvements to efficiency were required within the OEC.

Health professional participants reported that information varied in its style and content depending on the health professional delivering information. Interview findings from both patients and health professionals revealed that doctors were perceived to deliver information that provided an explanatory rationale and reason for intervention, whereas information from nursing staff focused on the day-to-day impact of oral SACT, and education from a pharmacist tended to focus more on management of the drug itself. While different health professionals provided different types of information, there was a sense from patients that all of these types of information were helpful. Relationship with the OEC facilitator and their communication skills was perceived as more important to the patient than the facilitators professional discipline; this view has not been reported in published literature. Whilst confidence in the OEC was high for most, several respondents reported a lack of confidence in commencing oral SACT, and in managing potential side effects (Section 4.4.3, P. 124). Interview findings with patients also identified that when education was being delivered it would sometimes appear scripted and lacking personalisation. The impact of repeating information, and not tailoring information to individual need and preference increased stress levels particularly where education on side effects was being repeated. A tension however exists within the respective qualitative data sets, as several health professionals reflected on the importance of repeating information. There was a view that due to the psychological impact of a cancer diagnosis and its treatments, ability to assimilate a significant amount of new information was compromised. It is possible therefore, that while overall the OEC was well received by patients, and held in high regard by health professionals, there are elements requiring improvement, namely,

identifying strategies to repeat information to ensure assimilation, without causing increased distress or anxiety.

Delivering education by telephone was well received by patients however professionals who acted as facilitators of the OEC described delivering telephone education as challenging. It was felt that the lack of non-verbal cues increased the challenge in ascertaining patient understanding. Logistical aspects to delivering education over the phone included the challenge of actually having patients answer their phone, but also difficulties with signal issues and the challenge of addressing silences; however this was perceived by health professionals as preferable to no education at all.

Findings of this study (from SIMS data, P. 128) also suggest that patients are less satisfied with information received at the OEC once they had been taking their oral SACT for several weeks. Some patients indicated a perception that information on how to live well with cancer was lacking. Further support and information was needed about holistic aspects of care, such as an individual's level of physical fitness, dietary habits and intimate relationships. This finding signposts to the fact that there is a lack of other sources of information. Some medical health professionals reported a view that nurses and pharmacists were best placed to discuss holistic aspects of care, yet no interview participants reported providing this level of information. While health professionals were previously commended by patient interview participants for being caring with high degrees of empathy, there was clearly a tension between identifying patient needs and desires as not all aspects of care for individuals were addressed.

Information overload was commonly reported by patient interviewees and identified as a risk by health professionals. Several patient participants reflected on their physical or psychological status having a direct impact on their ability to process and retain information. Whilst many participants described being offered the opportunity to ask questions, they often described not having time to process information received in the context of their own life, and thus develop questions or anticipate potential problem scenarios. This finding was echoed by health professionals who often shared about the psychological complexities in delivering information with patients often in a state of anxiety or distraction.

When education was delivered on potential side effects, all patient participants described feelings of anxiety and distress. To mitigate this distress, some patients reflected on the manner by which information could be shared to reduce anxiety. By sharing evidence-based information, health professionals might minimise the stress caused by hearing about side effects. However as previously discussed, health professionals however reported the value in reiterating patient education at future encounters – there was a sense that due to information overload, patients will not always assimilate

all information given to them and therefore it should be repeated where possible. Recognising patients' desire for more information, but the impact of repeated difficult information, health professionals should ensure that important information being emphasised is delivered in a sensitive and strategic manner, such as highlighting the likelihood of side occurrence or using statistical probabilities reported in the current scientific evidence base.

Overall, the OEC and clinical care received was effective at supporting PWC to safely commence an oral SACT. Improvements however are required to support individuals across the patient pathway following commencement of treatment with person-centred education and individually tailored support systems focussing on meeting an individual's desires, preferences and needs.

7.6 How is oral SACT managed safely?

When discussing patients' management of oral SACT at home, family members were perceived by both health professionals and patients as the main source of support. Many participants referred to their partner as providing a back-up for medicine taking, for triggering contact to the hospital and, for several male respondents, managing the daily administration of their oral SACT. This finding was echoed in health professional interviews, where family members were perceived to be a key source of support and often more informed than the patient; similarly, one patient participant referred to their partner as a personal pharmacist. Families were viewed as essential in supporting patients at home, with patient interviewees often recalling that their time at the hospital was limited, but in comparison their time spent around families significantly greater. Patient participants described concern for their families with several commenting that the cancer diagnosis was worse for the family members. When discussed in interviews, there was a clear sense that family members, whilst welcomed at appointments and encouraged to participate, were not supported by the hospital. No participants reported their family members being offered any direct support, or being directed towards systems of support such as the Maggie's centre or online resources or support groups. Recognising the valuable and important role of family, it was clear in both sets of interview data, family played a pivotal role in not only safe administration of SACT, but also safe management of care at home such as in the management of treatment toxicities. While health professional participants recognised the pivotal role of families, patient participants reported a lack of support for their family members, often adding to their worries and concerns.

Views on the role of the GP varied in both health professional and patient interview data sets. Some health professionals placed great value on the GP, referring to them as valuable for the physical assessment of patients in the primary care setting. Other professionals felt that GP expertise was in

general medicine and the GP had no role in assisting with the specialist care of managing the person with cancer. For PWC, a similar mixed view was held. All patient participants regarded the GP as a generalist, with knowledge of a wide range of conditions, but limited specialist cancer knowledge, and thus reported the GP having no role in managing cancer treatments. However, some described good relationships with their GP and had experience with their GP providing supportive care such as psychosocial support and assisting with supportive medicines – thus the GP had a favourable role in assisting with support for the patient, rather than managing the cancer treatment itself. It was clear, despite these varying experiences, that there was a lack of clarity on the GP role, both from the patient and health professional perspective.

Several patient participants also described the clinical nurse specialist (CNS) as invaluable. The CNS was seen to have a role in assisting the management of side effects and navigating the hospital system, such as arranging appointments, and for some, implementing telephone follow-up. Health professional participants also recognised the role of the CNS referring to their role in proactive management of patients and as a means to provide support to family members.

A final source of support for patients receiving an oral SACT was their peers. A few respondents reflected on the benefit of meeting somebody else with the same type of cancer, or receiving the same oral SACT. This bond enabled patients to have more detailed conversations and share their experiences. Participation in support forums (both virtual and in the form of support groups) also provided an opportunity for patients to learn from one another, with an example of an individual changing the timing of their oral SACT administration to lessen the experience of a side effect when taking it shortly after a meal.

Managing the tablets at home was reported to be unproblematic, but required the development and establishment of a routine. Once a routine was in place it was easy to manage, with many participants comparing their oral SACT to any other tablet. While some patients had other medications to take alongside their oral SACT, no problems were identified in managing this, with one participant describing the initial change to their routine of regular tablet taking, only required a little extra thought. Routine was regarded by patient participants as vital to effective oral SACT as this was the strongest factor in promoting adherence.

The importance of oral SACT for the individual's health was often discussed in interview, and the BMQ identified strong beliefs in the medication, with necessity outweighing concern. In essence, the importance of taking the medication appears to have led to PWC developing mechanisms to ensure adherence. With overall adherence identified as high in this study, adherence tended to be higher in men, in those between the ages of 70-89, those with no co-morbidities, an oncological

diagnosis rather than a haematological diagnosis, those living as married, and those without dependents. Health professionals expressed minimal concern regarding patient adherence and did not describe any methods used locally in their practice to ascertain a patient's degree of adherence.

Side effects were most commonly experienced within the first week of treatment. The most common side effect was fatigue and tiredness, which was mostly manageable at home, although advice on managing tiredness was rarely reported. A few participants reported no side effects. Side effects were often discussed with a patient's doctor at their next medical review, but some respondents indicated delaying seeking advice for a period of up to four days as they deemed the side effect not to be serious enough to warrant contacting the hospital and there was often a hope that the side effect would pass by itself. The point at which an individual would seek help by contacting the hospital was unclear for many interview participants, but was often triggered by a physical symptom or prompting by a family member.

Health professionals deemed certain patients to be at higher risk of adverse outcomes from oral SACT, which to some extent aligned with the characteristics of patients who needed support to self-manage their care. This included patients receiving capecitabine, older adults, and those with cognitive impairment or high levels of anxiety, and those who perceived oral SACT as less toxic than IV SACT. Strategies to manage higher-risk patients were based on enhanced communication through follow-up. Similarly, many patient respondents had concerns about the ability of older adults to successfully and safely manage oral SACT at home where issues of cognition and hydration might contribute to increased risks of mismanagement of the medication or its associated toxicities. Considering this finding arising from both data sets, it is suggestive that patients across a continuum of individual factors such as age, background or treatment complexity require different levels of support.

Analysis of patient interviews identified a typology of activation to self-manage. Two contrasting groups were identified where some individuals demonstrated high levels of activation to self-manage their oral SACT. These individuals felt confident in managing their side effects, identifying the point at which they should seek support and displayed a variety of coping strategies. A second group of participants required enhanced support and described anxieties with managing their oral SACT, namely around unclear information, the challenge in identifying when they should seek assistance to manage their side effects and difficulty in identifying which source to seek help from. While health professional interview findings did not directly refer to an individual patient's ability to activate to self-manage, as discussed previously, concerns were expressed about patient groups who might be at higher risk from adverse outcomes with oral SACT (Page 195); primarily older adults or

those with some degree of existing co-morbidity such as vision disturbances, cognitive impairment or those with stomas. This further signposts to the requirement for patients to be considered as individuals with differing levels of need, but identified that activation to self-manage could be the characteristic to assess and monitor as a potential risk factor, rather than existing co-morbidity.

7.7 Summary of findings

Through questionnaire and interviews with both patients and health professionals, this study has identified that oral SACT is well received by PWC, offering both a convenience and freedom of movement compared to IV treatments and that participants preferred oral SACT. The OEC was regarded as an acceptable model of care, however questionnaire findings and interviews with both patients and health professionals identified several areas where improvements could be made. Taking an oral SACT at home was relatively straight forward for PWC, however managing side effects presented some challenges. Individuals held strong beliefs regarding the importance of taking their oral SACT, and adherence to treatment was high. Support systems for individuals were often family members or peers however these systems were not always clearly recognised by health professionals. Patients often expressed concern for their families and offered few examples of health professionals offering support to family members. PWC generally preferred to contact health professionals attached to the cancer centre rather than in a primary care setting for any medical assistance and it was clear in both interview data sets that the role of the GP was somewhat unclear.

Data across all three data sets was in the most part complementary, where health professionals had an understanding of the patient experience similar to reports direct from individuals taking an oral SACT, however some differences were identified. Patient participants discussed how they found it difficult when the duration of taking the oral SACT was unclear, yet this impact was not recognised or discussed by health professionals. Questionnaire data identified difference of experience between genders but this was not observed in patient interview data when comparing cases by gender or referred to in health professional interview data. A clear desire for therapeutic relationship with health professionals encountered was identified from the patient interviews, but this was rarely discussed by health professionals, rather an inference that some patients would require ongoing follow-up because of their abilities to assimilate information or manage their medication. Finally, repeating information on side effects was deemed essential by multiple health professional interviewees, yet the impact of this on patients was significant in adding to psychological distress. These differences highlight the importance of a person-centred approach to patient assessment and support. By placing an emphasis on person-centred approaches, the key

desires, preferences and needs of individuals would be identified and the development of a therapeutic relationship enhanced.

7.8 Chapter summary

This chapter has presented results of this study following data integration. Three threads were developed based on the research questions and followed through all data sets: health professional interviews, patient questionnaire and patient interviews. Integrated findings highlighted that people's response to cancer, its treatment and its day-to-day management varied depending on the individual. Findings suggest that adoption of a person-centred, holistic approach to education and subsequent support would help identify individual's needs, preferences, worries and concerns, thus reducing stress and improving patient experience and outcomes. The next and final chapter of this thesis will discuss these findings within the context of existing published literature and examine the potential impact of a person-centred care approach to PWC receiving an oral SACT and critique the OEC as a model of care.

Chapter Eight: Discussion, Implications, Recommendations and Conclusions

8.1 Chapter outline

Integration of data sets identified that experience of a cancer diagnosis and treatment with oral SACT varied depending on the individual. In order for health professionals to meet the needs of PWC receiving oral SACT an individualised approach is required, therefore the following chapter will explore the practice of person-centred care within the context of oral SACT provision. Discussion points will include the implications of this study for the wider healthcare setting in order to optimise the care of people receiving oral SACT. The chapter will later address lessons learned for the PhD student, including a brief narrative of the ongoing requirement of reflexivity during the research process. Strengths and limitations of the study will be considered alongside reflections on the rigour of the study. A short discussion on the impact of this thesis and dissemination of findings will be presented before drawing this thesis toward conclusion.

8.2 Discussion

The emotional burden of a cancer diagnosis and stressors associated with treatment is widely recognised. Thoughts of death and a negative impact on an individual's mental health following a cancer diagnosis has been reported in published literature (e.g. Mitchell, 2006; Rosenstein, 2011) alongside reports of stigma and social isolation (e.g. Chapple, Ziebland and McPherson, 2004; Wilson and Luker, 2006; Hamilton *et al.*, 2010). Considering an individual's cognition and mental health in the context of safe cancer treatment and management has been reported in published literature. In a grounded theory study investigating reasons for delays in reporting neutropenic sepsis, Oakley et al (2016) reported that patients were often educated about neutropenic sepsis prior to starting SACT but at this time they were pre-occupied by the thought of imminent side effects and thoughts of dying. Therefore when considering delivering patient education and ensuring patients are prepared to safely manage oral SACT, consideration of an individual's mental state and coping is paramount.

In this study, it was clear through questionnaire and interview that participants preferred oral SACT to IV treatments. The advantages and preferences for oral SACT as reported by PWC in this study echo that reported by Simchowitz *et al.* (2010) where convenience, ease of use of oral SACT and freedom in movement led to clear preferences. A further similarity between this study and that of

Simchowitz *et al.* (2010) is the invocation of concern due to a lack of clarity on the duration of treatments. This finding was also reported where 'information gaps' about treatment efficacy (the time taken for capecitabine to be effective) and how one could tell whether the therapy is working was identified (Bhattacharya *et al.,* 2012).

This study points toward the influence of gender on an individuals' experience with cancer and treatment with oral SACT. The Cancer Patient Experience Survey (Quality Health, 2017) identified that satisfaction in female respondents is consistently lower than males across the cancer patient pathway. Gender differences have been observed in different healthcare situations, such as communication styles (Street, 2002) and coping strategies (Keller and Henrich, 1999; Volkers, 1999). A multivariate regression of 386 questionnaires by Wessels *et al.* (2010) highlighted the impact of gender on cancer patients' needs and preferences; they found that without exception female respondents placed higher importance on all aspects of care than male respondents. The authors, therefore, suggested that in order to optimise the care experience of PWC, an individualised, or gender-based approach might be required. An approach to care that is individualistic, might enable health professionals to identify individuals' preferences and/or expectations relating to their gender.

Common across all models of care identified in the systematic literature review and pivotal to safe administration of oral SACT was the delivery of patient education. Utilisation of the MASCC MOATT (Kav *et al.*, 2010), a guideline for delivering education, has resulted in high levels of adherence. As previously stated, the content of education delivered in the studies was rarely reported, but it was common in some studies to identify deficits in knowledge (Oakley *et al.*, 2010; Reginer Denois, 2010; Simchowitz *et al.*, 2010; Arber *et al.*, 2014). The role of families was also identified as a significant support to individuals receiving education secondary to a third parties' ability to assimilate different or increased levels of information; it is widely recognised that family and carers participate actively in patient education (Behar-Horenstein *et al.*, 2005; Marcus, 2014). Considering the wider body of literature regarding models of care for oral SACT provision, education was mostly delivered through face to face encounters. While in this study some participants received education by the telephone, finding this mostly acceptable, health professionals recognised the added challenge in assessing understanding when completing telephone education, a finding similarly reported by Shaw *et al.* (2013) where responding to patient cues on a telephone was recognised as an area requiring future training. Irrespective of the challenges in telephone communication, continued and reinforced education appears to be important, particularly in the first 6-8 weeks of treatment (Boucher *et al.*, 2015; Wu *et al.*, 2015), which is often delivered by telephone. Findings in the systematic literature review identified that when telephone follow-up or continued care contacts were implemented,

they provided an opportunity for the assessment of treatment related toxicity. These calls were often placed within the first 72 hours, or week of commencing treatment.

The experience of individuals meeting an array of health professionals lead to feelings of discontinuity in care and prevented the development of a therapeutic relationship. Therapeutic relationships have been defined as communication between a health professional and patient which is caring, non-judgemental and supportive, often during stressful periods as perceived by the patient (Mottram, 2009). Effective therapeutic relationships have been shown to improve patient experience (Kornhaber *et al.*, 2016) and engagement in communication (Tabler *et al.*, 2014), thus might have an impact on patient understanding. Such a relationship is viewed as essential in delivering an individually tailored consultation as advocated by the UK Oncology Nursing Society concerning the support and education provided to PWC receiving oral SACT (Oakley *et al.*, 2010).

Whilst empathy is a complex, multi-dimensional construct (Mercer and Reynolds, 2002), Rohani *et al.* (2018) argue that it is a skill that can be taught and should be considered as a core competency for nurses working within cancer care. Francis (2013) reported a sense that health professionals working within the NHS are lacking care, and exhausted and distracted by the focus on targets and ongoing financial pressures, which results in diminished patient experience (Klein and Maybin, 2012). Technically advanced and busy environments have been further shown to limit the delivery of compassionate care (Maben, Latter and Clark, 2007). New evidence, recently published by NHS England (Dawson, 2018) identified the link between NHS staff experience and patient satisfaction highlighting the need for organisations and institutions to focus on staff satisfaction and experience to have further impact on patient satisfaction.

PWC are in contact with an array of health professionals throughout the cancer journey. Clinical nurse specialists and general practitioners play an active role in supporting PWC both before diagnosis, during treatment and on cessation of treatments. The UK Oncology Nursing Society recognise the valuable role of the GP and practice nurses in supporting patients receiving an oral SACT (Oakley *et al.*, 2010) and advocate that there could be instances of shared care (NCAG, 2009). A survey in Germany of 740 people with cancer highlighted support for involvement of their GP in their cancer treatment identifying the need for shared care models (Lang *et al.*, 2017). While no similar survey has been found in a UK setting, there is a growing body of literature highlighting the increased role of primary care and the GP in the NHS pathway for PWC (Buckland, 2016) with an emphasis on improved outcomes and survivorship (Watson *et al.*, 2011). Further, nationally the role of the CNS is well recognised as an integral aspect of high-quality cancer care (Department of Health,

2007; Oakley *et al.*, 2010; Department of Health, 2014; Donald *et al.*, 2014) and findings from this study support their continued and sustained role in the cancer journey.

This study identified high levels of adherence to oral SACT, similar to previous reports. In an evaluation of a nurse led intervention to enhance medication knowledge and adherence, Boucher *et al.* (2015) reported a mean score of 7.12 (SD 1.01) in 27 patients using the MMAS-8 measure (highest score of complete adherence equal to 8). Sommers, Miller and Berry (2012) similarly reported a mean score of 7.89 (SD 0.55) in a sample of 30 patients with gastrointestinal cancer using MMAS-8. Eliasson *et al.* (2010) conducted a study utilising a medication events monitoring device (a means to measure adherence) and conducted in-depth interviews with 21 individuals diagnosed with chronic myeloid leukaemia taking imatinib. In this sample they identified unintentional non-adherence (forgetfulness) similar to that reported in this study. Notably the authors also identified intentional non-adherence where a dose of imatinib was omitted in the hope of minimising side effects experienced. With a larger sample (n=70) of multiple cancers in this study, adherence was slightly higher than those reported in the current evidence base and there were no reports of intentional non-adherence.

Evidence suggests factors that negatively influence adherence to oral SACT, including: social, economic and demographic factors; organisational barriers, such as inadequate education which leads to outcomes such as misunderstanding the timing of taking; disease-related factors, such as experience of treatment toxicity; treatment-related complexities from complex regimens or inconsistent guidance; and individual characteristics, such as impaired cognitive ability or poor health literacy (Partridge *et al.*, 2002; Partridge *et al.*, 2003; World Health Organisation, 2003; Ruddy, Mayer and Partridge, 2009; and Muluneh *et al.*, 2018). However, the findings of this study indicate high levels of adherence reported by patient participants were attributable to strong beliefs in the necessity of taking the oral SACT.

In the literature there is a consensus that patients with cancer generally adhere to oral SACT more thoroughly secondary to the gravity of their disease (Waterhouse *et al.*, 1993; O'Neil and Twelves, 2002; Weingart *et al.*, 2008; Spoelstra and Given, 2011; Wood, 2012) however some published studies have indicated adherence rates of ranging from 40% to 50% (Partridge *et al.*, 2002), and 43% in a small study of 51 patients with breast cancer receiving oral cyclophosphamide (Lebovits *et al.*, 1990). The findings of this study support the concept of high adherence due to the gravity of a cancer diagnosis; the importance of oral SACT for an individual's health encouraged a quick establishment of routine and placed emphasis on correct adherence. It is however important to note that patient participants in this study had high levels of education, and few ethnic minorities

were represented as nonadherence episodes are often linked to complex regimens (Spoelstra and Given, 2011), poor understanding of education received (Vioral *et al.*, 2014) and within the wider body of adherence related literature, socio-demographic factors (DiMatteo, 2004).

Findings from the systematic literature review addressed the challenge in accurately measuring adherence with few published studies reporting models of care using methods to regularly measure adherence in clinical practice. The majority of methods used to measure adherence utilised patient self-report. As this method of measurement is self-directed, by the individual, there is the potential for findings to be biased if patients did not want to disclose non-adherence. However, a study by Schneider *et al.* (2014) utilised both patient self-report and pharmacy refill rates identifying a positive correlation (p=0.0048) suggesting high accuracy of patient self-report.

It is imperative, for the delivery of safe healthcare provision, that patients receiving an oral SACT adhere to treatment appropriately and are able to identify the right source of support at the right time. In essence, it is essential that patients have the ability to self-manage their care at home by proactively managing side effects and seeking help when appropriate. Effective self-management requires a patient being 'activated' to do so. Patient activation is a term used to describe an individuals' knowledge, confidence and ability to take on the role of managing their own health and healthcare (Greene and Hibbard, 2012). In a systematic review, Kinney *et al.* (2015) identified that patients who had low levels of activation were more likely to attend emergency departments and be admitted to hospital. Greene and Hibbard (2012), in a cross-sectional study of 25,047 patients however demonstrated that highly activated patients were more likely to receive preventive care and identified that patient activation was strongly related to a broad range of health-related outcomes including improved clinical indicators such as blood pressure and low-density lipoprotein.

Within the cancer setting, research into patient activation and self-management is limited however Salgado *et al.* (2017) recently published a multi-centre, cross-sectional observational pilot study which aimed to assess the relationship between patient activation, confidence to self-manage side effects, and adherence to oral SACT. They identified across 125 respondents that higher levels of self-activation were not associated with better adherence to oral SACT, however it was a positive predictor of increased confidence to self-manage the symptoms of fatigue and nausea, or to seek support with side effect management. In essence, the study identified that adherence rates were not associated with activation to self-manage, however those with higher levels of self-activation were more confident in managing side effects or identifying the point at which to seek help. These findings support that of this study, where adherence was high, but that patients who described confidence in managing their oral SACT were able to demonstrate and discuss coping strategies;

thus, those activated to self-manage were more confident taking their oral SACT. Recommendations from Salgado *et al.* (2017) include a call for assessment of which health professionals could deliver interventions to assess activation to self-manage suggesting it requires an interdisciplinary approach.

A cross-sectional survey study conducted by Bos-Touwen *et al.* (2015) analysed associations between self-management activation and a range of socio-demographic, clinical and psychosocial determinants. The study included patients with type-2 Diabetes Mellitus, Chronic Obstructive Pulmonary Disorder, Chronic Heart Failure and Chronic Renal Disease. Poor activation to self-manage was associated with having a higher BMI, increased financial distress, a higher comorbidity index score, a medium education level, a short disease duration, a more negative illness perception, living alone and being depressed. While the diseases included in this study do not directly link to cancer, they are similarly managed as a chronic condition and identify a series of characteristics which might indicate to health professionals assessing an individual's ability to self-manage those who would be at higher risk, and thus, are less likely to activate to self-manage.

Rees and Williams (2009) argue that patient-orientated interventions are the most effective means to effecting positive self-care behavioural and health outcomes. In the case of oral SACT provision, the OEC would be a prime opportunity to deliver such an intervention, however patients in this study desired a person-centred model of care, which health professionals also referred to as an optimal model of care. Findings from this study indicated that patients viewed the OEC information as lacking personalisation and often scripted with several areas of limited or no information; therefore in order to encourage patients to safely manage their own care, or activate to self-manage, a person-centred approach is required.

8.2 Learning from patient experience: a model of person-centred care

The narrative thread throughout this thesis has identified an individualistic approach to PWC taking an oral SACT is required. Safe oral SACT provision involves the delivery of individually tailored patient education to people who are activated to self-manage. In order to assess where an individual sits on the spectrum of activation to self-management, an individualised, comprehensive and holistic assessment is required. Applying a person-centred care approach could serve as a means to address and identify the varying levels of need within the patient population.

Within the body of published healthcare literature, patient or person-centred care are not new terms. While both patient-centred care and person-centred care require recognition of an individual and their associated health problem as experienced by that individual, there are arguably differences between the two (Starfield, 2011). In essence, Starfield (2011) advocates that patient-

centred care can be episodic, or related to the individual disease as experienced by the individual, whereas person-centred care views the individual, not just as a patient, but rather as a *person* where the disease may be linked to other interrelated phenomena or holistic aspects of their life. This view is echoed by Ekman *et al.* (2011) who advocate that person-centred care eliminates the reduction of the person to just their disease and/or symptoms. Patient-centred care, as defined by Hurtado, Swift and Corrigan (2001), relates to delivering healthcare that "*[…] is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions"* (P. 3). The Health Foundation (2016) purport there is no single agreed definition for person-centred care, but rather four comprising principles: the person is treated with **dignity**, **compassion** and **respect**; offering **co-ordinated** care, support or treatment; offering **personalised** care, support or treatment; and **supporting people to recognise their own strengths and abilities** to enable them to live an independent and fulfilling life.

Several models of person-centred care exist; one such example, and a framework selected for further exploration and recommendation in this study is the person-centred nursing (PCN) framework (McCormack and McCance, 2010). The PCN is a mid-range theory developed from two abstract conceptual frameworks (McCance *et al.*, 2001; McCormack, 2003). The framework (Figure 7.11) is comprised of four constructs: prerequisites, the care environment, person-centred processes and expected outcomes. Through consideration of these constructs, the framework aims to produce person-centred outcomes resulting in the provision of holistic care, tailored to individual need.

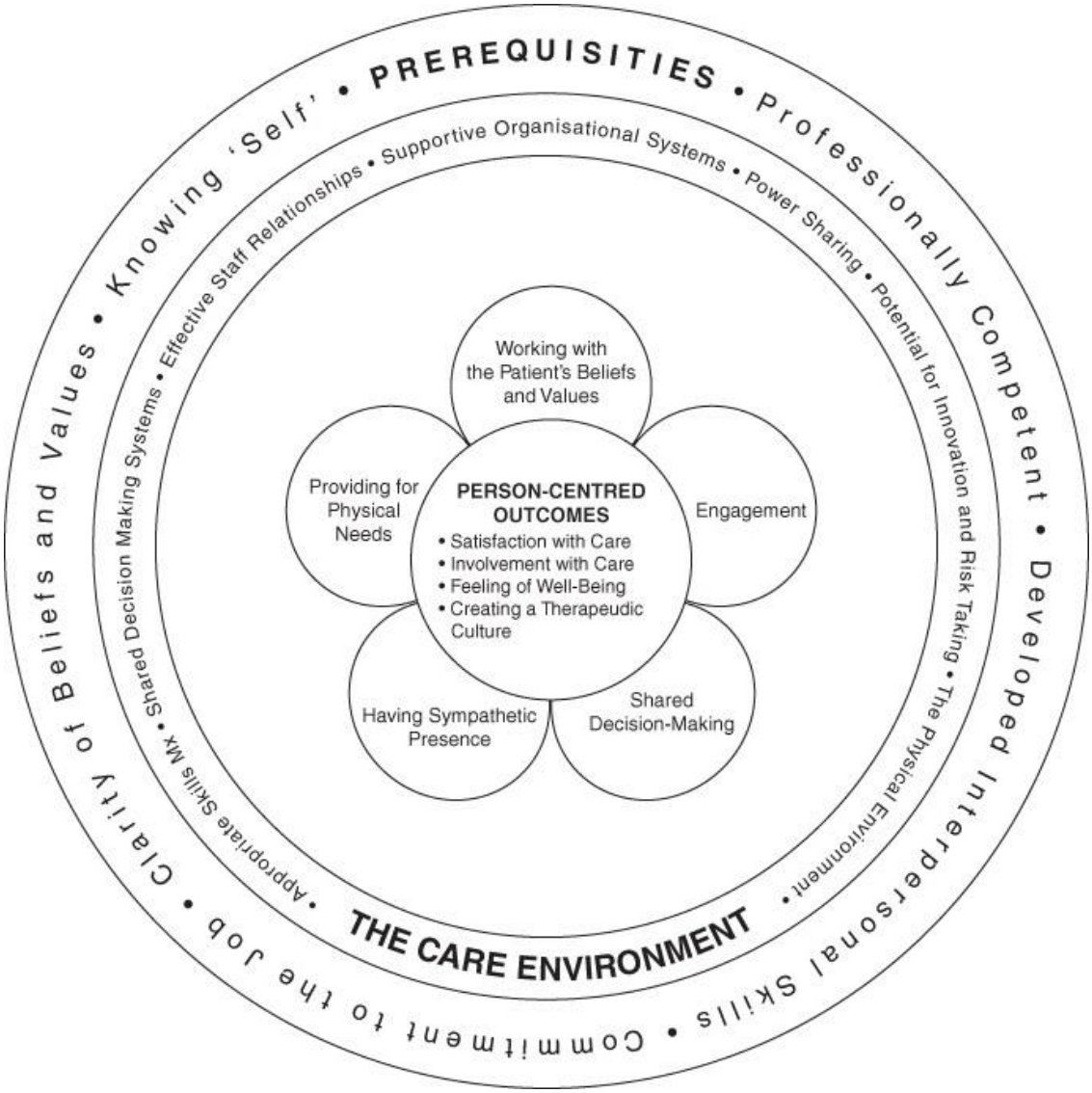

Figure 7.12 The PCN Framework (McCormack, 2003)

The OEC utilises both nursing staff and pharmacists to deliver the education. For the purpose of this chapter, the term PCN encompasses the role of the health professional delivering the OEC. The PCN framework was selected as an exemplar, practical outworking of person-centred care as it focusses on the 'person' rather than the 'patient'. People receiving an oral SACT have minimal and reduced contact with health professionals and clinical services but wish to be regarded as individuals; hence the need to focus on the person, rather than the patient. The model also includes key characteristics of self-management (Barlow *et al.*, 2002; Bos-Touwen *et al.*, 2015).

The first of the four constructs in the PCN framework are prerequisites that focus on the attributes of the health professional: professional competence; development of interpersonal skills; commitment to the job; being able to demonstrate clarity of personal beliefs and values; and having

knowledge of self. This construct focuses on the ability of the health professional to make decisions about needs and prioritise care, and in the context of oral SACT refers to knowledge about oral SACT and the enablement of self-management regarding escalation of treatment-related toxicity. It also requires the health professional to have developed advanced interpersonal skills to communicate at various levels to conduct a holistic assessment and deliver individually tailored education. Further, as this study has identified, support for the patient following oral SACT education was desirable from multiple patient participants and regarded as a positive intervention from health professional participants. Therefore professional competence is also required in the health professionals ability to identify not only what patients might require enhanced ongoing support but also the level of that support. Commitment to the job implies a dedication and genuine desire for the health professional to provide and deliver high-quality care that is in the patient's best interests. The final two attributes are closely linked and refer to the health professional's ability to understand the importance of knowing their own personal beliefs and views and how these can have an impact on decisions made by the patient with whom they are interacting. Findings from this study demonstrated the majority of patients wanted health professionals to have high-level communication skills and the knowledge to address any questions or concerns raised by the patient. Health professionals in this study recommended that the OEC facilitator should be someone with advanced communication skills and a working knowledge of oral SACT, not only of the treatment itself, but also the impact on daily life of the person receiving this treatment.

The care environment addresses the context within which care is delivered: appropriate skill mix; systems facilitating shared care; effective staff relationships; supportive organisational systems; power sharing; potential for innovation and risk taking; and the physical environment. While most patient participants were satisfied with the OEC, several talked about how disorganised the OEC was and for health professional participants, the telephone appointment was not always the most appropriate way to deliver education about oral SACT. Within the health professional interviews some reference was made to the efficiency of the OEC, with one facilitator perceiving improvements required. No reference was made by any participants to governance of the OEC or systems and processes which review the quality of the service. Another health professional participant reflected on the potential of replicating the OEC at other local district general hospitals to minimise the burden of attendance for patients, but also increase the opportunity for care closer to home. The staff involved within the OEC therefore had ideas for innovation demonstrating a commitment to their role as a facilitator, but also the potential for innovation – a process by which to explore health professional views on innovation however was not explored in depth during interviews.

Person-centred processes, the third construct within the PCN framework has five attributes that align with models of self-management (Barlow *et al.*, 2002; Bos-Touwen *et al.*, 2015): working with the patient's beliefs and values; engagement; shared decision-making; having sympathetic presence; and providing for physical needs. Working with the patient's beliefs and values encourages the health professional to assess and identify what is of value to the patient and their understanding of the current situation. A key finding within this study has been the identification of patient beliefs about oral SACT, and how this can inform subsequent management of their treatment. By conducting an assessment and considering an individual's belief about oral SACT, such as why oral SACT was considered to be less burdensome than IV SACT, might help in planning care for safe self-management. If an individual placed value on time spent with family and being able to holiday, this might direct the health professional to focus on aspects of education regarding managing repeat prescriptions, or travelling with an oral SACT, resulting in education delivered being tailored to that individual's needs. A further example could be how one patient participant their relationship with their spouse and aspects of sexuality were not explored during their cancer treatments – true engagement and holistic assessment could have identified that this key relationship within the patient's life was of vital importance. Providing an opportunity for discussion or ongoing support might have enhanced their treatment experience for not only the patient, but also their spouse.

Engagement, a further attribute of the person-centred process, reflects the quality of the relationship between the healthcare provider and the patient. This study highlights the perceived importance of the patient-professional relationship. Attending appointments with a variety of health professionals results in a lack of continuity that prevented the development of a therapeutic relationship, where the health professional demonstrates attentiveness by being present. A challenge specifically for the OEC however is the stand-alone appointment. Both health professional and patient participants reflected on the desire for follow-up support, yet at present this was not available. By exploring a means to appropriately tailor ongoing support would be an opportunity to further develop relationship, a key desire of patient participants.

The fourth and final construct of the PCN framework refers to person-centred outcomes. Attributes of this include satisfaction with care, involvement with care, feelings of well-being and creating a therapeutic culture. These outcome measures provide appropriate and valid means to evaluating the OEC if it were to pursue a model of care with increased focus on person-centredness in the future.

Overall, while person-centred care has been purported as having the potential to transform patient care and clinical practice, for the approach to be successful it requires a power shift and mind-set to

change allowing the space, time and opportunity to focus on the patient narrative and partnership (Moore *et al.*, 2017).

8.3 Implications for practice: optimising patient care

In order to optimise the care of patients receiving an oral SACT, quality in healthcare delivery and experience must be considered (Sitzia and Wood, 1998). Following the publication of Lord Darzi's report, *High Quality Care for all* (Darzi, 2008) and the Francis Inquiry into failings at Mid Staffordshire NHS Foundation Trust (Francis, 2013) the importance of involvement of individuals and their families in their care has been highlighted. Failings in care often focused on a lack of identification of patient desires and decisions about care being made without involvement from the patient and/or their families and carers. The appropriate implementation of person-centred care is viewed as a means to prevent and limit failings in care, and highlight strategies to identify patient desires, wishes and preferences, and provide a means to measure quality of care.

Quality care was originally a craft-based approach, where quality would be measured by evaluation of the health professional (Boaden *et al.*, 2008). It is now widely accepted that measurement of patient experience is the key to ascertaining the quality of healthcare provision. In 2011, the NHS National Quality Board (2011) published the NHS Patient Experience Framework agreeing on a definition of patient experience to help guide its measurement. The framework highlighted eight areas for consideration: respect for patient-centred values, preferences and expressed needs; coordination and integration of care; information, communication and education; physical comfort; emotional support; welcoming the involvement of family and friends; transition and continuity; and access to care. Notably, respect for patient-centred value is a key characteristic; thus one method of evaluating the quality of care delivered is to use a person-centred care framework.

Kornhaber *et al.* (2016) proposed a conceptual relationship between therapeutic listening, patient-centredness and responding to patient emotions and unmet needs. They argued that this was a key requirement required from health professionals. Relational care has also been reported to be associated with improved patient satisfaction, adherence, quality of life, mental health and a decreased cost to healthcare (Step *et al.*, 2009; Shay *et al.*, 2012; Kelley *et al.*, 2014). The importance of relational care (as a vehicle to develop an effective therapeutic relationship) was evident throughout participant interviews, with words like trust, consistency, continuity and familiarity being referred to.

8.3.1 The Oral Education Clinic (OEC) as a model of care

One key driver for this study has been to explore both the patient experience of participation in the OEC but also the perspectives of health professionals involved in managing the care of patients receiving an oral SACT. While the OEC was well regarded by and in some respects, viewed as a progressive and innovative approach to healthcare, areas for improvement were identified. Patient participants in this study recognised the need to learn about their new medication, how to safely manage the medication at home, how to take the treatment as prescribed, what they might expect to feel and how they might manage potential side effects, yet a common tension was voiced. The process for receiving a significant amount of important information was often aligned with frustration and associated with increased stress, particularly where education was being delivered on side effects and often in a scripted, fast-paced fashion. Health professionals equally recognised the volume of information required was significant, but felt this was essential for safe treatment. To counter this, health professionals reported welcoming and including families and support systems in receiving the education, yet within this study sample, several participants attended the OEC alone. A tension therefore exists between the need for health professionals to deliver sufficient education to ensure safe, autonomous administration of oral SACT at home, yet for individuals receiving this information, the information is too much to assimilate in full, and often lacked a personal touch – serious consideration should therefore be given to implementing a strategy of follow-up contact and a means to deliver education in a paced manner ensuring optimum assimilation.

Moving forward, as the findings of the study clearly suggest, the OEC needs to identify a process where essential information can be delivered and assimilated in a format that addresses an individual's needs and concerns. Truccolo *et al.* (2015) commented that there is a shift from unidirectional, medical-centred patient education to a bidirectional patient-centred education style, where the proactive involvement of the patient is encouraged. Considering the OEC as a model of care critiqued alongside the PCN Framework and the findings from this study, I suggest that the following six processes might better meet the needs of patients attending this clinic:

1. Standardised system for staff training and support. During health professional interviews, few participants described any training specific to delivering patient education, rather referring to competence and knowledge or oral SACT itself. McCormack and McCance (2010) detail within the 'prerequisites' domain that health professionals require high quality interpersonal skills coupled with a grounded understanding of their personal beliefs and value system to facilitate person-centred care. Practically for health professionals working within a clinical setting, this could translate to completion of the 'advanced communication skills' training course, open to all NHS staff and

facilitated at local levels for health professionals involved with facilitating complex conversations. Health professionals facilitating complex patient education should all therefore have completed, or be trained in advanced communication skills. Secondly, the domain also refers to knowledge of self and the health professional's own belief and values system – grounded knowledge of this is best achieved through clinical supervision, where individuals' are supported to review their practices, feelings and through clinical supervision journey through their own internal belief constructs and how this impacts upon their clinical practice. Clinical supervision is regarded as a means to enhance experiential learning, skills competence and therapeutic relationship qualities (Nellaney *et al*., 2013). The study site should therefore consider the inclusion of advanced communication skills training and a regular program of clinical supervision for all staff delivering patient education.

2. Development of an oral SACT governance group. Considering the PCN Framework regarding the 'care environment', the development of a working group within the hospital structure to meet regularly and review the function of the OEC would assist with reviewing ongoing issues of quality such as process review to ensure supportive systems and power sharing. Members of an oral SACT governance group should include medical prescribers, nursing and pharmacy staff who deliver education and patient representatives who can offer authentic engagement and involvement.

3. Providing written information prior to attendance at the OEC. It was common in patient interviews for individuals to report a sense of the unknown, unclear on what to expect from attendance at the OEC, accounting for some individuals attending alone, when on reflection being accompanied would have potentially aided knowledge retention. Written information provided prior to the OEC should detail the following: what to expect from the OEC, the purpose of the OEC, recommendation to bring a third party or have them listen in on the telephone if appropriate, a description of potential side effects, and associated medical information about their oral SACT. Providing this level of information might help patients envisage taking an oral SACT in the context of their own lives. It might also be helpful to include a series of health professional designed 'frequently asked questions' to help stimulate patients to consider what they might want to ask when given the opportunity.

4. Assessing the patient's beliefs about oral SACT before the delivery of information about the oral SACT. A view was held among health professionals interviewed that patient beliefs about their oral SACT might impact on their adherence behaviour or reporting of treatment toxicity. Once attending the OEC, it would be beneficial for the nurse or pharmacist to conduct a narrative assessment and discuss their beliefs about their oral SACT. In doing so, the health professional would also have the opportunity to be able to assess the patient's current level of understanding, address any negative

concerns they had, consider their social and family situation and ultimately appropriateness and safety of commencing an oral SACT.

5. Assess understanding before the end of the OEC appointment. The checklist used by OEC facilitators to ensure all essential aspects of education have been covered was criticised by some patients, as their education felt scripted and lacked compassion. While checklists serve as an aid memoire for some health professionals, it can hinder the development of a therapeutic relationship. By using a form of assessment at the end of the OEC session, such as implementing the SIMS measure, the health professional can confirm that all essential areas of education delivery have been covered as perceived by the patient, and it also gives the individual receiving the education opportunity to ask questions which might have arisen.

6. Assess the need for telephone follow-up (TFU) and implement if required. Telephone follow-up was viewed as non-essential for some, but required for others. Several patients gave examples where if they did not have the support of their family, they would require a TFU call. It was suggested that individuals who lived alone or did not have the support of an actively involved family should have additional follow up by telephone. Similarly, concerns were addressed for older patients who are frail. Further, a sub-group of patients were identified as requiring assistance to activate to self-manage. By discussing the place of TFU, after the delivery of tailored, person-centred education, the patient could identify, areas of confusion or apprehension still remaining and decide whether TFU would be required. Based on findings reported herein, the timing of a telephone follow-up call is best placed at day seven. The telephone follow-up call could provide an opportunity to assess for treatment related toxicity and address any deficits in knowledge.

Through implementing these steps, it is argued that care of patients receiving oral SACT will be optimised. Figure 7.12 is an updated illustration of the patient pathway (Figure 1.1 referred to in Chapter 1, P. 32), with recommendations found in red text boxes.

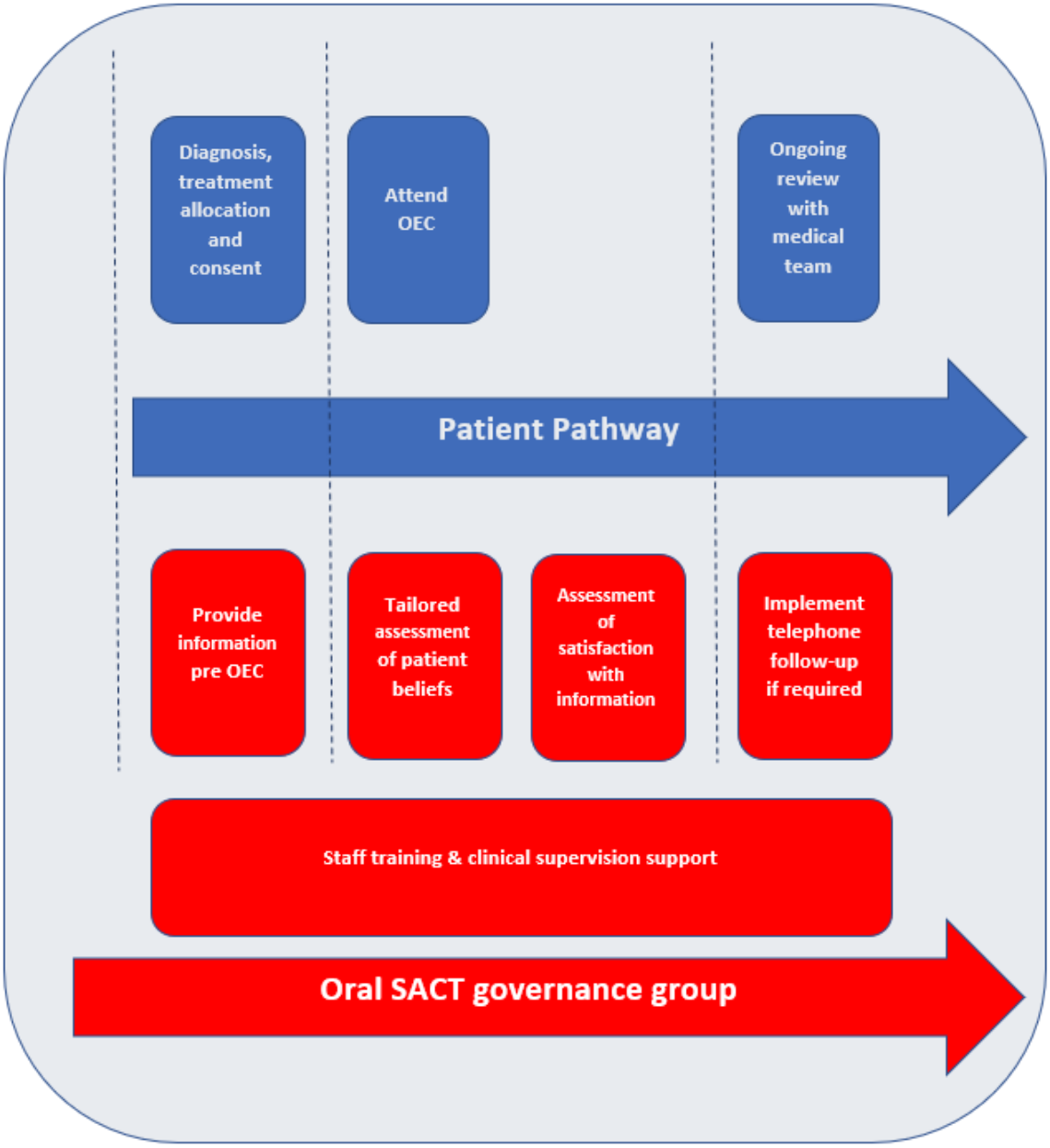

Figure 7.13 Recommendations to optimise patient experience before, during and after the OEC visit

8.3.2 Recommendations for future research

Findings from this study have indicated that the priority for the future development of safe, high quality care for patients receiving an oral SACT should focus on the delivery of person-centred care. Use of a person-centred approach would arguably enable care to be tailored toward the individual, and if administered correctly should result in a person-centred outcome, as defined by McCormack and McCance (2010):

- Satisfaction with care
- Involvement with care
- Feelings of well-being
- Creating a therapeutic culture

With person-centred care as a priority, the emphasis for future research moves away from the need to identify a gold-standard model of care, but rather identifying high quality delivery of person-centred processes within the context of oral SACT provision.

This study has also identified that individuals receiving an oral SACT require different levels of support to safely manage their own care. The typology of activation to self-manage highlighted that patients sit on a spectrum of ability and recent research has identified a link between an individual's ability to self-manage their care and treatment outcomes (Salgado *et al.*, 2017). Future research should therefore investigate the patient experience of self-management with an oral SACT to further inform the delivery of future healthcare services.

8.4 Strengths and limitations of this study

A key strength of this study was to use a mixed methods approach. The questionnaires included several validated measures, SIMS, MMAS-8 and BMQ, to compare outcomes with other published studies, and qualitative interviews enabled exploring perceptions and experiences in greater depth than has been previously reported, such as factors that influence adherence to treatment.

The response rate to this study was 24% - which is low for a questionnaire study and limited the ability to use inferential statistics. The low response rate also impacts the potential for non-response bias where views of various sub-groups might not be represented. While strategies were put in place to promote participation within the study, the response rate remained low. It was felt that inviting participants to participate in the study when they attended the OEC might promote engagement in the study however in hindsight timing of the invitation might not have been ideal as patients received the study information together with written information about their oral SACT. The OEC appointment was often referred to as a stressful process and several participants described information overload. During interview, some patient participants reflected on a reluctance to examine the written information provided after their OEC visit, so some potential participants might have been lost to recruitment due to this. The study was also longitudinal in nature, involving completion of a second questionnaire and the option for a subsequent interview, so the response rate might have also been reduced due to the perceived burden of being in the study. A further

limitation is that the study was conducted at a single study site limiting the generalizability of the findings.

The decision was made to sample all participants receiving care through the OEC, rather than those of one cancer type only. The focus of enquiry was on the experience of education and involvement with the oral education while taking an oral SACT, rather than on the experience of a single cancer type. In some respects, this is a strength of the study in that the views of patients with a variety of cancer diagnoses have been represented. However, it has limited the ability to conduct subgroup analyses.

There was a lack of diversity in the patient participants. All patient respondents were white. Findings from the national cancer patient experience survey repeatedly demonstrate that patient experience of cancer care is lower in individuals from black and minority ethnic populations (Quality Health, 2017), but also lower in those from areas of deprivation. The questionnaire did not include an item to assess economic deprivation, although the study sample was highly educated and thus likely not representative of economically deprived populations. Within the sample however there was a sufficient balance of gender and a range of ages.

Finally, with regard to questionnaire design, few questions were asked about holistic aspects of care or patients perceived abilities to self-manage. Some questions within the SIMS tool and across student additional designed questions referred to holistic aspects of care such as sexuality, but no section within the questionnaire directly enquired about the wider impact of oral SACT on an individual's life. In retrospect and following analysis of data, it would have been helpful to include a measure of self-management.

8.4.1 Reflections on rigour

Where quantitative data is concerned, issues of rigour are focussed on validity, reliability, replicability and generalizability (Bryman et al., 2008). On the other hand, rigour is challenged within qualitative data by considering credibility, transferability, dependability and confirmability (Lincoln and Guba, 1985). Addressing rigour in a mixed methods study presents an added layer of complexity as both types of data are used with overall findings often identified *following* integration of the respective data sets. The question of validity within mixed methods study is still subject to debate (Onwuegbuzie and Johnson, 2006) however the Good Reporting of a Mixed Methods Study (GRAMMS) guidelines (O'Caithan et al., 2008, P. 97) have been used to assess the quality of mixed methods studies following publication (Brown et al., 2015). To consider the rigour of this present study, the GRAMMS guidelines were used to consider the quality and transparency of reported

methods and findings. Each of the six guidelines will be considered individually (O'Caithan et al., 2008, P. 97):

1) *Describe the justification for using a mixed methods approach to the research question.*

This study has aimed to explore the experiences of patients receiving oral SACT and the views of key health professionals to inform models of care. As part of this exploration, a patient's experience of receiving healthcare through the OEC investigated. Where 'experience' is concerned, qualitative research was best placed to investigate in depth an individual's feelings and perspectives regarding their own experience. However, considering a specific model of care, in this case the OEC, use of survey was best placed to sample a wider range of individuals and ask questions of their experience. Use of survey ensured that specific questions about the OEC were addressed by a larger sample of participants, whilst use of interview enabled me to explore in more detail their experience of oral SACT in general, not solely their experiences participating in the OEC. Justification for using mixed methods was reported in this thesis in Section 3.2.1. P. 89.

2) *Describe the design in terms of the purpose, priority and sequence of methods.*

The purpose of this study has been clearly defined with the use of an appropriate research aim, and 5 specific research questions. Due to a small response rate to the questionnaire aspect of this study, equal weight and priority was given to all sets of data. Health professional interview data was included in this study as the OEC was a key aspect of investigation, thus the experience of both the facilitator was required as well as the patient experience to inform a holistic view of the service. The sequence of methods was reported in Section 3.3.1. P. 92. Due to ethics requirements, health professional interview data was collected in the first instance to allow overall data collection to commence whilst allowing further time to design a survey.

3) *Describe each method in terms of sampling, data collection and analysis.*

The methods used within this study have reported in detail in chapter 3. For qualitative data, Thematic Analysis using Framework (Ritchie and Spencer, 1994) was used to analyse both health professional and interview data. This method of analysis was chosen as it is widely used within health services research and members of the supervisory team had practical experience in using this method. Descriptive statistics were used to analyse quantitative data; due to a low response rate and subsequent small sample, use of inferential statistics was limited but explored where appropriate.

4) *Describe where integration has occurred, how it has occurred and who has participated in it.*

Data integration was achieved through using a method reported by Moran-Ellis *et al.* (2006) as 'Following a Thread'. A series of threads were developed based on the research questions and used to map all data sets respectively. A detailed explanation on how this occurred was reported in Section 3.4.3 P. 96. Data integration was conducted initially by myself, but reviewed by my supervisory team with iterative changes made following discussion and debate.

5) *Describe any limitation of one method associated with the presence of the other method.*

A primary advantage of using a mixed method design is using different types of data to off-set respective limitations. For example, in this study one limitation of questionnaire data, due to sample size and question design, was the ability to identify explanations through the use of inferential statistics – use of qualitative data enabled me to explore potential explanations in an individual capacity. Practically, adherence was found to be high in this study through the use of the MMAS-8 scale, but exploration in patient interviews identified that adherence was high because of an individual's view of their oral SACT. A limitation of quantitative data was that the explanation for high adherence could not be directly identified, but through the use of interview, this could be explored further.

Overall limitations of this study have been presented in the previous section.

6) *Describe any insights gained with mixing or integrating methods.*

Several insights were gained through the process of data integration, one such example having been presented in the previous paragraph with regards to explanation for high adherence. A further example of this is in regard to an individual's belief about their medicine. In questionnaire 1 the BMQ was used and identified that respondents had strong beliefs in both the necessity and concern of taking their oral SACT. However, through the use of interview, I identified that strong beliefs regarding oral SACT were in place because of the threat of cancer and associated mortality with several participants referring to their medication as important for their health, and in some instances, referring to the drug as something that was keeping them alive. Without the use of a mixed methods design, this finding could have been suggested, but it would have been without evidence.

Overall, I believe that the reporting in this study has been transparent and considering the guiding research questions, the correct methods have been chosen. Following consideration of the GRAMMS guidelines, I find this study to be reliable and have the acceptable rigour required for a small, mixed methods study.

8.5 Reflexivity and lessons learned

All research, either qualitative or quantitative is subject to research bias, whereby the researcher, or research team may approach their enquiry with preconceived ideas, experiences and/or opinions. Malterud (2001) comments:

> *"A researcher's background and position will affect what they choose to investigate, the angle of investigation, the methods judged most adequate for this purpose, the findings considered most appropriate, and the framing and communication of conclusion"* (Malterud, 2001, P. 483)

Reflexivity is, therefore, viewed as an ongoing process of self-awareness where the researcher repeatedly reflects on and questions their interpretation of findings and potential for bias. I am a registered nurse by background, with over 10 years' experience in various cancer nursing settings, so it was vital that I exercised reflection and reflexivity to address or at least be transparent about any preconceptions I brought to this study. Below I explain how I achieved reflexivity, with reference to my research journal.

Since the vast majority of my professional experience as a qualified nurse has been in a cancer setting, I have become very familiar with the challenges people with cancer face on a day-to-day basis. I have an in-depth understanding of not only the pathophysiology of cancer and pharmacology of its treatments, but also the impact of cancer treatments on an individual's life. I approached this PhD study very much as a nurse, with a grounded, working understanding of what I perceived to be required for effective and safe cancer nursing practice. While working on a cancer ward and before undertaking this PhD, I gained further experience of cancer, this time of a personal nature as my sister received a diagnosis of breast cancer at 43 years old. Through discussions with my sister, I was personally reminded about the importance of patient experience and the impact high quality care can have:

> *"I was talking to my sister just last night about my potential plans for the PhD and how I had an interest in potentially undertaking some qualitative interviews […] She reminded me how she looked forward to having her radiotherapy, because the radiographer would always greet her with a smile, and that health professionals should never underestimate the impact of a smile on a patient's day"* – May 2015, Michael Mawhinney.

While a survey would traditionally be used to investigate patients' experiences of a service, this discussion with my sister highlighted the importance of gaining an in-depth understanding of the patient experience, best understood through interview and discussion, and ultimately led me to undertake a mixed-methods study.

One of the strengths of this study has been, in my opinion, my supervisory team. While I come from a nursing background, I have one other supervisor with decades of experience in cancer nursing, from clinical practice, research and higher education. I have a professor who researches supportive care needs of people with cancer, and finally a third supervisor who has practised in a variety of clinical settings, who has expertise in reflective practice. It has been a strength to have a professor who, whilst familiar with the role of the nurse, can challenge data from a non-nursing perspective. A practical example, of how experienced researchers can support a novice researcher or PhD student can be found in the following excerpt where I reflected on feedback received when first approaching an area of quantitative analysis:

> *"I received very valuable feedback today through an email and was reminded to "put on my clinical hat" when considering my findings, and not just look at the statistics […] a small number of patients (<10%) reported low levels of confidence in the questionnaire – the 'researcher' in me viewed this as a low proportion and I had not interrogated this data any further, but feedback from a supervisor highlighted, that <10% inferred more than 1 person, and in this case, if more than 1 person had low levels of confidence in managing a cytotoxic drug, this was a significant finding"* June 2018, Michael Mawhinney

This excerpt clearly demonstrates the effective working of a research 'team', but also the value in sharing and discussing findings with researchers who are experienced within their own fields. I think perhaps without the years of experience that I was supported by within my team, I might not have come to the same depths of understanding.

One of the most challenging areas for me as a researcher during this PhD has been in developing a deep understanding of the philosophical stance of knowledge and truth. By background, as part of my MSc at University College London, I had completed modules in advanced medical statistics and epidemiology, having a grounded and working understanding of inferential statistics. I had approached this data and theory, and subsequently interpreted the reporting of statistics as truth demonstrated through statistical significance and appropriate analysis. I found it easy to apply these findings to practise e.g. a large data set demonstrating an effect of an intervention, and thus it is better to apply the new intervention rather than the current standard of care. Analysing qualitative data, however, was a new challenge for me and I was very thankful to my supervisory team who helped guide me through this complex and iterative process.

I recognised that it was rare, or certainly difficult to quantify narrative findings or qualitative data, but equally recognised the importance of qualitative data to define and further explore perceptions and experiences, to inform the development of health policy and future quality improvement

initiatives. I have used a pragmatic approach, which was driven by the research question and applied a variety of research methods to achieve the aim of the study. This pragmatic stance, has largely been guided by a professional, nursing view of the world, where the nurse is constantly seeking immediate resolution, to the problem in hand, and the use of any means to achieve such resolution in a timely, efficient manner.

Identifying the paradigm in which to place this study was not a straightforward process. I began this PhD with a strong personal rooting in positivism, where I believed in the significance of findings that could be tested, such as cause and effect, such as the findings from a large randomised controlled trial. This worldview, however, did not always sit well with my nursing background, as I recognised in my own practice I would not rely on 'numbers' alone to inform my assessment of a patient. For example, if I had a patient who reportedly felt unwell in the hospital setting, I would collect a set of clinical observations, this would provide me with numbers, which I could assess against the recognised normal parameter, which might indicate where the problem could be. However, I would not rely on this assessment alone, but where possible question the patient, such as, 'when did you start to feel unwell?' or 'have you experienced this feeling before?' In essence, this approach to nursing assessment uses pragmatic enquiry; data collection is guided by the problem.

Reflexivity in this study has been managed through monthly supervision meetings, detailed discussion of my data, and through my reflective journal. A strength in the use of qualitative data, was the iterative refinement of the findings. There were many times where I felt I had completed analysis, but on presentation of my interpretation to the supervisory team, I needed to conduct another iteration of data analysis to respond to their line of questioning. Reflecting back on my own preconceptions before commencing this study, I did not think the main findings would come back to person-centred care, but rather,

> "[…] *ultimately, I think it will come down to people needing to feel supported by having regular contact with a CNS, so the final recommendations will be something around the implementation of improving continued care or telephone follow-up*" November 2015, Michael Mawhinney

I can, therefore, conclude that the reported findings, discussion and recommendations, were not biased by my nursing background, but rather were enhanced from understanding of the importance of in-depth analysis of the patient experience.

Any potential ethical conflict that might have arisen from being a nurse conducting qualitative research interviews was mitigated from not being known to the patient participants from any

previous clinical context (my clinical work has always been from a different geographical location) and I did not disclose I was a qualified nurse.

I have also learned about the importance of research impact. Recommendations for practice and future research have already been discussed with key members involved in the care of patients receiving oral SACT at the study site. These recommendations will be considered in more detail and presented to a wider audience of health professionals at the study site in 2019. I have presented some of these findings at several national conferences. An abstract of the complete PhD findings will be submitted to an international cancer nursing conference in 2019. A publication reporting the findings from synthesis of data has been prepared, and in collaboration with all members of the research team will be submitted to a high impact journal in early 2019.

I also became an ambassador for the UK Oncology Nursing Society during this PhD, so plan to offer support to other UKONS members who seek advice about undertaking a PhD, through activity of the UKONS Research Members Interest Group. I have also recently been appointed as a committee member within the UKONS Living With and Beyond Cancer Members Interest Group where I will be able to further disseminate my research findings and influence future quality improvement initiatives across the UK.

I was also awarded a Winston Churchill Travel Fellowship in 2018 and have already travelled and will continue to travel in 2019 to America and Canada to investigate an international response to the implementation of models of care for oral SACT. As part of this travel exchange, my PhD findings will be presented to a variety of audiences including academics and clinicians across six states in America and in Ontario, Canada. I have also had the opportunity to meet with several internationally recognised researchers such as Professor Sandra Spoelstra to discuss not only my finings, but their most recent work and up-coming publications and findings. I am hugely thankful for this fellowship as it has opened doors which will lead to impact of this PhD study. I am currently assisting in developing a link between the American Oncology Nursing Society and the UK Oncology Nursing Society to aid the sharing of good practices. I will also be undertaking a piece of work with a senior manager in the Oncology Nursing Society to begin to develop an international position statement on best practices in the safe care of oral SACT provision. This piece of work would not be possible without both conducting this PhD, and through the award of the Winston Churchill Travel Fellowship.

8.6 Novel contribution

Through the use of mixed methods several novel contributions have been made with regards to the experience of people receiving an oral SACT and for health professionals providing and facilitating safe oral SACT management. Most importantly, this study has detailed patient perceptions of oral SACT. In the limited literature regarding patient experience, oral SACT is often referred to as a preferable option by health professionals and researchers. This study has provided the rationale as to ***why*** oral SACT is preferable; with convenience, freedom of movement and invocation of a sense of normality it is understandable why this treatment fairs favourably when compared to IV treatments.

While oral SACT was clearly a preferable option, it was not without elements of concern. Both health professional and patient participants expressed concern about unclear treatment durations, a finding not yet presented in any published literature regarding oral SACT. It appeared that goal setting was a key coping strategy for several individuals and the idea of an unknown timeline for treatment invoked stress and worry. Where oral SACT is concerned therefore health professionals should make every effort where a lack of clarity exists to be transparent and use evidence based medicine to offer ideas of how long treatments might last. Concerning this, it would be helpful also if patients were able to receive consistent information from medical staff rather than different health professionals, delivering different information. While many oral SACT are new regimens, and longevity of treatment difficult to determine for several, this study has identified that consistency of information and relational care are vital in the face of this unclear duration. Particular emphasis should be placed on consistency and follow-up contacts to ensure individualised patient support is provided.

As a cancer nurse by background, I approached this study with the idea of conducting an in-depth service evaluation of a model of care to inform future service delivery. Findings within this study however have challenged my perception on the use of 'models of care'. The gold standard for safe oral SACT provision is not identifying the best model of care, rather, it is to identify the most effective strategies to deliver person-centred care, tailoring healthcare interventions to an individual's needs and preferences whilst enabling and supporting activation to self-manage. This study has therefore identified that the goal of the future researcher should not be to identify the singular best model of care to support an individual receiving oral SACT, rather identify how best education and subsequent support can be tailored toward the individual. This focus has not been reported in the published literature.

Through the use of qualitative, patient interview data, this study identified a typology of activation to self-manage. I identified that within the interview sample, a sub-sample of individuals' were activated to self-manage, they were engaged in their treatment plans and informed about safe management. Others in the sample however required further support with heightened anxiety in comparison. Again, this finding adds to the argument that for safe oral SACT management, healthcare interventions should be tailored towards delivering person-centred care, identifying those that need support to self-manage. A focus of self-management, or indeed strategies to assess or identify self-management have not been reported in published literature regarding practices of oral SACT delivery.

The OEC facilitators included pharmacists and nursing staff. Whilst one might assume one of these health professionals might be perceived to be more appropriate to deliver patient education, it was clear from interview data with both patients and health professionals, that both professions were appropriate to deliver the education. Specifically from a patient perspective, the type of profession was irrelevant, rather their ability to communicate and develop a therapeutic relationship was of utmost importance. Trust played a significant role in patients feeling support and cared for.

Finally, this study is the first to identify that adherence to oral SACT is high because of the importance placed on the medication. Questionnaire data demonstrated higher levels of adherence than that reported in the published literature, but interview data enabled an exploration into why adherence was so high. Patient participants described detailed strategies of developing routines including the use of reminders to ensure they had taken their medication. On questioning, the reason for this was often explained because of the importance of the medication for their health. Oral SACT was viewed as a drug that would either prolong life, or cure their cancer, thus the importance of the medication was paramount and had a direct impact on their medicine taking behaviour.

8.7 Thesis summary

Through the use of a mixed methods design using survey and interview, this study has investigated the experience of patients receiving an oral SACT and the views of key health professionals involved in the management of care of this patient group. Thematic analysis using Framework (Ritchie and Spencer, 1994; Ritchie *et al.*, 2003) was used to analyse qualitative interview data and descriptive statistics were used to analyse survey data. Synthesis of data sets was achieved through using 'Following a thread' (Moran-Ellis *et al.*, 2006).

84 respondents with a variety of cancer diagnosis completed questionnaire 1 and 70 respondents completed and returned questionnaire 2. Analysis of survey data identified the OEC as an effective means to prepare people with cancer to commence oral SACT. Satisfaction of the OEC was high and similarly, high levels of confidence were reported in those commencing treatment. Adherence to treatment was found to be high within the sample, and this was often attributed to the strong beliefs held by the patients. Instances of non-adherence were all caused by a change in routine or forgetfulness with no unintentional non-adherence reported. The most common side effect experienced was fatigue, and similarly this side effect was the most common to require intervention.

28 semi-structured interviews with patients identified three thematic areas: a person's experience of cancer is challenging, and how they cope depends on the individual; patient perceptions and experiences of oral SACT; and models of care should be tailored towards the needs of the individual. Oral SACT was found to be a favourable form of treatment as it provided patients with the opportunity to aim for a normal life whilst receiving cancer treatment and enabled people to spend more time at home. The OEC was viewed by patient participants as an acceptable means to commence oral SACT and receive education, but it was commonly reported that education was not tailored toward an individual and that on occasion the health professionals encountered appeared stressed, busy and lacked compassion. As in survey data, adherence was found to be high with instances of non-adherence caused by forgetfulness or change in routine. Patient participants described a variety of coping strategies employed during treatment but recognised that everyone is individual and thus support needs would vary based on the individual. The experience of carers or family members was not investigated within this study, however patient reports indicate that whilst family members are welcomed in appointments, they are not directly offered support. A typology of activation to self-manage was identified. Some participants demonstrated an ability to self-manage through the use of coping strategies with high levels of confidence in managing oral SACT and an awareness of the right time to seek help and the right source from which to source help. Other participants demonstrated the need for additional support in managing their oral SACT and in identifying who to seek help from and at which point.

23 interviews with health professionals included nursing staff, medical staff and pharmacy staff. Similarly, the OEC was perceived by a range of health professionals to be an effective model of care. Participants described the need to provide tailored education and discussed the varying intellectual abilities of patients and desire for different levels and type of information. Some participants identified types of patients they deemed to be at higher risk of treatment with oral SACT including those receiving capecitabine, older adults and those living alone. The GP was seen as having a significant role by many in the primary care setting, but not in the management of oral SACT itself.

Synthesis of data, guided by each research question associated with the study enabled the research student to address in detail the aim of this PhD. Findings were found to be complementary and highlighted the need for an enhanced person-centred approach to care provision.

8.8 Conclusion

As the availability of oral SACT will increase it is imperative healthcare providers embed safe practices to support people receiving these medications. This study has described the patient experience of receiving an oral SACT who received education delivered in person or by phone through the OEC and explored the perspective of health professionals involved in the care of this patient group. Future initiatives and healthcare services should seek to train health professionals to deliver relational, person-centred care, as implementation of such processes would identify individual patient preferences and needs, identify individuals requiring support to self-manage, enhance therapeutic relationships, patient experience, and the quality of care provided.

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Appendices

Appendix 1 – Standard Operating Procedure of the OEC

Identifiable information redacted. MMawhinney 03/06/18

[redacted]

Standard Operating Procedure for Education Sessions for Patients Starting on cycle 1 day 1 Oral Anti-Cancer Agents.

This is for oral anti-cancer agents for cancer malignancy only.

1. **Before 1st Cycle of Oral Anti-Cancer Agent**

1.1. Clinician consents patient and gives patient a copy of the drug information sheet and the consent form.

1.2. Clinician completes Oral Chemotherapy Referral Form. Clinician places the referral form in DTU referrals box. Patient will be invited to attend new patient education session or offered a telephone consultation (if appropriate).

1.3. Clinician prescribes treatment for approximately 1 week before required start date.

1.4. Chemo coordinator collects referral forms daily and records on ARIA notes that referral form has been received.

1.5. When screening prescriptions for cycle 1 of an oral agent pharmacists will print the referral form and give to chemo co-ordinator if there is no note on ARIA to state 'referral form received by chemo admin'.

1.6. Chemo coordinator schedules patient to the next available slot.

1.7. Chemo co-ordinator checks that treatment is prescribed on Aria and adjusts the start date so cycle 1, day 1 matches the oral education clinic date. Pharmacy and clinic trained nurses informed by email.

1.8. Chemo co-ordinator is responsible for contacting patient via telephone and by sending an appointment letter which will also include blood request card and appointment card: Advise the patient to report to reception desk of OPD on arrival.

1.9. Chemo co-ordinator asks patient to have blood taken 2 days prior to education session.

1.10. Chemo coordinator arranges relevant OPA prior to cycle 2.

1

[redacted]

2. Prior to Attendance at Oral Education Clinic

2.1. Chemo co-ordinator to check on Aria that the prescription has been screened.

2.2. Chemo co-ordinator arranges for patient's medical notes to be available on the day of clinic & attaches outpatient appointment card, patient addressographs and outcome form.

2.3. Pharmacist allocated to clinic prepares MRC's for all patients due in clinic.

2.4. Practitioner arranges collection of the patient's medication from the pharmacy dispensary.

2.5. Practitioner to check on Aria Referral Form and medical notes that patient is fit to proceed and undertake any additional checks required.

2.6. Practitioner to check that patient has signed consent for treatment.

2.7. Practitioner collects together the following information for each patient. (Documents available on Cancer Intranet: **Document Library>oral chemotherapy**).

2.7.1. Oral Medication Record Chart – to be completed for individual patient.

2.7.2. Drug specific side effect chart pack produced by the manufacturer (if available)

2.7.3. Macmillan patient information sheet for specific drug

2.7.4. Oral Treatment pack – available in clinic/Dr's office containing:

- Oral Education Session checklist
- Oral Anti-Cancer Agent Information Leaflet for patients
- Alert Card
- Treatment record book
- Mouthcare Information Sheet
- GP Advice Sheet on Chemotherapy & Immunization
- Parking permit valid for 3 months
- Maggies & Macmillan leaflets

[redacted]

2.8. Practitioner to check the most recent blood results and calculate creatinine clearance (using Wright equation). Compare to recent results and ensure within protocol limits. Baseline bloods to be rechecked if older than 7 days.

3. **On Attendance at Oral Education Clinic**

3.1. Receptionist checks patient in and asks them to wait in Area B in waiting room.

3.2. Practitioner collects patient and takes them to interview or clinic room.

3.3. Answer any questions from patient or relatives/friends.

3.4. Practitioner informs patient of the purpose of the appointment and educates on the following information using checklist and gathered paperwork:

3.4.1. Content of treatment record book, including reporting toxicities, triage assessment tool and 24 hour telephone number.

3.4.2. Side effects of oral anti-cancer drug.

3.4.3. Counsel patient on oral anti-cancer drug administration and use of supportive care, using medication record card and medications as an aid.

3.4.4. Advise about safe storage of medication and return of unwanted medication.

3.5. Ensure patient has blood card to have blood test at GP 2 days prior to next outpatient review.

3.6. Explain purpose of their next clinic appointment with the clinician for review of treatment tolerance and prescription of next cycle of treatment.

3.7. Practitioner to document consultation in medical and ARIA notes (use oral education session template), and file checklist in notes.

3.8. Practitioner to counter-sign the consent form & file in medical notes.

3.9. Record on Aria in drug administration section that treatment has been given to patient.

3.10. At the end of the education session, practitioner hands completed outcome forms to Reception immediately. Receptionists will check patient out and code the oral anti-cancer agent accordingly (see figure 1 below).

[redacted]

Figure 1: How to complete outcome form

Section C: (tick) GIVEN ORAL CHEMO OR PROCEDURE TODAY: COMPLETE BOX OVERLEAF Section D: (endorse) confirm patient has appointment booked for X weeks time Back of form: (tick) corresponding drug and write number of cycles supplied

3.11. Practitioner returns the medical notes to DTU Admin office.

3.12. Practitioner to double check that next OP with consultant has been made prior to patients receiving cycle 2 (see above)

[redacted]
25/02/2013
Updated by [redacted]
Updated by [redacted]
[redacted]
Updated by [redacted]

4

Patient Name:

Hospital Number: [redacted]

Oral Education Session - CHECKLIST

Date of Education Session:

Check ARIA Referral form and medical notes for conditions of 'fitness to proceed'.	
Check & document blood results – *Routine biochemistry and FBC*	
Check consent, co-morbidities, current medication for interactions & allergies	
Collect medication from pharmacy – *check doses against ARIA prescription*	
Complete Oral Medication Record Card	
Collect / Prepare patient pack to contain – *Treatment Record Book*	
Car Parking Permit	
Vaccination Information Sheet	
Mouth Care Sheet	
Oral Chemotherapy Information Sheet	
Oral Chemotherapy Alert Card	
Print Macmillan Patient Information Sheets for specific drug	
Collect Company information pack/information booklet(if available)	
Discuss oral treatment – *can be as toxic as intravenous chemotherapy, advise about safe storage and destruction of medication*	
Give and explain medication & medication record card – *include strengths/size, with/without food, what to do if miss dose or vomit after taking, duration of treatment*	
Information about side effects appropriate to medication and how to manage them – *include traffic light system and treatment record book, driving, alcohol, dentist, immunisations. Take and record blood pressure if appropriate to drug*	
Discuss drug interactions – *to inform GP or community pharmacist if starting new drug incl. OTC*	
Discuss when to seek help / stop drugs, including Triage number	
Check patient has blood card for next outpatient appointment (2 days before next cycle)	
Record / sign administration on ARIA in Drug Admin - *may require date change*	
Write note on ARIA and in medical notes	
Countersign consent form to indicate that patient still consents to treatment	
Complete Outcome form and hand to Outpatient Reception Desk	
File this checklist in medical notes	

Additional Notes:

Signature: Date:

Generic Oral Educational Session Checklist V3.0 July 2014 [redacted]

Appendix 2 – Questionnaire 1

Questionnaire 1 v 1.8 11.07.2016
REC number: 16/NW/0586 IRAS: 204177

Unique study ID	

[redacted]

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Optimising the care of patients receiving oral anti-cancer treatments
Questionnaire 1

Thank you for agreeing to participate in this study. In your information pack you will also find a participant information sheet detailing why this study is running and what it involves, along with a reply paid envelope to return this completed questionnaire.

You have been asked to complete this questionnaire because you have been prescribed an oral anti-cancer medicine (tablets). We are interested in your views about the information you have received and your experience of taking this medication.
We ask for your contact details on the last page of the questionnaire – this will be detached upon receipt and stored separately, so that your answers are kept with your name removed. We require this personal information in order to send you a second questionnaire in 6 weeks' time.
The questionnaire is in several sections:

Section A: About your cancer
Section B: About your appointment
Section C: About the information you received
Section D: Your beliefs about your oral anti-cancer medicine
Section E: About you
Section F: About anything we missed
Section G: About contacting you

If you require any assistance, require the questionnaire in larger print, or would like further information, please contact Michael Mawhinney on tel: 01865 482697 or email: 14110227@brookes.ac.uk

Thank you very much for your help

1

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Section A: About your cancer

This section of the questionnaire asks about your diagnosis, treatments so far (if any) and some general questions about your past medical history.
If there is anything you do not wish to disclose, please just leave the question blank and continue to the next question.

Please indicate your response by placing a ✓ in the appropriate box.

A1	Do you know what type of cancer you have?	☐	Yes
		☐	No
A2	If you answered yes, please can you write it in the space provided? If no, please go to A3.		
A3	When were you diagnosed?	Month/Year ____/____	
A4	When you discussed your treatment with the doctor, were you offered more than one treatment option? (Some types of cancer might have more than one treatment option, but not all.)	☐	Yes
		☐	No
A5	Were you given an option for which type of treatment to have? Please write which treatment you chose in A6 or continue to question A7.	☐	IV (drip)
		☐	Oral (tablet)
A6	Please write the main reason for choosing this treatment.		
A7	If you know the name of your oral anti-cancer medicine(s) please write it here.		
A8	Have you had any medicine to treat your cancer before?	☐	Yes
		☐	No (please go to A10)

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A9	If yes, please tick all that apply: ☐Injection into your vein (usually an infusion, but may also be given as an injection over a few minutes) ☐Injection into your abdomen (tummy) or thigh ☐Implant into your abdomen (tummy) that a Doctor or nurse inserts under your skin ☐Tablet, capsule or pill that you swallow (oral cancer medicine)			
A10	Do you have any of the following longstanding conditions?			
	☐ A heart condition	☐ Angina	☐ High blood pressure	☐ Asthma or other chronic chest problem
	☐ Liver disease	☐ Problems with your stomach, bowels or gallbladder	☐ Problems with your pancreas	☐ Kidney disease
	☐ Diabetes	☐ Stroke	☐ Alzheimer's disease or dementia	☐ Epilepsy
	☐ Other long standing neurological problem	☐ A diagnosis of arthritis	☐ Other: (please state)	
A11	Do you take daily medicines other than your oral anti-cancer medicine?	☐	Yes	
		☐	No	
A12	If yes, how many medicines other than your oral anti-cancer medicine do you take daily?	☐	1-2	
		☐	3-4	
		☐	5-6	
		☐	7-8	
		☐	9+	

Please continue to section B

Section B: About your appointment The next set of questions asks about the education appointment you had at the Cancer Centre about your new oral anti-cancer medication. Please indicate your response by placing a ✓ in the appropriate box.			
B13	How long after discussing your treatment with the doctor did you wait to receive your education appointment?	☐	1 - 3 days
		☐	4 – 7 days
		☐	1 - 2 weeks
		☐	2 - 3 weeks
B14	Did you receive your oral anti-cancer medicine before your appointment? If no, please continue to question B17.	☐	Yes
		☐	No
B15	If yes, did you start taking your oral anti-cancer medicine before your appointment?	☐	Yes
		☐	No
B16	Were you offered:	☐	An appointment at the cancer centre
		☐	A telephone appointment
B17	Would you have preferred:	☐	An appointment at the cancer centre
		☐	A telephone appointment
B18	If you came to the cancer centre for your appointment, did anyone come with you? If yes, please go to B19. If no, please go to B20.	☐	Yes
		☐	No
B19	If yes, who attended your appointment with you?	☐	Partner
		☐	Parent
		☐	Child
		☐	Friend
		☐	Other *(please state relation)*

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B20	If no, would you have liked someone to come with you?	☐	Yes
		☐	No
B21	If you answered question B20, who would you have liked to come?	☐	Partner
		☐	Parent
		☐	Child
		☐	Friend
		☐	Other (please state relation)
B22	Did the person you saw at your appointment tell you their name?	☐	Yes
		☐	No
B23	Do you know if they were a nurse or a pharmacist?	☐	Nurse
		☐	Pharmacist
		☐	Don't know
B24	Would you have preferred to be seen by:	☐	Doctor
		☐	Nurse
		☐	Pharmacist
		☐	Don't mind
B25	How confident were you about the knowledge and skills of the pharmacist or nurse who you had your appointment with?	☐	Very confident
		☐	Confident
		☐	Not confident
		☐	Not at all confident

Continued overleaf ...

		Yes	Yes, a little	No, not really	No, not at all
B26	Did you feel you had the chance to discuss your concerns and feelings about taking the oral anti-cancer medicine?	☐	☐	☐	☐
B27	Did you feel that you received a clear explanation of how to take your oral anti-cancer medicine?	☐	☐	☐	☐
B28	Were you given written information about your oral anti-cancer medicine?	☐	☐	☐	☐
B29	Did you feel that all your questions were answered at the appointment?	☐	☐	☐	☐
B30	Do you know at which point you should seek help or advice?	☐	☐	☐	☐

		Yes	No
B31	Were you given a red chemotherapy diary (often called your 'red book')?	☐	☐
B32	Were you offered the opportunity to contact anyone after the appointment if you had any further questions that you thought about afterwards?	☐	☐
B33	Were you given contact details of who to contact if you felt unwell when you started taking the oral anti-cancer medicine?	☐	☐
B34	Were you given additional medicines to treat any side effects you might have?	☐	☐
B35	Were you given details about your next appointment?	☐	☐
B36	Were you told what to do if you drop a tablet on the floor?	☐	☐
B37	Were you told what to do if you are sick (vomit) within 3 hours of taking your tablet?	☐	☐

B38	If you attended your appointment at the Cancer Centre, how much time did you need to spend before the appointment travelling to the Cancer Centre, if driving park, and wait for the appointment?	☐	0 – 30 min
		☐	30 – 60 min
		☐	1 – 2 hours
		☐	2 – 3 hours
		☐	3 – 4 hours
		☐	4 – 6 hours
B39	Was any delay due to:	☐	Travelling
		☐	Travel and parking
		☐	Waiting for your appointment
B40	Overall, how satisfied were you with your appointment?	☐	Very satisfied
		☐	Satisfied
		☐	Dissatisfied
		☐	Very dissatisfied
B41	If you had someone with you at the appointment, please state below how satisfied you think they were with the appointment.	☐	Very satisfied
		☐	Satisfied
		☐	Dissatisfied
		☐	Very dissatisfied
B42	How confident did you / do you feel starting your oral anti-cancer medicine?	☐	Very confident
		☐	Confident
		☐	Not confident
		☐	Very unconfident
B43	How confident do you feel about managing any side effects?	☐	Very confident
		☐	Confident
		☐	Not confident
		☐	Very unconfident

Continued overleaf ...

B44	Overall, how confident do you feel managing to take your oral anti-cancer medicine at home:	☐	Very confident
		☐	Confident
		☐	Not confident
		☐	Very unconfident

Free text space for any further comments you may have about your appointment

Please continue to section C.

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Section C: About the information you were given

This section is specifically interested in the education you received from the health professional who taught you about your medication.

Please indicate by placing a ✓ in the relevant box.

	How much information were you given about …	Too much	About right	Too little	None received	None needed
C45	… what your oral anti-cancer medicine is called?	☐	☐	☐	☐	☐
C46	… what your oral anti-cancer medicine is for?	☐	☐	☐	☐	☐
C47	… what it does?	☐	☐	☐	☐	☐
C48	… how it works?	☐	☐	☐	☐	☐
C49	… how long it will take to act?	☐	☐	☐	☐	☐
C50	… how can you tell if its working?	☐	☐	☐	☐	☐
C51	… how long you will take your oral anti-cancer medicine?	☐	☐	☐	☐	☐
C52	… how to take your oral anti-cancer medicine?	☐	☐	☐	☐	☐
C53	… how to get a new supply?	☐	☐	☐	☐	☐
C54	… the side effects of your oral anti-cancer medicine?	☐	☐	☐	☐	☐
C55	… the risks of you getting side effects?	☐	☐	☐	☐	☐
C56	… what to do if you experience side effects?	☐	☐	☐	☐	☐
C57	… whether you can drink alcohol whilst taking your oral anti-cancer medicine?	☐	☐	☐	☐	☐
C58	… whether your oral anti-cancer medicine interferes with other medicines?	☐	☐	☐	☐	☐
C59	… whether your oral anti-cancer medication will make you feel drowsy?	☐	☐	☐	☐	☐
C60	… whether your oral anti-cancer medication will affect your sex life?	☐	☐	☐	☐	☐
C61	… what you should do if you forget to take a dose?	☐	☐	☐	☐	☐

Section D: Beliefs about your new medicines

We would like to ask you about your personal views about your oral anti-cancer medicine.
These are statements other people have made about their medicines.
Please indicate the extent to which you agree or disagree with them by ticking the appropriate box.

Please indicate by placing a ✓ in the relevant response.

	Statement	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
D62	My health, at present, depends on me taking my oral anti-cancer medicine	☐	☐	☐	☐	☐
D63	Having to take oral anti-cancer medication worries me	☐	☐	☐	☐	☐
D64	Taking oral anti-cancer medication makes me feel I am taking positive steps to treat my cancer	☐	☐	☐	☐	☐
D65	Without taking my oral anti-cancer medicine I would be very ill	☐	☐	☐	☐	☐
D66	I sometimes worry about long-term effects of taking my oral anti-cancer medicine	☐	☐	☐	☐	☐
D67	Oral anti-cancer medicines are a mystery to me	☐	☐	☐	☐	☐
D68	My health in the future will depend on my oral anti-cancer medicine	☐	☐	☐	☐	☐
D69	Taking oral anti-cancer medicine disrupts my life	☐	☐	☐	☐	☐
D70	I sometimes worry about having my oral anti-cancer medicine over a long period of time	☐	☐	☐	☐	☐
D71	My oral anti-cancer medicine helps protect me from becoming worse	☐	☐	☐	☐	☐

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Questionnaire 1 v 1.8 11.07.2016
REC number: 16/NW/0586 IRAS: 204177

Section E: About you

This section contains questions about your background and domestic circumstance. This information will help us organise our results and help make sure our results are representative of all patients returning the questionnaire.

Please indicate by placing a ✓ in the relevant response.

E72	What is your gender?	☐	Male
		☐	Female
		☐	Transgender
E73	What is your date of birth?	Day/Month/Year ___/___/___	
E74	What is your current marital status?	☐	Married or living as married
		☐	Divorced or separated
		☐	Widowed
		☐	Single
		☐	Other *(please specify)*
E75	Do you have any other dependents for whom you personally provide care?	☐	Yes
		☐	No
E76	Which of these best describes your current employment status?	☐	In paid work (including self-employment) – full or part time
		☐	Temporarily off sick from my job
		☐	Unemployed
		☐	Retired from paid work
		☐	Unable to work because of long-term disability or ill health
		☐	In full-time education, training or work experience
		☐	Unpaid work/Volunteer
		☐	Other *(please specify)*

Continued overleaf ...

E77	Which of the following ethnic groups would you say you belong to?	☐	White - British
		☐	White – Eastern Europe
		☐	White – other white groups
		☐	Black – Caribbean
		☐	Black – African
		☐	Black – other black groups
		☐	Asian – Middle East
		☐	Asian – Far East
		☐	Mixed Background *(please specify)*
E78	What is your highest level of education?	☐	Secondary School
		☐	Further Education/College
		☐	University degree
		☐	University postgraduate degree e.g MSc, PgDip
		☐	PhD

Section F: About anything we've missed?

Please use this section to comment on anything you feel may be relevant or important about your experience that has not been covered in this questionnaire.

Please also remember, your comments will be de-identified.

Page left intentionally blank.

Please turn over.

Section G: About contacting you Please note. This section of the questionnaire will be detached upon receipt and stored separately. Your responses will therefore remain anonymous. Your contact details are recorded only in order to post a second, shorter questionnaire in approximately 6 weeks' time which seeks to explore your experience of taking your medication after some time.	
Date of your oral education appointment	
Name	
Address	
Postcode	
Home telephone	
Work telephone	
Mobile telephone	
Email address	
A sincere thank you for taking the time to complete this questionnaire. Your responses are hugely valuable and will have an impact on informing the development of future healthcare practices for patients taking oral anti-cancer treatments.	

Please note: This page will be detached from your questionnaire and stored separately. Your answers will therefore remain confidential.

When you have completed your questionnaire, please place into the reply paid envelope provided and return at your earliest convenience.

In the event of any questions or concerns regarding your treatment, please contact [redacted]

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Appendix 3 – Questionnaire 2

Questionnaire 2 v 1.8 11.07.2016
REC number: 16/NW/0586 IRAS: 204177

[redacted]

Unique study ID	

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Optimising the care of patients receiving oral anti-cancer treatments
Questionnaire 2

Thank you for agreeing to participate in this study. You have been sent this questionnaire because you are taking an oral anti-cancer treatment and received pre-treatment education. You have already completed questionnaire 1 and this is the last questionnaire in the study.

We are interested in how your pre-treatment education has helped you in taking your medication and managing your health at home.

Please do not write your name or any identifying details on this questionnaire – your responses will be kept de-identified and confidential.

The Questionnaire is in six sections:

Section A: About how useful you found the information you were given
Section B: About taking your oral anti-cancer medication
Section C: About side effects
Section D: Your views about your anti-cancer medicine
Section E: About how we can make things better
Section F: About taking part in an interview

If you require any assistance with this questionnaire, require the questionnaire in larger print or would like further information, please contact the chief investigator Michael Mawhinney on tel: 01865 482 697 or email: 14110227@brookes.ac.uk

Thank you very much for your help!

Questionnaire 2 v 1.8 11.07.2016
REC number: 16/NW/0586 IRAS: 204177

Section A: About how useful you found the information you were given

Now that you've taken your medication for some time, this section asks about the education you received on your anti-cancer medication at the start of your treatment. Please think back to the appointment you had with the pharmacist or nurse when answering the following questions.
Please indicate by placing a ✓ in the relevant box.

	Can you remember how much information you were given at your appointment with the nurse or pharmacist at the start of your treatment about ...	**Too much**	**About right**	**Too little**	**None received**	**None needed**
A1	... what your oral anti-cancer medicine is called?	☐	☐	☐	☐	☐
A2	... what your oral anti-cancer medicine is for?	☐	☐	☐	☐	☐
A3	... what it does?	☐	☐	☐	☐	☐
A4	... how it works?	☐	☐	☐	☐	☐
A5	... how long it will take to act?	☐	☐	☐	☐	☐
A6	... how can you tell if its working?	☐	☐	☐	☐	☐
A7	... how long you will take your oral anti-cancer medicine?	☐	☐	☐	☐	☐
A8	... how to take your oral anti-cancer medicine?	☐	☐	☐	☐	☐
A9	... how to get a new supply?	☐	☐	☐	☐	☐
A10	... the side effects of your oral anti-cancer medicine?	☐	☐	☐	☐	☐
A11	... the risks of you getting side effects?	☐	☐	☐	☐	☐
A12	... what to do if you experience side effects?	☐	☐	☐	☐	☐
A13	... whether you can drink alcohol whilst taking your oral anti-cancer medicine?	☐	☐	☐	☐	☐
A14	... whether your oral anti-cancer medicine interferes with other medicines?	☐	☐	☐	☐	☐
A15	... whether your oral anti-cancer medication will make you feel drowsy?	☐	☐	☐	☐	☐
A16	... whether your oral anti-cancer medication will affect your sex life?	☐	☐	☐	☐	☐
A17	... what you should do if you forget to take a dose?	☐	☐	☐	☐	☐

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A18	Overall, how well do you think you can remember what you were told about your medicine at your appointment with the nurse or pharmacist at the start of your treatment?	☐	Very well – I remember everything or nearly everything
		☐	Quite well – I remember most things
		☐	Not well – I don't remember many things
		☐	Not at all well – I only remember very few things
		☐	Can't remember
A19	Please use this space to write down anything that has helped you to remember the advice and information you were given about your oral anti-cancer medicine		

Please continue to section B.

Questionnaire 2 v 1.8 11.07.2016
REC number: 16/NW/0586 IRAS: 204177

Section B: About taking your oral anti-cancer medication

This section asks about how you have been taking your medication <u>over the past two</u> **weeks.**
Please remember your answers will be treated in strict confidence and individual's answers will not be shared with the clinical team so answer as honestly as possible.

Please indicate by placing a ✓ in the relevant response.

B20	Do you sometimes forget to take your medicine?	☐ ☐	Yes No
B21	People sometimes miss taking their medicines for reasons other than forgetting. Over the past 2 weeks, were there any days when you did not take your medicine?	☐ ☐	Yes No
B22	Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?	☐ ☐	Yes No
B23	When you travel or leave home, do you sometimes forget to bring your medicine?	☐ ☐	Yes No
B24	Did you take all your medicine yesterday?	☐ ☐	Yes No
B25	When you feel like your symptoms are under control, do you sometimes stop taking your medicine?	☐ ☐	Yes No
B26	Taking medicine every day is a real inconvenience for some people. Do you ever feel stressed about sticking to your treatment plan?	☐ ☐	Yes No
B27	How often do you have difficulty remembering to take all your medicine?	☐ ☐ ☐ ☐ ☐	Never/rarely Once in a while Sometimes Usually All of the time

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B28	How do you usually remember how to take your anti-cancer medication? *Please use this box for any further comments*	☐	I keep a diary or write down when I take them
		☐	I made them part of my daily routine
		☐	I set a reminder
		☐	Other: *(please state)*
B29	Do you find it difficult to swallow your tablets? If no, continue to C32	☐	Yes
		☐	No
B30	Why do you find it difficult to swallow your tablets? *Please use this box for any further comments*	☐	Too big
		☐	Too many
		☐	Coating sticks to my tongue, mouth or throat
		☐	Other: *(please state)*
B31	Were you given any advice about how to manage difficulty in swallowing your tablets? If yes, please can you write below what advice you were given? *Please use this box for any further comments*	☐	Yes *(please state)*
		☐	No

Please continue to section C.

Section C: About side effects

In this section the questions are about any side effects you might have experienced while taking your anti-cancer medication.

Please indicate by placing a ✓ in the relevant response.

C32	How long after starting your anti-cancer medication did you experience your first side effect?	☐	1-2 days
		☐	3-5 days
		☐	6-7 days
		☐	8-10 days
		☐	11-14 days
		☐	After 3 weeks
		☐	After 4 weeks
		☐	No side effects

Please indicate by ticking (✓) in the boxes below if you experienced any of the side effects listed and if so, how severe your side effects were:

		Mild and/or temporary – they passed in a few hours	*Tolerable – I could manage them without professional help*	*Bothersome – I needed some advice or I had to get extra medicines*	*Quite severe – I needed to see a Doctor or go to the hospital*	*Very severe – I needed to be admitted to hospital for urgent treatment*
C33	**Nausea**	☐	☐	☐	☐	☐
C34	**Vomiting**	☐	☐	☐	☐	☐
C35	**Diarrhoea**	☐	☐	☐	☐	☐
C36	**Constipation**	☐	☐	☐	☐	☐
C37	**Sore or sensitive mouth**	☐	☐	☐	☐	☐
C38	**Loss or change in taste**	☐	☐	☐	☐	☐

		Mild and/or temporary – they passed in a few hours	*Tolerable – I could manage them without professional help*	*Bothersome – I needed some advice or I had to get extra medicines*	*Quite severe – I needed to see a Doctor or go to the hospital*	*Very severe – I needed to be admitted to hospital for urgent treatment*
C39	Loss or change in smell	☐	☐	☐	☐	☐
C40	Dry lips or mouth	☐	☐	☐	☐	☐
C41	Rashes	☐	☐	☐	☐	☐
C42	Hair changes (including eyelashes)	☐	☐	☐	☐	☐
C43	Nail changes	☐	☐	☐	☐	☐
C44	Skin dryness	☐	☐	☐	☐	☐
C45	Headaches	☐	☐	☐	☐	☐
C46	Physical weakness	☐	☐	☐	☐	☐
C47	Fatigue	☐	☐	☐	☐	☐
C48	Infection	☐	☐	☐	☐	☐
C49	Flu-like symptoms	☐	☐	☐	☐	☐
C50	Difficulty concentrating	☐	☐	☐	☐	☐
C51	Anxiety	☐	☐	☐	☐	☐
C52	Sleep disruption	☐	☐	☐	☐	☐
C53	Pain	☐	☐	☐	☐	☐
C54	Loss of appetite	☐	☐	☐	☐	☐

		Mild and/or temporary – they passed in a few hours	*Tolerable – I could manage them without professional help*	*Bothersome – I needed some advice or I had to get extra medicines*	*Quite severe – I needed to see a Doctor or go to the hospital*	*Very severe – I needed to be admitted to hospital for urgent treatment*
C55	**Low mood**	☐	☐	☐	☐	☐
C56	**Sore hands**	☐	☐	☐	☐	☐
C57	**Sore feet**	☐	☐	☐	☐	☐
C58	**Tingling sensation in hands or feet**	☐	☐	☐	☐	☐
C59	**Nose bleeds**	☐	☐	☐	☐	☐
C60	**Sore eyes**	☐	☐	☐	☐	☐
C61	Cough	☐	☐	☐	☐	☐
C62	Other:	☐	☐	☐	☐	☐
C63	Other:	☐	☐	☐	☐	☐
C64	Other:	☐	☐	☐	☐	☐

C65	Were you told at your appointment with the nurse or pharmacist at the start of your treatment what side effects to expect?	☐	Yes
		☐	No
C66	Were these side effects the ones you experienced?	☐	Yes
		☐	No
C67	If no, please write below the side effect(s) you had that you were not expecting:		

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C68	Did you discuss your side effects with your doctor at your next appointment with them?	☐	Yes
		☐	No
C69	Did you phone for advice about any of your side effects?	☐	Yes
		☐	No
C70	Did you phone the triage service using the contact number you were given at your appointment with the nurse or pharmacist?	☐	Yes
		☐	No
C71	If no, please indicate who you called for advice	☐	GP
		☐	999 emergency service
		☐	111/NHS out of hours
		☐	Local A&E
		☐	Local chemist/pharmacist
C72	How soon did you phone for advice after onset of your side effect?	☐	Within an hour
		☐	Within 3-4 hours
		☐	Within a day
		☐	Within 2 days
		☐	Within 3 days
		☐	4 days or more
C73	Who called for advice about your side effect?	☐	You
		☐	Family member you live with
		☐	Family member who you do not live with
		☐	Paid carer
		☐	Neighbour/Friend
		☐	Other: *(please state)*

Continued overleaf ...

C74	If you didn't call the triage service first, were you referred to:	☐	Triage service
		☐	A&E
		☐	GP
		☐	Other: *(please state)*
C75	If you spoke to the triage service, did they address your concerns?	☐	Yes
		☐	No
C76	How confident were you that the health professionals you spoke to knew how to manage your side effect?	☐	Very confident
		☐	Quite confident
		☐	Not confident
		☐	Not at all confident
C77	If you had side effects, but didn't call for advice, why was this?	☐	I didn't think the side effect was serious or severe enough
		☐	The side effect passed by itself in a few of hours
		☐	I didn't want to bother anyone
		☐	I thought I could manage it myself
		☐	Other: (please state)
C78	Have you kept a record of your side effects?	☐	Yes
		☐	No
C79	Have you used your red chemotherapy book? If yes continue to C80, if no please continue to D82	☐	Yes
		☐	No

C80	How helpful was your red chemotherapy book?	☐	Very helpful
		☐	Quite helpful
		☐	Helpful
		☐	Not helpful
		☐	Not at all helpful
		☐	Further info:
C81	If you found the red chemotherapy book unhelpful, please can you write below why that was:		

Please continue to section D.

Questionnaire 2 v 1.8 11.07.2016
REC number: 16/NW/0586 IRAS: 204177

Section D: Your views of your cancer medicine

The following pages ask some questions about how you have felt about your oral anti-cancer medication. Please read each question and answer as honestly as you can using your own experiences. There are no right or wrong answers; the answers should be based on your own personal experiences.
All of your answers will remain confidential.
Please indicate by placing a ✓ in the relevant response.

		Always	Most of the time	Some-times	Rarely	Never
D82	In general, how often have you felt that your oral anti-cancer medication would help you to return back to a normal life?	☐	☐	☐	☐	☐
D83	How often have you felt that your oral anti-cancer medication would get rid of the cancer?	☐	☐	☐	☐	☐
D84	How often have you felt that your oral anti-cancer medication would help prevent the cancer from coming back?	☐	☐	☐	☐	☐
D85	How often have you felt that your oral anti-cancer medication would stop the cancer from spreading?	☐	☐	☐	☐	☐
D86	How often have you felt that your oral anti-cancer medication limited your daily activities?	☐	☐	☐	☐	☐
D87	How often have you felt upset about the side effects?	☐	☐	☐	☐	☐
D88	How often have you felt that your oral anti-cancer medication was worth taking even with the side effects?	☐	☐	☐	☐	☐
D89	How often have you felt that your oral anti-cancer medication would help you live longer?	☐	☐	☐	☐	☐
D90	How often have you felt about stopping your oral anti-cancer medication?	☐	☐	☐	☐	☐
D91	How often have you had trouble remembering to take your oral anti-cancer medication?	☐	☐	☐	☐	☐
D92	How often have you taken your oral anti-cancer medication exactly as directed by your doctor? For example, instructions about when to eat before or after taking your medicine.	☐	☐	☐	☐	☐

Continued overleaf ...

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D93	If you didn't always take your oral anti-cancer medication as directed, why was this?	☐	I forgot
		☐	It was inconvenient
		☐	I felt I needed a break
		☐	I felt I did not need it
		☐	Side effects
		☐	Other: (please specify)
D94	How inconvenient was it for you to take your oral anti-cancer medication?	☐	Very inconvenient
		☐	Inconvenient
		☐	Neither
		☐	Convenient
		☐	Very convenient
D95	How bothered were you by the amount of time it took to take your oral anti-cancer medication?	☐	Very bothered
		☐	Quite bothered
		☐	Moderately bothered
		☐	A little bothered
		☐	Not bothered at all
D96	Overall, how worthwhile is/was your oral anti-cancer medication?	☐	Very worthwhile
		☐	Quite worthwhile
		☐	Moderately worthwhile
		☐	A little worthwhile
		☐	Not worthwhile

Continued overleaf ...

D97	Was taking your oral anti-cancer medication as difficult as expected?	☐	Much more difficult than I thought it would be
		☐	Somewhat more difficult than I thought it would be
		☐	As difficult as I thought it would be
		☐	Somewhat easier than I thought it would be
		☐	Much easier than I thought it would be
D98	How well did the benefits of your oral anti-cancer medication meet your expectations?	☐	Much better than my expectations
		☐	Somewhat better than my expectations
		☐	Met my expectations
		☐	Somewhat worse than my expectations
		☐	Much worse than my expectation
D99	Were the side effects of your oral anti-cancer medication as you expected?	☐	Much better than I expected
		☐	Somewhat better than I expected
		☐	Exactly as I expected
		☐	Somewhat worse than I expected
		☐	Much worse than I expected
D100	How satisfied were you with oral anti-cancer medication?	☐	Very satisfied
		☐	Satisfied
		☐	Neither satisfied nor dissatisfied
		☐	Dissatisfied
		☐	Very dissatisfied

Continued overleaf ...

D101	Overall, how satisfied were you with your cancer therapy?	☐	Very satisfied
		☐	Satisfied
		☐	Neither satisfied nor dissatisfied
		☐	Dissatisfied
		☐	Very dissatisfied
D102	Taking everything into consideration, if given the choice again, would you decide to take this oral anti-cancer medication?	☐	Yes definitely
		☐	Probably yes
		☐	I don't know
		☐	Probably not
		☐	Definitely not

Please continue to section E.

Section E: About how we can make things better

This section of the questionnaire is for you to share anything you feel may be helpful for the research team that has not been covered in your questionnaires.

Please write anything you think that could make the service better for people taking oral anti-cancer medications.

There is no obligation to complete this space.

Page left intentionally blank.

Please turn over.

Questionnaire 2 v 1.8 11.07.2016
REC number: 16/NW/0586 IRAS: 204177

Section F: About taking part in an interview

We plan to interview several patients to further explore their experience of taking an oral anti-cancer medication. You will find further information and a consent form in the pack you have been sent containing this questionnaire. You do not need to complete and return the consent form as if you participate in an interview, this will be completed on the day of interview.

Please indicate below if you would be willing to be interviewed by placing an **X** in the appropriate box and Michael Mawhinney will be in touch.

Yes I am willing to be interviewed. Please contact me to arrange a time. ☐	No I am not willing to be interviewed. ☐
The best way to contact me is: Phone: _____ Email: _____ _____	

When you have completed your questionnaire, please place into the reply paid envelope provided and return at your earliest convenience.

In the event of any questions or concerns regarding your treatment, please contact [redacted]

Appendix 4 – Ethical approvals for stage 2 (Health professional interviews)

OXFORD BROOKES UNIVERSITY

Michael Mawhinney
Faculty of Health and Life Sciences
Marston Road Campus

12 November 2015

Dear Michael,

Re. Optimising the care of patients receiving oral systemic anti-cancer treatments: a mixed methods study

Thank you for your recent correspondence, detailing your response to my letter dated 21 October 2015.

I can confirm that all the points raised in my letter have been comprehensively addressed. I am therefore pleased to approve the research on behalf of the Faculty of Health and Life Sciences Research Ethics Committee and enclose an E3 ethics approval form to this effect.

Good luck with the data collection.

Yours sincerely,

Hazel Abbott
Chair, Faculty of Health and Life Sciences Research Ethics Committee

Cc. Dr Verna Lavender, PhD Supervisor

E3/FH&LS

Oxford Brookes University

Faculty of Health and Life Sciences

Decision on application for ethics approval

The Departmental Research Ethics Officer (DREO) / Faculty Research Ethics Committee (FREC) has considered the application for ethics approval for the following project:

Project Title: Optimising the care of patients receiving oral systemic anti-cancer treatments: a mixed methods study

FREC Study Number: 2015/10

Name of Applicant: Michael Mawhinney

Name of Supervisors: Dr Verna Lavender and Professor Eila Watson

Please tick one box

1. The Faculty Research Ethics Committee gives ethical approval for the research project. √ ☑

   Please note that the research protocol as laid down in the application and hereby approved must not be changed without the approval of the DREO / FREC

2. The Departmental Research Ethics Officer / Faculty Research Ethics Committee gives ethical approval for the research project, subject to the following: ☐

3. The Departmental Research Officer / Faculty Research Ethics Committee cannot give ethical approval for the research project. The reasons for this and the action required are as follows: ☐

Signed: ...Hazel Abbott... Approval Date: .....12 November 2015.....

Designation: Departmental Research Ethics Officer

(Signed on behalf of the Faculty Research Ethics Committee)

Date when application reviewed (*office use only*): 13 October 2015.....

H&LS/FRec/E3 August 2011

OXFORD BROOKES UNIVERSITY

Hazel Abbott
Departmental Research Ethics Officer

MR1/39 Marston Road Campus
Jack Straws Lane Marston Oxford OX3 0FL
t. +44 (0)1865 482639 f. +44 (0)1865 851171
heabbott@brookes.ac.uk
www.brookes.ac.uk

To: Research and Development Department

12 November 2015

To whom it may concern,

Re. Optimising the care of patients receiving oral systemic anti-cancer treatments: a mixed methods study

I am writing to confirm that Oxford Brookes University is accepting the role of Research Sponsor for the above project. This is in accordance with the role and responsibilities of Sponsor, as it is laid out in the Research Governance Framework for Health and Social Care (2005).

Michael Mawhinney is a PhD student in the Faculty of Health and Life Sciences at Oxford Brookes University. He will be supervised by Dr Verna Lavender, Senior Lecturer in Cancer Care and Professor Eila Watson, Professor of Supportive Cancer Care.

Oxford Brookes University has public liability, professional indemnity and clinical trials insurance and will provide insurance for this study.

Yours faithfully,

Hazel Abbott
Departmental Research Ethics Officer, Faculty of Health and Life Sciences

Cc: Louise Wood, Research and Business Development Office

[redacted]

HH/FM/PID: 11707

Mr Michael Mawhinney
Oxford Brookes University
Jack Straw's Lane
Marston
Oxford
OX3 0FL

Dear Mr Mawhinney,

Re: Optimising the Care of Patients Receiving Oral Systemic Anti-Cancer Treatments: the clinician's view

Research and Development Reference: 11707
Oxford Brookes University FREC Reference: 1015/10

Confirmation of Trust Management Approval
On behalf of the [redacted] Trust, I am pleased to confirm Trust Management Approval and Indemnity for the above research on the basis described in the application, protocol and other supporting documents.

Conditions of Approval
Your attention is drawn to the attached conditions of approval. Breach of these conditions may result in Trust Management Approval being revoked.

Recruitment

The agreed total recruitment target for your study at [redacted] site is 20 participants by 27 May 2016 as specified in the SSI Form.

Your first participant recruitment target date is: 16 March 2016

To suppo[redacted]t and national recruitment targets, R&D will monitor and publish recruitment for your study: 1. Performance against the 70 calendar day period benchmark from the time of receipt of a valid research application in R&D to the date of recruitment of first participant to your study; and for interventional trials; 2. Recruiting planned participants to time and target. The R&D office will contact you to request recruitment progress against both targets. If you recruit your first participant into the study then please send the date to researchrecruitment@[redacted] If you miss this target you will be required to give reasons that can be reported to the DoH/NIHR.

[redacted]

Ethics Correspondence
In order to facilitate good communications and avoid unnecessary delays please copy all correspondence with the Research Ethics Committee (REC) to R&D, providing copies of all relevant documents.

Research Sponsorship

It is noted that Oxford Brookes University has agreed to Sponsor this trial.

Site Specific Assessment

This Trust Management Approval letter also incorporates site specific assessment for the [redacted] NHS Trust site.

Approved Documents
The documents approved for use at this trust are as listed in the:

Research Ethics Approval Letter(s) dated:
Oxford Brookes University FREC: 12 November 2015

Study Staff

The CVs and GCP certificates of staff listed on the SSI form have been reviewed.

I wish you every success with the study.

Yours sincerely,

[redacted]

R&D Lead

Copy to:	Sponsor:	heabbott@brookes.ac.uk
	Key Contact:	michael.mawhinney-2015@brookes.ac.uk
	[redacted]	
	Supervisors:	ewatson@brookes.ac.uk vlavender@brookes.ac.uk

[redacted]

Standard Conditions of Approval by [redacted] Trust for Research studies other than Clinical Trials of Investigational Medicinal Products or Medical Device Trials

Issued to Chief Investigators and Principal Investigators

1) **Commencement of the Study**

Before the study commences the Chief Investigator/Principal Investigator is responsible for the following:

a) Ensuring that all members of the research team are appropriately qualified to undertake their role(s) through education, training and experience

b) Establishing a Study Master File/Site File, which should be maintained throughout the study and be readily available to the study team.

c) Ensuring that all members of the research team who have access to patients, their organs, tissues, data or access to NHS staff, information and facilities have [redacted] substantive/honorary contracts or appropriate research passports/honorary research contracts/letters of access in place prior to their involvement in the study.

d) Ensuring that all appropriate approvals are in place and remain so for the duration of the study

e) Ensuring that all investigators in the study are aware of and comply with the Regulatory Framework surrounding research practice, which includes but is not limited to:
   - The Department of Health Research Governance Framework for Health and Social Care 2005
   - Mental Capacity Act 2005
   - The Human Tissue Act 2004
   - The Declaration of Helsinki 2000
   - The Human Rights Act 1998
   - The Data Protection Act 1998
   - ICH Good Clinical Practice 1996

2) **Conduct of the Study**

a) The study will be conducted according to the all applicable regulations, principles of Good Clinical Practice and applicable [redacted] Trust policies.

b) The study will be conducted in accordance with the approved protocol.

[redacted]

c) Essential documents will be made available for audit and inspection purposes where required.

d) The Trust must be made aware of any Intellectual Property that arises from the research study.

3) **Protocol Amendments**

a) [redacted]tors must submit protocol amendments to R&D Department **prior** to submission the Research Ethics Committee and MHRA, to assess any implications for the Sponsor.

b) All **substantial** amendments must be submitted to the appropriate Research Ethics Committee for approval. Documents should also be forwarded to the R&D Department for assessment as to whether the amendment affects Trust Management Approval.

c) In order for the Trust to meet its responsibilities under the Research Governance Framework **all amendments, including non-substantial amendments** must be submitted to R&D department. You should include all supporting documents.

d) Submission of substantial amendments will be acknowledged by a letter confirming on-going Trust Management Approval, non-substantial amendments will be acknowledged by email.

e) **NO** substantial amendment, except those that relate to an urgent safety measures, should be implemented until all appropriate approvals have been obtained.

4) **Change of key Site Personnel - Chief investigator/Principal Investigator**

a) Any change of nominated Chief investigator/Principal Investigator (e.g. due to relocation, maternity leave, retirement etc.) at th[redacted]ust should be notified to the R&D Department **immediately**; the host organisation needs to ensure any on-going studies have been reviewed and appropriate oversight is in place; or where needed studies have been terminated within the required timeframes.

b) All other changes in study staff should be maintained via a study delegation log.

5) **Safety reporting**

a) Appropriate safety reporting procedures will be agreed according to the perceived risks to study participants and/or the Trust. Any safety reporting requirements will be communicated in writing by the R&D Lead to the Chief/Principal Investigator.

6) **REC Annual Progress Reports and Monitoring of the Study**

[redacted]

a) The Chief Investigator should ensure that the REC Annual Progress Reports are completed and submitted in a timely manner on each anniversary of the REC Approval, and copied to R&D.

b) The need for on-site monitoring of the study will be assessed according to risk to study participants and/or the Trust. Any special requirements will be communicated to the Chief Investigator/Principal Investigator in writing.

c) The Trust may audit a number of hosted CTIMPs and interventional studies.

7) **NIHR and NHS Quality Accounts**

a) The Trust is obliged to submit data to the Department of Health annually. The Chief Investigator/Principal Investigator must provide to R&D department in a timely manner, such information about the study as to enable to Trust to meet its obligations.

b) In particular the Chief Investigator/Principal Investigator will forward the first participant recruited date to R&D department by emailing the information to the email address provided in the NHS permission letter.

c) In addition the Chief Investigator/Principal Investigator will update the R&D department periodically throughout the life time of the trial on trial progress including on-going recruitment data and changes in the status of the trial.

8) **Conclusion of the Trial**

a) The Trust R&D Department should be informed within 60 days of the close of the study and a final report provided.

b) If the study is stopped early, the Trust R&D Department should be informed within 30 days outlining the reasons.

9) **Termination of Trust Management Approval**

a) The Trust reserves the right to revoke Trust Management Approval or Sponsorship for any project that is not conducted according to Trust policy or the applicable regulatory or legal framework. However, any such action will not be taken without prior discussion with the R&D Lead and/or the Medical Director together with the Chief or Principal Investigator. Furthermore, all researchers undertaking research at the Trust are subject to the Misconduct and Fraud Policy.

All Trust policies for the conduct of research within the organisation can be found at [redacted]

Appendix 5 – Ethical approvals for patient questionnaire and interview

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Michael Mawhinney
Faculty of Health and Life Sciences
Marston Road Campus

14 July 2016

Dear Mike

Re. Optimising the care of patients receiving oral systemic anti-cancer treatments: the patient's view

Thank you for your recent correspondence, detailing your response to my letter dated 22 June 2016.

I can confirm that all the points raised in my letter have been comprehensively addressed. I am therefore pleased to approve the research by Chair's Action, on behalf of the Faculty Research Ethics Committee.

I enclose hard copies of the necessary information for forwarding with you application to the NRES. Please go ahead and book a review slot with the NRES and I will authorise the application electronically when forwarded to me by the LREC.

Good luck with the data collection.

Yours sincerely,

Hazel Abbott
Chair, Faculty of Health and Life Sciences Research Ethics Committee

Cc. Professor Eila Watson, PhD Supervisor
Dr Verna Lavender, PhD Supervisor

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Oxford Brookes University

Faculty of Health and Life Sciences

Decision on application for ethics approval

The Departmental Research Ethics Officer (DREO) / Faculty Research Ethics Committee (FREC) has considered the application for ethics approval for the following project:

Project Title: Optimising the care of patients receiving oral systemic anti-cancer treatments: the patient's view

FREC Study Number: 2015/41

Name of Applicant: Michael Mawhinney

Name of Supervisors: Dr Verna Lavender and Professor Eila Watson

Please tick one box

1. The Faculty Research Ethics Committee gives ethical approval for the research project. √ [√]

   Please note that the research protocol as laid down in the application and hereby approved must not be changed without the approval of the DREO / FREC

2. The Departmental Research Ethics Officer / Faculty Research Ethics Committee gives ethical approval for the research project, subject to the following: [ ]

3. The Departmental Research Officer / Faculty Research Ethics Committee cannot give ethical approval for the research project. The reasons for this and the action required are as follows: [ ]

Signed: ...Hazel Abbott ..... Approval Date: .....14 July 2016 .....

Designation: Departmental Research Ethics Officer

(Signed on behalf of the Faculty Research Ethics Committee)

Date when application reviewed (*office use only*): 21 June 2016 .....

H&LS/FRec/E3 August 2011

E4/FH&LS

Oxford Brookes University

Faculty of Health and Life Sciences

Research Ethics Committee

Scientific Peer Review Form

The Faculty of Health and Life Sciences Research Ethics Committee (REC) has undertaken an independent scientific peer review of the following research proposal:

Project Title: Optimising the care of patients receiving oral systemic anti-cancer treatments: the patient's view

Name of Researcher: Michael Mawhinney

Name of Supervisors: Dr Verna Lavender and Professor Eila Watson

Application Number: 2015/41

Following review on 21 June 2016 by the Faculty of Health and Life Sciences Research Ethics Committee, the above research is considered to be both ethically and scientifically sound.

Signed: .....

Designation: Research Ethics Lead

(Signed on behalf of the Faculty of Health and Life Sciences Research Ethics Committee)

Date: 14.07.2016

Independent scientific peer review undertaken by the following members of the FH&LS REC:	
Mrs Hazel Abbott (Chair)	Dr Dido Green
Mr Dan Butcher	Dr Sue Schutz
Ms Leisle Ezekiel	

HEA/REC/E4/14.07.2016

NHS
Health Research Authority

Mr Michael Mawhinney
[redacted]
Email: hra.approval@nhs.net

Dear Mr Mawhinney

Letter of HRA Approval

Study title:	**Optimising the care of patients receiving oral systemic anti-cancer treatments: a mixed methods study**
IRAS project ID:	**204177**
REC reference:	**16/NW/0586**
Sponsor	**Oxford Brookes University**

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

Participation of NHS Organisations in England

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

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

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

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

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details

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and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

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

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

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

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

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

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HRA Training

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

Your IRAS project ID is **204177**. Please quote this on all correspondence.

Yours sincerely

Michael Pate
Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Hazel Abbott – Oxford Brookes University – Sponsor's contact*
[redacted]

IRAS project ID	204177

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [OBU sponsorship]	1.0	14 July 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Oxford Brookes insurance 2016-17]		18 July 2016
Interview schedules or topic guides for participants [Interview Topic Guide]	1.0	08 June 2016
IRAS Application Form [IRAS_Form_19072016]		19 July 2016
Letter from sponsor [FREC approvals]	1.0	14 July 2016
Letters of invitation to participant [Invitation letter 1]	1.0	09 March 2016
Letters of invitation to participant [Study Invitation Letter 2]	1.0	08 June 2016
Letters of invitation to participant [Study Reminder Letter]	1.1	11 July 2016
Non-validated questionnaire [Questionnaire 1]	1.8	11 July 2016
Non-validated questionnaire [Questionnaire 2]	1.8	11 July 2016
Other [Statement of Activities - VALIDATED]	1	08 September 2016
Other [Schedule of Events - VALIDATED]	1	08 September 2016
Other [Previous recommendations from FREC]	1.0	22 June 2016
Other [Peer review confirmation]	1.0	14 July 2016
Other [Collaboration Letter OBU/OUH]	1.0	19 October 2015
Participant consent form [Consent form]	1.3	08 September 2016
Participant information sheet (PIS) [Information sheet 1]	1.2	08 September 2016
Participant information sheet (PIS) [Information sheet 2]	1.2	08 September 2016
Research protocol or project proposal [Research Protocol]	1.0	11 March 2016
Summary CV for Chief Investigator (CI) [Michael Mawhinney CV]	1.0	04 December 2015
Summary CV for student [MM CV]	1.0	04 December 2015
Summary CV for supervisor (student research) [EW CV]		
Summary CV for supervisor (student research) [VL CV]		22 September 2015

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Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Ms Hazel Abbott (01865 482639, heabbott@brookes.ac.uk)

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	Confirmed with applicant that Oxford University Hospitals NHS Foundation Trust is the single site, and not Oxford Health NHS Foundation Trust, as per the submitted IRAS form.
2.1	Participant information/consent documents and consent process	Yes	Following a REC favourable opinion, the information sheets and consent form were revised to bring them in line with HRA standards. These documents are incorporated in this letter of HRA approval.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A Statement of Activities will form the agreement between the Sponsor and participating NHS site.

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Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No funding will be provided to the participating NHS site.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

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Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
This is a single site study with a University Sponsor; therefore, one site type. • **Local collaborator will identify potential participants** • **Student will distribute study packs, consent, administer questionnaires and conduct interviews.** The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
Participating NHS organisations in England that are recruiting sites **will be expected to formally confirm their capacity and capability to host this research.** • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

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Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A local collaborator should be in place at participating NHS sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
The doctoral researcher, Michael Mawhinney, is external to the NHS organisation and will distribute study packs, take consent and undertake interviews with patients on NHS premises. Michael should be directly supervised by an employee of Oxford University Hospitals NHS Foundation Trust, or someone with an honorary clinical contract. If not directly supervised, a letter of access will be required and a standard DBS and occupational health clearance should be confirmed.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
. • The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

HH/FM/PID:12217

[redacted]

Mr Michael Mawhinney
Oxford Brookes University
Marston Road Campus
Jack Straw's Lane
OX30FL

Dear Mr Mawhinney,

06 October 2016

Re: Optimising the care of patients receiving oral systemic anti-cancer treatments: a mixed methods study
IRAS Reference: 204177
Research and Development Reference: 12217
Research Ethics Committee Reference: 16/NW/0586

Confirmation of Trust Management Approval

On behalf of the [redacted] Trust, I am pleased to confirm Trust Management Approval and Indemnity for the above research on the basis described in the application, protocol and other supporting documents.

Conditions of Approval

Your attention is drawn to the attached conditions of approval. Breach of these conditions may result in Trust Management Approval being revoked.

Recruitment

The agreed total recruitment target for your study at the OUH site is 100 participants by 01 September 2017.

Your first participant recruitment target date is 12 December 2016.

To support [redacted] and national recruitment targets, R&D will monitor and publish recruitment for your study: 1. Performance against the 70 calendar day period benchmark from the time of receipt of a valid research application in R&D to the date of recruitment of first participant to your study; and for interventional trials; 2. Recruiting planned participants to time and target. The R&D office will contact you to request recruitment progress against both targets. If you recruit your first participant into the study then please send the date t[redacted] If you miss this target you will be required to give reasons that can be reported to the DOH/NIHR.

[redacted] May 2016

HH/FM/PID:12217 [redacted]

In order to facilitate good communications and avoid unnecessary delays please copy all correspondence with the Research Ethics Committee (REC) to R&D, providing copies of all relevant documents.

Research Sponsorship

It is noted that Oxford Brookes University has agreed to Sponsor this trial.

Capacity and Capability Assessment

This Trust Management Approval letter also incorporates capacity and capability assessment for the [redacted] ust site.

Approved Documents

The documents approved for use at this trust are as listed in the:

Health Research Authority Approval Letter dated: 15 September 2016

Research Ethics Approval Letter dated: 27 July 2016

Study Staff

The CVs and GCP certificates of staff have been reviewed.

I wish you every success with the study.

Yours sincerely,

[redacted]

Head of Research Governance

Copy to:	Collaborator- Pharmacy:	nicola.stoner@ouh.nhs.uk
	Sponsor:	heabbott@brookes.ac.uk
	Supervisors:	vlavender@brookes.ac.uk ewatson@brookes.ac.uk
	[redacted]	

[redacted] May 2016

HH/FM/PID:12217

[redacted]

Standard Conditions of Approval b[redacted]
Foundation Trust for Research studies other than Clinical Trials of Investigational Medicinal Products or Medical Device Trials

Issued to Chief Investigators and Principal Investigators

1) **Commencement of the Study**

Before the study commences the Chief Investigator/Principal Investigator is responsible for the following:

a) Ensuring that all members of the research team are appropriately qualified to undertake their role(s) through education, training and experience

b) Establishing a Study Master File/Site File, which should be maintained throughout the study and be readily available to the study team.

c) Ensuring that all members of the research team who have access to patients, their organs, tissues, data or access to NHS staff, information and facilities h[redacted] substantive/honorary contracts or appropriate research passports/honorary research contracts/letters of access in place prior to their involvement in the study.

d) Ensuring that all appropriate approvals are in place and remain so for the duration of the study

e) Ensuring that all investigators in the study are aware of and comply with the Regulatory Framework surrounding research practice, which includes but is not limited to:
   - The Department of Health Research Governance Framework for Health and Social Care 2005
   - Mental Capacity Act 2005
   - The Human Tissue Act 2004
   - The Declaration of Helsinki 2000
   - The Human Rights Act 1998
   - The Data Protection Act 1998
   - ICH Good Clinical Practice 1996

2) **Conduct of the Study**

a) The study will be conducted according to the all applicable regulations, principles of Good Clinical Practice and [redacted]

b) The study will be conducted in accordance with the approved protocol.

c) Essential documents will be made available for audit and inspection purposes where required.

d) The Trust must be made aware of any Intellectual Property that arises from the research study.

3) **Protocol Amendments**

a) Where t[redacted]taken on the role of Sponsor, investigators must submit protocol amendments to R&D Department **prior** to submission the Health Research Authority or Research Ethics Committee and MHRA, to assess any implications for the Sponsor.

b) All **substantial** amendments must be submitted to the appropriate Health Research Authority or Research Ethics Committee for approval. Documents should also be forwarded to the R&D Department for assessment as to whether the amendment affects Trust Management Approval.

c) In order for the Trust to meet its responsibilities under the Research Governance Framework **all amendments, including non-substantial amendments** must be submitted to R&D department. You should include all supporting documents.

d) Submission of substantial amendments will be acknowledged by a letter confirming on-going Trust Management Approval, non-substantial amendments will be acknowledged by email.

e) **NO** substantial amendment, except those that relate to an urgent safety measures, should be implemented until all appropriate approvals have been obtained.

4) **Change of key Site Personnel - Chief investigator/Principal Investigator**

a) Any change of nominated Chief investigator/Principal Investigator (e.g. due to relocation, maternity leave, retirement etc.) at th[redacted]should be notified to the R&D Department **immediately**; the host organisation needs to ensure any on-going studies have been reviewed and appropriate oversight is in place; or where needed studies have been terminated within the required timeframes.

b) All other changes in study staff should be maintained via a study delegation log.

5) **Safety reporting**

a) Appropriate safety reporting procedures will be agreed according to the perceived risks to study participants and/or the Trust. Any safety reporting requirements will be communicated in writing by the R&D Lead to the Chief/Principal Investigator.

[redacted]

6) **REC Annual Progress Reports and Monitoring of the Study**

a) The Chief Investigator should ensure that the REC Annual Progress Reports are completed and submitted in a timely manner on each anniversary of the REC Approval, and copied to R&D.

b) The need for on-site monitoring of the study will be assessed according to risk to study participants and/or the Trust. Any special requirements will be communicated to the Chief Investigator/Principal Investigator in writing.

c) The Trust may audit a number of hosted CTIMPs and interventional studies.

7) **NIHR and NHS Quality Accounts**

a) The Trust is obliged to submit data to the Department of Health annually. The Chief Investigator/Principal Investigator must provide to R&D department in a timely manner, such information about the study as to enable to Trust to meet its obligations.

b) In particular the Chief Investigator/Principal Investigator will forward the first participant recruited date to R&D department by emailing the information to the email address provided in the NHS permission letter.

c) In addition the Chief Investigator/Principal Investigator will update the R&D department periodically throughout the life time of the trial on trial progress including on-going recruitment data and changes in the status of the trial.

8) **Conclusion of the Trial**

a) The Trust R&D Department should be informed within 60 days of the close of the study and a final report provided.

b) If the study is stopped early, the Trust R&D Department should be informed within 30 days outlining the reasons.

9) **Termination of Trust Management Approval**

a) The Trust reserves the right to revoke Trust Management Approval or Sponsorship for any project that is not conducted according to Trust policy or the applicable regulatory or legal framework. However, any such action will not be taken without prior discussion with the R&D Lead and/or the Medical Director together with the Chief or Principal Investigator. Furthermore, all researchers undertaking research at the Trust are subject to the Misconduct and Fraud Policy.

All Trust policies for the conduct of research within the organisation can be found at

[redacted]

[redacted]May 2016

Appendix 6 – Health professional consent form

OXFORD BROOKES UNIVERSITY

[redacted]

FREC study number: 2015/20
IRAS: 11707

Health Professional Consent Form

Optimising the care of patients receiving oral systemic anti-cancer treatments: the clinician's view

Please initial if you agree with the following statements:

	Please initial
1. I confirm that I have read and understand the information sheet for the above study, that I have had the opportunity to ask questions and have had these answered satisfactorily as required.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason.	
3. I agree to be interviewed.	
4. I understand that the interview would be audio-recorded	
5. I agree to take part in the above study.	

Please circle yes or no in response to the following statements:

	Please circle
6. I understand that by taking part, I am agreeing that the researchers may use anonymous extracts from the transcripts of my audio recording in publications and presentations about the findings of this study.	Yes No
7. I agree that my data gathered in this study will be stored (after it has been anonymised) in Oxford Brookes University and may be used for future research.	Yes No
8. I give consent for the research team to share anonymised written and recorded material collected in this study with other researchers.	Yes No

Please turn over ...

Project title: Optimising the care of patients receiving oral systemic anti-cancer treatments: the clinician's view
Version 1.1 04.11.2015

FREC study number: 2015/20
IRAS: 11707

Name (please print): _____

Signature: _____

Date: _____

Researcher taking consent (please print): _____

Signature: _____

Date: _____

Project title: Optimising the care of patients receiving oral systemic anti-cancer treatments: the clinician's view
Version 1.1 04.11.2015

Appendix 7 – Patient consent form

IRAS reference number: 204177

OXFORD BROOKES UNIVERSITY

[redacted]

Participant Consent Form

Optimising the care of patients receiving oral systemic anti-cancer treatments: the patient's view

Please initial if you agree with the following statements:	Please initial
1. I confirm that I have read and understand the information sheet for the above study, that I have had the opportunity to ask questions and have had these answered satisfactorily as required.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason.	
3. I agree to be interviewed.	
4. I understand that the interview would be audio-recorded	
5. I agree to take part in the above study.	

Please circle yes or no in response to the following statements:	Please circle	
6. I understand that by taking part, I am agreeing that the researchers may use anonymous extracts from the transcripts of my audio recording in publications and presentations about the findings of this study.	Yes	No
7. I agree that my data gathered in this study will be stored (after it has been anonymised) in Oxford Brookes University and may be used for future research.	Yes	No
8. I give consent for the research team to share anonymised written and recorded material collected in this study with other researchers.	Yes	No

Please turn over ...

Project title: Optimising the care of patients receiving oral systemic anti-cancer treatments: the clinician's view
Version 1.3 08.09.2016

IRAS reference number: 204177

Name (please print):_____

Signature:_____

Date:_____

Researcher taking consent (please print):_____

Signature:_____

Date:_____

Contact details for Michael Mawhinney
Tel: 01865 482 697
Fax: 01865 482 775
Email: 14110227@brookes.ac.uk

Please photocopy providing a copy for the patient and a copy for the site file

Project title: Optimising the care of patients receiving oral systemic anti-cancer treatments: the clinician's view
Version 1.3 08.09.2016

Appendix 8 – Patient study invitation letter

Study Invitation Letter 1 Version 1.0 09.03.2016

[redacted]

OXFORD BROOKES UNIVERSITY

Research Ethics Committee Study Number: 16/NW/0586
IRAS ID: 204177

13.09.2016

Reference: Optimising the Care of Patients Receiving Oral Systemic Anti-Cancer Treatments: the patients view

You are being invited to participate in the above study, because you have attended the oral education clinic at the [redacted]. The aim of this study is to evaluate the oral education clinic to identify how well it meets the needs of people taking oral anti-cancer medication and where patient care could be improved. This study also aims to inform guidelines on how the care of people taking oral anti-cancer medication should be managed.

The research team on this study are Michael Mawhinney, who is conducting this study as part of his PhD at Oxford Brookes University, and Michael's PhD supervisors, Professor Eila Watson and Dr Verna Lavender. This study is being conducted in collaboration [redacted].

A patient information sheet is included with this letter, which contains more details about this study and what it would involve if you wished to take part. Involvement in the study is entirely voluntary. If you decide not to participate in the study your care will not be affected in any way. If you do decide to participate you can withdraw at any time without giving any reason.

If you have any further questions that have not been answered in the patient information sheet, please do not hesitate to contact me for further information. Thank you for taking the time to read this letter.

Yours sincerely,

Michael Mawhinney MSc BSc (Hons) RN
PhD student
Oxford Brookes University

Professor Eila Watson, PhD
Professor of Supportive Cancer Care
PhD Co-Director of Studies
Oxford Brookes University

Dr Verna Lavender, PhD, PGCE, BSc(Hons), RGN
PhD Co-Director of Studies
Senior Lecturer in Cancer Care

FACULTY OF HEALTH AND LIFE SCIENCES

Jack Straw's Lane Marston Road
Oxford OX3 0FL UK

T +44 (0) 1865 482967
M +44 (0) 7XX XXXXXX
F +44 (0) 1865 482775
Michael.mawhinney-2015@brookes.ac.uk

Appendix 9 – Patient participant information sheets

IRAS reference number: 204177

[redacted]

OXFORD BROOKES UNIVERSITY

Study title: Optimising the Care of Patients Receiving Oral Systemic Anti-Cancer Treatments: the patient's view (by questionnaire)

Introduction and invitation

My name is Michael Mawhinney and I am a PhD student at Oxford Brookes University. In association with the [redacted] we are conducting a research study about patients receiving oral anti-cancer medicines. This study will contribute towards my PhD thesis.
Thank you for considering taking part. Before you decide, it's important to understand why the research is being done and what it will involve.

Please take time to read the following information explaining the study and your involvement within it. Contact us if anything is not clear, you would like more information, or to receive this information sheet in a larger font.

What is the purpose of the study?

In recent years use of oral cancer medicines has increased. Oral cancer medicines can cause side effects that are as serious as when chemotherapy is given through a vein. Because patients prescribed oral cancer medicine take it at home, it's important for them to understand what the side effects are and what to do if they have them. For these treatments to be given safely, the hospital provides education about oral cancer medicines, how they should be taken, and what to do if they have side effects.

One of the aims of this study is to find out what people taking oral anti-cancer medicines who have attended the education clinic think and feel about the education received and how it has helped them manage their medications and side effects. Information will be collected by two questionnaires and 30 patients will be invited to interview. Participants will be recruited to the study over a period of approximately 18 months.

Why have I been invited to participate?

You are being invited to participate in this study because you attended the oral pre-chemotherapy education clinic. We will be asking more than 100 people who have attended the clinic to answer questionnaires, and from those people we would like to invite approximately 30 participants to be interviewed. The interviews can be conducted at the

hospital to coincide with an appointment, at Oxford Brookes University or in your own home.

Do I have to take part?

Your involvement with this study is entirely voluntary and will not affect the care you receive in anyway. Your choice to participate or not will have no impact on the academic assessments of the PhD student or their future studies.

What will happen to me if I take part?

You would complete the questionnaire (entitled 'Questionnaire 1') you received with this document and return it in a reply paid envelope. At the end of questionnaire 1 you will find a space to record your contact details. This is so we can post you a second questionnaire in 6 weeks' time along with some information about the potential of participating in an interview.

Your contact details will be detached from your questionnaire on receipt and your answers will be kept with your name removed.

The first questionnaire should take no longer than 30 minutes and is designed to explore your thoughts and feelings about your oral anti-cancer treatment and the education appointment you attended. If you come across any questions you would rather not answer, please feel free to leave blank and move on to the next question.

The second questionnaire will be sent to you after approximately 6 weeks and is designed to explore your experience of taking your medications at home. This questionnaire will be similar to the first and take approximately the same amount of time.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part in this study. However, the information you provide will be used to inform how people taking oral medication for their cancer are cared for.

What are the possible disadvantages of taking part?

Discussing your cancer treatment and care can be challenging and answering questions either by questionnaire or interview may be distressing. We have sought to minimise the risk of participation, but appreciate there is time involved in completing the questionnaire and returning it by post. If any distress has been caused by participation, please contact [redacted]

Will what I say in this study be kept confidential?

All information collected about participants in this study will be kept strictly confidential subject to legal limitations. The data will be kept with your name removed. Data collected from you will be assigned a random number and can only be traced to you by the researcher. Your data will be kept at Oxford Brookes University in accordance with the University's policy on Academic Integrity for a period of 10 years, after which point it will be destroyed.

What should I do if I want to take part?

If you wish to participate in this study, please complete the questionnaire found in this pack. Instructions on completing the questionnaire can be found at the front of the questionnaire form. These documents can be returned via the reply paid envelope.

What will happen to the results of the research study?

Once the collected information has been de-identified it will be analysed and reported as a PhD thesis. Results will be discussed at research conferences and reported to NHS staff at the Churchill Hospital. Publications from the research will also be published in appropriate health care and nursing journals. Should you wish to read a copy of published work, please get in touch with the Department of Applied Health and Professional Development at Oxford Brookes University who will be able to provide a copy on 01865 482 565.

Who is organising and funding the research?

This research is being conducted at Oxford Brookes University under the supervision of Professor Eila Watson and Dr Verna Lavender. This study has been funded by the Department of Applied Health and Professional Development via an Oxford Brookes University PhD studentship.

Who has reviewed the study?

This study has been discussed and reviewed with a patient representative who has received cancer treatment. Questionnaires were also reviewed and tested by several patients receiving cancer treatments. It has also had approval from the Faculty Research Ethics Committee at Oxford Brookes University, a National Research Ethics Service and been granted NHS R&D permission.

Contact for Further Information

Should you have any further questions about the study, please do not hesitate to get in touch with Michael Mawhinney or Dr Verna Lavender, contact details can be found below.

Michael Mawhinney (student)	*Dr Verna Lavender (supervisor)*
Tel: 01865 482 697	Tel: 01865 483 921
Fax: 01865 482 775	Fax: 01865 482 775
Email: 14110227@brookes.ac.uk	Email: vlavender@brookes.ac.uk

If you have any concerns regarding how this study has been conducted please contact the Chair of the Faculty Research Ethics Committee, Hazel Abbott at Oxford Brookes University on heabbott@brookes.ac.uk

Thank you

A sincere thank you for taking the time to read this information sheet.

This next participant information sheet is a second version, which was sent along with questionnaire 2, 6 weeks after a respondent had returend questionnaire 1.

IRAS reference number: 204177

[redacted]

OXFORD BROOKES UNIVERSITY

Study title: Optimising the Care of Patients Receiving Oral Systemic Anti-Cancer Treatments: the patient's view (by questionnaire and interview)

Introduction and invitation

My name is Michael Mawhinney and I am the PhD student at Oxford Brookes University who is running the study you have previously completed a questionnaire for.
This information sheet gives you a bit more information about completing questionnaire 2 and participating in an interview about your experience of taking your anti-cancer medication.

Please take time to read the following information explaining the study and your involvement within it. Do contact us if there is anything that is not clear or you would like more information about or would like the text in a bigger font.

What is the purpose of the study?

One of the aims of this study is to find out more about the experience of patients taking an oral anti-cancer medication.

Why have I been invited to participate?

You are being invited to participate in this study because you attended the oral pre-chemotherapy education clinic and previously completed a questionnaire about your experience.

Do I have to take part?

Your involvement with this study is entirely voluntary and will not affect the care you receive in anyway. Your choice to participate or not will have no impact on the academic assessments of the PhD student or their future studies.

What will happen to me if I take part?

If you decide to take part, you would complete and return questionnaire 2 using the enclosed reply paid envelope. At the end of 'Questionnaire 2' there is a box to indicate if you are willing to be interviewed. If you tick this box, Michael will get in touch to arrange

an interview time convenient for you. This interview will be audio recorded and last approximately 45 minutes. It can be conducted at [redacted] at Oxford Brookes University or in your own home.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part in this study. However, the information you provide will be used to inform how people taking oral medication for their cancer are cared for.

What are the possible disadvantages of taking part?

Discussing your cancer treatment and care can be challenging and answering questions in your interview may be distressing and this would be a disadvantage of taking part. We have sought to minimise the cost of participation, but appreciate there is time involved in completing the questionnaire and returning it by post. If you decide to participate in an interview at the hospital or Oxford Brookes University this does take time and involve travel expenses. If any distress has been caused by participation, please contact Eliz Flanagan, lead chemotherapy nurse on number 0300 304 7777.

Will what I say in this study be kept confidential?

All information collected about participants in this study will be kept strictly confidential subject to legal limitations. The data will be anonymous, and therefore, your name will not be used. Data collected from you will be assigned a random number and can only be traced to you by the researcher. Your data will be kept at Oxford Brookes University in accordance with the University's policy on Academic Integrity for a period of 10 years, after which point it will be destroyed.

What should I do if I want to take part?

If you wish to participate in this study, please complete the questionnaire found in this pack. Instructions on completing the questionnaire can be found at the front of the questionnaire form. At the end of the questionnaire, you can indicate if you are willing to be interviewed and Michael will be in touch to arrange a time convenient for you to complete the interview. Your questionnaire can be returned via the reply paid envelope. The consent form included needs to be completed prior to your interview, which can be immediately prior to your interview. You do not need to return the consent form. If you sign it beforehand please remember to bring with you to your interview. Michael will also bring a blank copy of the consent form to the interview if you wish to sign your consent immediately before the interview and do not have a form with you.

What will happen to the results of the research study?

Once the collected information has been de-identified it will be analysed and reported as a PhD thesis. Results will be discussed at research conferences and reported to NHS staff at [redacted] Publications from the research will also be published in appropriate health care and nursing journals. Should you wish to read a copy of published work, please get in touch with the Department of Applied Health and Professional Development at Oxford Brookes University who will be able to provide a copy on 01865 482 565.

IRAS reference number: 204177

Who is organising and funding the research?

This research is being conducted by a PhD student at Oxford Brookes University under the supervision of Professor Eila Watson and Dr Verna Lavender. This study has been funded by the Department of Applied Health and Professional Development via an Oxford Brookes University PhD studentship.

Who has reviewed the study?

This study has been discussed and reviewed with a consumer research group, which includes patients of a local NHS Trust. It has also had approval from the Faculty Research Ethics Committee at Oxford Brookes University, a National Research Ethics Service and been granted NHS R&D permission.

Contact for Further Information

Should you have any further questions about the study, please do not hesitate to get in touch with Michael Mawhinney or Dr Verna Lavender, contact details can be found below.

Michael Mawhinney (student)	*Dr Verna Lavender (supervisor)*
Tel: 01865 482 697	Tel: 01865 483 921
Fax: 01865 482 775	Fax: 01865 482 775
Email: 14110227@brookes.ac.uk	Email: vlavender@brookes.ac.uk

If you have any concerns regarding how this study has been conducted please contact the Chair of the Faculty Research Ethics Committee at Oxford Brookes University, Hazel Abbott on heabbott@brookes.ac.uk.

Thank you

A sincere thank you for taking the time to read this information sheet.

Appendix 10 – Patient interview schedule

Optimising the care of patients receiving oral systemic anti-cancer treatments: the patient's view

Interview Schedule

Introductions:

- *Before we begin, can I confirm you have received the information about this study?*
- *We have gone through the consent form together, did it all make sense ok?*
- *The session will be audio-recorded; I will then write that up into a transcript and erase the recording.*
- *We can stop the interview at any time, so if you need a break or you want to stop that's no problem.*
- *I'll cover several different topic areas, but these are all questions about your experience so it's more like a conversation between us, there is no right or wrong answer.*
- *Before we begin, do you have any questions?*

Topic	Question	Prompts
Background	Can you give me a little bit of background about your cancer diagnosis and treatment so far? Drug name:	Treat as ice breaker Conversational
Chemotherapy	Before you started any treatment for your cancer, what did you think of chemotherapy? Did you choose whether to have a tablet or drip/infusion? So in your own words, what's your understanding of how your tablets work? Some patients have said before they felt increased responsibility taking an oral treatment. Do you ever feel like that?	 Why? Given a choice? To explore perceived effectiveness. Explore why?
What it's like taking chemotherapy	Okay, so you're letting me talk to you today because you're taking (tablet name) … What did you feel when you heard your treatment was going to be a tablet? Can you tell me a bit about your experience of taking a tablet to treat your cancer?	Explore why? What has been challenging? Advantages? disadvantages? Surprises? Expectations?
Oral Education Clinic	I'm going to ask you a bit about the oral education appointment, this will be the appointment with a	What was it like? What was good? Why?

	pharmacist or nurse where you talked about your cancer tablet. I'm really interested to hear about your experience of this appointment? Is there anything else you would have liked at this appointment? Were you bothered or fussed about whether you were seen by a doctor, nurse or pharmacist for this appointment?	More information? Why?
Managing at home	How has managing your tablets at home been for you? It's very common for people to forget to take a medicine sometimes. Have you ever forgotten to take one of your cancer tablets? Does remembering or forgetting to take the tablets cause any anxiety? Has anyone supported you in remembering to take your tablets? Are there other reasons than forgetting to take a tablet, when you have not had your tablet as instructed? Have you had any side effects from your treatment? What do you think it's been like for your family/carers whilst you've been taking … (cancer tablet)? Do you think there are ways the hospital might support you and your family/friend better? How do you feel about a pharmacist or nurse phoning you to check in and see how you're getting on with treatment?	Storage? Missing a dose? New prescription? Why? What helps? What do you do if you've forgotten one? Report to nurse/pharmacist? Family? Friends? HCP's? Carers? Why? Which? How severe? How did you manage? Did you seek help? Admission? Dealing with diagnosis, appointments, meal times, help managing side effects? More contact? More support? Can you tell me more about that? Why? How often? Requested? District nurse? Proactive GP? Relationship? Trust? GP? Hospital? Explore decision making re help seeking

	Have you had any help from your GP or GP surgery? If unwell, who would be the person you would contact? Would you have liked more help from your GP or GP surgery, including a practice nurse or district nurse?	behaviour What and why?
Resources	At your oral education appointment you were probably given some written information. Can you remember what you were given to read? Has this been helpful?	 Why? Used it much? Red book? Diary?
Future care	I'd be interested to know what you think about hospitals and GP surgeries using things like the internet and e-mail, for example to provide information and keep in contact with you. Do you have access to or use the internet? What do you mostly use the internet for? How would you feel about contacting your doctor/nurse/pharmacist through the internet? Do you have a smart phone or tablet where you can download apps? How would you feel about completing a diary on an app that the healthcare team could then review?	If no, why? IT friendly? Sensory/visual impairments? Too tired? Internet savvy? Frequency of use? E.g. looking up cancer information Like email, Facetime, Skype If no, why? Smartphone technology? Understanding of apps? Reason for answer? How often to update?
Finally	LAST question ☺ Is there anything that I've not asked you about your experience of taking cancer tablets that you would like to talk about? Anything else?	

"Well, you'll be pleased to hear I'm sure we're all done. Thank you so much for your time and for agreeing to take part in this study, your comments are so valuable."

Appendix 11 – Questionnaire 1 evaluation page

Oxford University Hospitals NHS
NHS Foundation Trust

OXFORD BROOKES UNIVERSITY

Please indicate how easy it was to complete this questionnaire: (please circle)

1	2	3	4	5	6	7	8	9	10
Very difficult									Very easy

Can you suggest any ways in which this questionnaire could be improved?

Many thanks,

Michael Mawhinney

Appendix 12 - Themes and sub-themes derived from coding patient interview data

Cancer and its treatment has an impact that needs to be coped with

- Asked for treatment to be put off
- Cancer never goes away
- Cancer treatments are terrible
- Challenges in discussing sex
    - Importance of talking about sex
    - No education given about sex
- Chemotherapy becomes normalised after a while
- Coping strategies
    - Acceptance
    - Activities
    - Attitude of living life
    - Busyness
    - Control
    - Distraction
    - End goal
    - Exercise
    - Families support
    - Getting on with it
    - Hope
    - Mindset of you've just go to do it
    - Positive view
    - Switching off
    - Taking a break
    - Taking each day as it comes
    - Timeline
    - Trust in HP's
    - Use of a diary
- Describing difficulty of working during cancer treatment
- Describing experience with combination chemotherapy
- Describing side effects of immunotherapy
- Emotional aspects of cancer affecting cognition
- Emotional impact of having cancer
- Expectation a new treatment will work
- Fed up with cancer treatments
- Imaginings what chemotherapy would be like
- Impact of animals on psychological coping
- Importance of body image
- Importance of family on wellbeing
- IV SACT was quite an event
- Life with cancer
- Perception of cancer

- Perception of chemotherapy
- Perception of IV treatments
- Shock of diagnosis
- Stress affecting cognition
- Such a fuss with IV SACT it feels there's more to it
- Thoughts of death

How a person responds to cancer and its treatments is dependent on their personal attributes

- Age effecting memory
- Age impacting view of doctors
- Age impacting views of oral SACT
- Cannot hear on telephone
- Doesn't want too much information on own cancer
- Everyone is individual
- Expert in cancer treatments
- Never been to a doctor
- Never forgotten to take oral SACT as anally retentive
- Older people living longer
- Past experience informing how to manage side effects
- Past experience of chemotherapy as measure for experience of side effects
- Patient needs to have right expectations
- Perceptions on person-centred care
- Personally adapted to routines, oral SACT not extra responsibility
- Professional background informing how to manage treatment
- Unable to share with family
- Views on alternative medicine
- Health seeking behaviours
    - Answer machine can be off-putting
    - Contact CNS or triage for help
    - Continuing oral SACT against medical advice
    - Deciding when to seek help
    - Delayed reporting problems until next medical review
    - Delaying seeking advice
    - Describing reluctance to health seeking behaviour
    - Difficult to know when to seek help
    - Little information on when to seek help
    - Little niggles not work bothering anyone about
    - Not given on advice on when to seek help
    - Rather battle on than seek help or explanation
    - Reasons for reluctance to acknowledge problems
    - Reluctant to report problems as doesn't want to stop treatment
    - Reluctant to report problems as health professional appears busy or distracted
    - Reluctant to report side effects as hope they will resolve
    - Seeking help for signs of disease progression rather than side effect occurrence
    - Unsure who to contact to ask questions
    - Will seek help if required

  - Would contact hospital over GP
  - Would contact pharmacy for assistance with side effects

Experiences of the healthcare system are mixed

- Accessibility
  - Early inpatient discharge on a Friday ineffective
  - Hardship in navigating the system
  - Hospital accessible
  - Parking difficulties
- Administration
  - Accepts time delays as experience of being a cancer patient
  - Appointments often delayed
  - Cannot hear on telephone
- Decision making
  - Describing experience with MDT
  - Emotional experience of decision making
  - Historically health professionals told you what to do, now you have a choice
  - Involvement in treatment
  - Preference to doctors making treatment decisions
  - Process in treatment decision making
  - Wasn't given a choice of treatments
- Follow-up (medical review with doctors)
  - Amount of follow-up about right
  - Patient led regular reviews
- Perceptions of health professionals
  - Consultant lovely
  - Difference in talking to nurse or pharmacist vs oncologist
  - Doctors should focus on medical side of consultation for better time management
  - Experience of seeing different doctors
  - Health professionals should be more upbeat
  - Lack of compassion in health professionals
  - Meeting nurses can be disorganised
  - Non-cancer specialists lack knowledge re cancer
  - Nurses and pharmacists well positioned to answer queries
  - Oncologist not picking up on minor side effects
  - Perception health professionals fearful of lawsuit
  - Perception hospital staff don't have much time
  - Pharmacist less used to dealing with people
  - Pharmacist researched drug interactions, reassuring
  - Pharmacist was confident and knowledgeable
  - Pharmacist was good
  - Positive view of health professionals in NHS
  - Positive views of NHS
  - Seeing different oncologist
  - Would like to see same oncologist
- Views of the hospital

  - Authoritarian view of hospital
  - Care closer to home
  - Comparing administration in study site to another acute cancer centre
  - Comparing private care and NHS care
  - Describing benefits of attending hospital
  - Hospital accommodating with work
  - Hospitals always call back if enquiry made
  - Hospital environment feels safer
  - Hospital gives good support
  - Impact of hospital environment
  - Positive view of hospital
  - Some hospital appointments could be done over the phone
  - View the hospital is inefficient
- Views of the NHS
  - Learning how to be an NHS user
  - NHS is at maximum capacity
  - NHS overworked
  - Perceptions on funding within the NHS

<u>The manner by which information is exchanged is important</u>

- Communication
  - Communications of hospital to GP
  - Describing a positive encounter with a consultant
  - Describing good communication skills
  - Describing talking to a consultant
  - Inconsistent communication styles between oncologists
  - Oncologist has good communication skills
  - Poor inter-hospital communication
- Individual information experiences
  - Importance of being informed about oral SACT
  - Making notes helps memory
  - Not interested in how tablets work
  - Only reads information on what individual needs to do
  - Reluctant to share info with family to prevent worry
  - Reluctant to share information with doctors
  - Wants to know minimum information
  - Would rather know information than not know
- Information overload
  - Bombarded with information
  - Doesn’t need to know all information given
  - Receives too many hospital letters
- Misinformation
  - Conflicting information about oral SACT
  - Conflicting information becomes confusing
  - Impact of conflicting information
  - Lack of information on oral SACT and prognosis

    - Misheard information
    - Misinformation because didn't take notes
    - Missed written information
    - More information needed on oral SACT
    - Not sure how to tell if oral SACT working well
    - Unclear information
    - Unclear on food interactions
    - You don't know what you don't know
- Receiving information
    - Disease well explained
    - Doctors don't mind patients asking questions
    - Glad of clear information
    - Impact of repeating information
    - Oncologist only focuses on cancer
    - Physical feeling effecting cognition
    - Receiving right amount of information from hospital
- Seeking information
    - Accessing videos on internet for information helpful
    - Careful about searching the internet for information
    - Forget questions when meeting health professionals
    - Hospital staff welcome any questions or enquiry
    - Independent researching for information
    - Information on internet not always authoritative
    - Prepared with questions
    - Questions only thought of after meetings
    - Using the internet to find information
- Tailored information
    - Oncologist talks to you as a person
    - Personal conversation gives feeling of being care for
- Timing of information
    - Time needed to formulate questions
    - Time needed to process information
    - Would like information as early as possible to prepare questions
- Written information
    - A lot of paper work, less inclined to look at it
    - Disadvantage to written information
    - Doesn't refer back to written information
    - Format of written information, would like a bullet point format
    - Given information before OEC helpful
    - Given loads of written information
    - Good to have written information to take away
    - Keeps written information close to hand
    - MRC helpful at beginning to refer back to
    - Preference for technology over paper
    - Referring back to written information
    - Right amount of written information
    - Would like a newsletter
    - Written information about possible risks

- Written information complements technology
- Written information duplicated
- Written information easy to read
- Written information given in stages, not bombarded
- Written information helpful for family
- Written information helpful for other non-cancer health professionals
- Written information informing what to do in event of nonadherence
- Written information personalised
- Written information used to check anything

Patient experience of the OEC

- Attendance of others
  - Another person would be helpful at OEC
  - Attending OEC alone
  - Clear expectations of OEC so can attend alone
  - Families experience of OEC
  - OEC easier with someone there
  - Third party helps remember information at OEC
- Education
  - Aspects of education lacking
  - Comparing OEC to previous education
  - Desire to leave hospital impacting on receiving education
  - Doctor explaining oral SACT before OEC
  - Education adding stress
  - Education at OEC given too quick
  - Education easy to follow
  - Education not clear
  - Education not tailored to patient needs
  - Education on alcohol
  - Education on exercise
  - Education on side effects
    - Deadened to hearing about side effects
    - Describing experience of education on potential side effects
    - Good to hear about potential side effects
    - No education on managing side effects
    - Education on side effects explained as could happen
    - Education on side effects tailored to the individual
  - Education on alcohol
  - Education tailored to the individual
  - Expectations for education before starting oral SACT
  - Feels OEC repeating information that is already known
  - Impact of fear on receiving education
  - Importance of emphasising learning points
  - No education on contraindications
  - OEC information all more practical
  - Oral SACT very clearly explained

    - Perception that age of health professional giving education relates to their experience
- Face to face vs telephone education
    - Describing telephone OEC appointment
    - Face to face communication preferred
    - No choice for telephone or face to face OEC
    - No preference for telephone vs face to face education
    - Preference for face to face education
    - Preference toward telephone OEC appointment
- OEC Facilitator
    - Describing interactions with OEC educator
    - No preference for nurse or pharmacist at OEC
    - Nurse appropriate to deliver OEC
    - Nurse or pharmacist equally reassuring in the OEC
    - Perception OEC staff didn't have enough time
    - Perception OEC staff inexperienced
    - Pharmacists role in OEC
    - Preference to pharmacist doing OEC as they are in the world of drugs
    - Preference toward nurse for OEC
    - Success of OEC down to the individual
- Questioning
    - Couldn't ask questions at OEC
    - OEC, opportunity to ask questions
    - Questions answered before they're asked
    - Questions being answered at OEC
- Remembering information
    - Challenges in assessing patient understanding
    - Difficulty remembering OEC education
    - Felt need for follow-up conversation
    - Knowledge after OEC appointment
    - Misinformation at OEC
    - Remembering information from OEC
    - Risk of information overload at OEC
- Suggested improvements
- Understanding of OEC
    - Unsure what to expect from the OEC
- Views of OEC
    - Attitude towards OEC appointment
    - Burden of attendance
    - Describing the OEC appointment
    - Got all information needed at OEC
      Helpful treatment couldn't start until OEC
    - OEC a good way to provide support
    - OEC appointment disorganised
    - OEC convenient
    - OEC daunting
    - OEC effective way of starting people off on an oral SACT

- OEC venue comfortable
- OEC was positive and straight forward

Experiences with Oral SACT ([reorganised]Oral SACT compares favourably to intravenous SACT)

- Adapting oral SACT regimen
  - Adapting oral SACT regimen to make it easier
  - Changing oral SACT regimen to help manage side effects
  - Some lifestyle changes as a result of taking oral SACT
- Adherence
  - Alarm reminder to take oral SACT
  - Alarm reminders promote adherence
  - Change in routine leads to nonadherence
  - Contact hospital if non-adherent
  - Decreasing side effects increasing risk of nonadherence
  - Describing what to do if dose forgotten
  - Difficult to remember a tablet 3 times a day
  - Doesn't use dosette box
  - Dosette box as a visual aid
  - Dosette box as convenient
  - Dosette box helps adherence
  - Family help with adherence to oral SACT
  - Forgot to take tablet as out for meal
  - Friends help with remembering to take oral SACT
  - Importance of developing a routine with oral SACT
  - Independent with remembering to take oral SACT
  - Managing a non-adherence event
  - MRC helps you not to forget what to take
  - No nonadherence episodes
  - No stress or anxiety in remembering to take oral SACT
  - Nonadherent event due to forgetfulness
  - Strategies to remember oral SACT
  - Tablets labelled as what day to take helps with adherence
  - Using alarms as reminders for medication
  - Visual aid to remember oral SACT
- Advantages of oral SACT
  - Excited by oral SACT as no need for needles
  - Happy with oral SACT provided efficacy
  - Oral SACT convenient
  - Oral SACT described as effective by doctor, reassuring
  - Oral SACT easier for both patient and family
  - Oral SACT easy to manage at home
  - Oral SACT is a relief
  - Oral SACT more convenient
  - Oral SACT nice to be at home and in control
  - Oral SACT prevents need for surgery
  - Oral SACT promotes autonomy
  - Oral SACT provides control

    - Oral SACT provides more time at home
    - Oral SACT too easy somehow
    - Oral SACT you can take it and then forget about it
- Choice and oral SACT
    - Difficulty in finding right treatment for patient
    - Given choice of treatment options
    - Own choice of treatment impacting experience
    - Potential side effects direct choice of treatments
- Comparing oral SACT and IV SACT
    - IV SACT feels definite, taking tablets is a different feel
    - More personal safety measures for IV than oral SACT
    - Oral SACT hasn't medical paraphernalia around ti like IV has
    - Oral SACT less medicalised than IV
    - Perception IV treatment is stronger
    - Perception oral SACT administration costs less
    - Preference for infusion over oral SACT
    - View oral SACT differently to standard chemotherapy
    - Worry about adherence and effectiveness with oral SACT, not with an IV
- Disadvantages of oral SACT
    - Oral SACT stressful for family
    - Worried about swallowing oral SACT
- Getting a new supply
    - Collect oral SACT from hospital as assumed to live nearby
    - Ease of getting a new prescription
    - Getting a new prescription is clumsy
    - Ideal would be pharmacy to contact patient to say new prescription ready
    - Not happy about getting a new supply of oral SACT
    - Oral SACT delivered on time
    - Patient has to be on the alert for when new oral SACT required
- Polypharmacy
    - Describing polypharmacy
    - Impact of polypharmacy
    - Many medications not difficult to manage
    - Polypharmacy, you just have to accept that
    - Responsibility attached to polypharmacy
    - Worried about drug interactions
- Responsibility of oral SACT
    - Confidence with oral SACT increases over time
    - No increase in stress or responsibility with oral SACT
    - Personal responsibility in taking an oral SACT
    - Planning involved with oral SACT
- Routine
    - Oral SACT fits into a daily routine
- Safety considerations
    - Careful of storage as child at home
    - Expressing need for an individual treatment card in case of emergency
    - Perception that family should be aware of medication taken by patient

- Starting regimen
    - Feelings of taking first oral SACT
    - Hard starting oral SACT
    - Keen to start treatment ASAP
    - Nervous starting oral SACT
    - Speed of starting oral SACT
    - Started oral SACT before OEC
- Oral SACT cost
    - Concerns about funding of oral SACT
    - Cost of drug increasing responsibility
    - Views on cost of oral SACT
- Views of oral SACT
    - Comparing oral SACT to any other tablet
    - More conscientious at start of taking oral SACT
    - No difficulty in swallowing oral SACT
    - Oral SACT a reminder of having cancer
    - Oral SACT as chemotherapy makes you feel rough
    - Oral SACT as position
    - Oral SACT gives perception cancer is not as serious
    - Oral SACT hard to pronounce
    - Oral SACT is important, makes it a priority
    - Oral SACT not viewed as chemotherapy
    - Past experience of treatment reducing anxiety of starting new oral SACT
    - Perception of effectiveness of oral SACT
    - Perception oral SACT minimal side effects
    - Perceptions on length of treatment with oral SACT
    - Preference towards oral SACT
    - Reaction to being told about oral SACT
    - Unaware SACT could be taken orally
    - Understanding of how oral SACT works
    - Views of oral SACT promotes adherence
- Life with oral SACT
    - Carry out a normal life when on oral SACT
    - Drinking water
    - Ease in taking oral SACT
    - Encouragement in use of dosette box as you see tablets disappear
    - Oral SACT are big tablets
    - Unclear how long to take oral SACT
- Managing oral SACT at home
    - Describing self management
    - Difficult to dispense oral SACT
    - Easy to manage oral SACT at home
    - Knowledge of what to do in event of missed dose
    - Storing oral SACT
    - Taking oral SACT with you out of home
    - What to do if drop a tablet at home
- Treatment toxicities

- Always tired
- Being vigilant for reporting side effects
- Brain fog as side effect of cancer
- Clinic advised how to manage side effects
- Describing experience of side effects
- Experience of managing tiredness
- Experience of peripheral neuropathy
- Experience of side effects leading to not wanting to take oral SACT
- Experience of toxicity effecting cognition
- Hospital slow to react to new symptom
- No advice given to manage tiredness
- No side effects, feels a fraud
- Not stopping oral SACT until told to stop
- Reluctant to acknowledge side effects as will effect life activities
- Reluctant to dose reduce
- Reluctant to restart oral SACT
- Should be prepared to manage side effects at home
- Side effects of oral SACT not dramatic compared to other drugs
- Strategies to manage side effects
- Tiredness unexpected
- Toxicity resulting in dose reduction
- Traffic light chart would be helpful for oral SACT patients
- Treatment toxicity – diarrhoea
- Treatment toxicity – mucositis
- Treatment toxicity – skin
- Treatment toxicity – tiredness
- Visual aid helps remember risk of side effects

Types of support desired

- Advice for other patients
- Clinical nurse specialist (CNS)
    - CNS breaking bad news
    - CNS channel of communication
    - CNS provides backup
    - CNS provides proactive monitoring
    - CNS source of information
    - CNS well identified and accessible
    - Contact CNS rather than GP
    - Contacting CNS not that helpful
    - Describing relationship with CNS
    - Difficult to contact CNS
    - Experience of first meeting CHS
    - Introduced to CNS at diagnosis
    - Less contact with CNS as managing well
    - Lucky to have a CNS
    - No CNS as on maternity leave

  - Not given a CNS
  - Perception CNS is busy
  - Put out due to change in CNS
  - Relationship with CNS
  - Role of CNS
- Diaries
  - Diary and or record perceived as waste of time
  - Diary not required after sometime as developed routine
  - Diary provides sense of control
  - Not using red chemotherapy diary
  - Preference for paper diary over technological
  - Red chemotherapy book more for health professional
  - To improve OEC provide a blank patient diary
  - Use of a diary to remember taking tablets
  - Use of diary promotes routine
  - Useful to keep a diary
  - Wouldn't want a chemotherapy diary
- Families and carers
  - Effect of cancer on family
  - Effects on family not guided by type of SACT
  - Family help manage treatments
  - Family involved in treatment
  - Family members helping process information
  - Family welcomed at appointments
  - Hospital does enough to support family
  - Hospital glad to see family members
  - Hospital not supporting family
  - Hospital supporting family might give added stress
  - Information overload helped by having someone there
  - Many appointments, family can't come to all
  - Organises medication by self, spouse as back-up
  - Reliance on partner to retain information
  - Spouse helps decision to seek help
- GP and community care
  - Age of GP effects how responsive they are
  - Describing experiences with practice nurse
  - DIffernet GP, no opportunity to build relationship
  - Difficult to get appointment with GP
  - During cancer treatment, overlook the GP
  - GP diagnosing cancer
  - GP diligent
  - GP doesn't have advanced communication skills
  - GP doesn't know about rarer cnacers
  - GP doesn't want to advise on cancer problems
  - GP follow-up
  - GP giving wrong advice
  - GP is not a specialist
  - GP is time limited

  - GP misdiagnosing – slow to diagnose
  - GP not associated with cancer related health
  - GP not hot on drug interactions
  - GP not involved, hospital supervising treatment
  - GP not reading patients note, disrespectful
  - GP records should hold alerts for their cancer patients
  - GP up to date by hospital letters
  - GPs don't consider cancer risk
  - GPs need education on oral SACT
  - Guilt in attending GP
  - Has to pressure GP for help
  - Hospital referring patient to GP
  - Hospital requesting GP to complete tasks
  - Health professionals advising seeing GP
  - Never see same GP
  - No sense of back-up from GP
  - Perceives GP to give wrong advice
  - Perspectives on community pharmacist
  - Poor perception of GP
  - Poor relationship with GP
  - Positive relationship with GP
  - Positive view of GP
  - Rarely visits GP
  - Role of the GP in cancer health
  - Seeing different GP
  - Slowness of GP practices
  - Some GPs use proactive monitoring
  - Suggesting to have one GP with more knowledge
  - Trust hospital more than GP
  - Would contact GP about cancer health
- Peer support
  - Choosing peer support over CNS for advice
  - Impact of peer support
  - Would like peer support of people on same medication
  - Would like to read about other patients experiences
  - Peer support helping treatment tolerance
  - Bonding with other patients quickly
- Support services
  - Aware of Maggie's but not required or wanted to use
  - Awareness of Maggie's
  - Awareness of support services available
  - Describing a Macmillan online support forum
  - Describing good community support
  - Describing poor experience with Macmillan
  - Describing reluctance to attend support groups
  - Good support from Maggie's entre
  - Lak of support services
  - No need to access support services

    - Nurses promoting Maggie's centre
    - Support group not positive
    - Support groups not required ass well supported
    - Use of a community emergency button
- Telephone follow-up
    - Assessing need for telephone follow-up
    - Comfort in telephone follow-up
    - Consultations need to be face to face, not by telephone
    - Initiative to come from patient as healthcare feels threatening
    - Patient knows best replaces need for telephone follow-up
    - Regularity of telephone follow-up
    - Telephone follow-up not particularly urgent or necessary
    - Telephone follow-up not required
    - Telephone follow-up opportunity to ask questions
    - Telephone follow-up required at the start, but not after treatment established
    - Telephone follow-up required for some
    - Telephone follow-up wouldn't do any harm
    - Would like telephone follow-up
- The use of technology
    - App helps with managing side effects
    - App might help recall
    - Contacting health professionals using technology
    - Describing experience with patient knows best
    - Describing experiences with a cancer monitoring app
    - Does hospital have capacity to manage electronic monitoring?
    - Email an efficient way to speak to people
    - Email hard to communicate
    - Feels too old to use apps
    - Has access to internet
    - Patient knows best as first channel of communication
    - Technology could be useful but might feel a nuisance
    - Technology only for essential information
    - Use of apps a good idea
    - Use of apps not for everyone
    - Views of prospect of video technology
    - Would use apps for cancer health
- Triage
    - Describing experience with triage
    - Not given triage number
    - Triage are friendly
    - Triage is personal
    - Unable to get through to triage

Appendix 13 - Health Professional Recruitment Poster

[redacted]

OXFORD BROOKES UNIVERSITY

'Optimising the care of patients receiving oral systemic anti-cancer treatments: the clinician's view'

- Are you a Doctor, Registered Nurse, pharmacist or pharmacy technician?
- Do you help manage the care of patients receiving oral systemic anti-cancer treatments?
- Are you willing to be interviewed about your experiences?

Then we want to hear from you! Oxford Brookes and OUH NHS Foundation Trust are collaborating in a project to identify ways to improve the care given to patients receiving oral systemic anti-cancer treatments. The interviews will take approximately 30 minutes at the Churchill site conducted by PhD student and OUH nurse Michael Mawhinney. Please contact Michael on 14110227@brookes.ac.uk for further information, or request an information sheet from [redacted]

We look forward to hearing from you,

Michael Mawhinney *MSc BSc (Hons) RN*
Doctoral Research Student Oxford Brookes University

Appendix 14 – Health professional participant information sheet

FREC study number: 2015/10
R&D number: 11707

[redacted]

OXFORD BROOKES UNIVERSITY

Study title: Optimising the Care of Patients Receiving Oral Systemic Anti-Cancer Treatments: the clinician's view

Introduction and invitation

My name is Michael Mawhinney and I am a PhD student at Oxford Brookes University. In [redacted]pital we are conducting a research study about patients receiving oral cancer medicines. This study will contribute towards my PhD thesis.
Thank you for considering taking part in this study. Before you decide, it's important to understand why the research is being done and what it will involve.

Please take time to read the following information explaining the study and your involvement within it. Please read this information sheet carefully and contact me if there is anything that is not clear or you would like more information about.

What is the purpose of the study?

In recent years use of oral cancer medicines has increased. Oral cancer medicines can cause side effects that are as serious as when chemotherapy is given through a vein. Because patients prescribed oral cancer medicine take it at home, it's important for them to understand what the side effects are and what to do if they have them. For these treatments to be given safely, the hospital provides education about oral cancer medicines, how they should be taken, and what to do if they have side effects.

One of the aims of this study is to find out what health professionals think and feel about the care given to patients receiving these oral treatments who have received pre-treatment education via a nurse/pharmacy lead clinic.

Information will also be collected from patients by questionnaires and interviews in the next phase of the research.

Why have I been invited to participate?

You are being invited to participate in this study because you have a professional role where you come into contact with patients receiving oral cancer treatments. We will be inviting approximately 20 people in various roles to attend an interview. The interviews can be conducted at the hospital at a time convenient for you or at Oxford Brookes University.

Do I have to take part?

Your involvement with this study is entirely voluntary. If you would like to take part, you should retain this information sheet and contact me on the contact details provided at the end to arrange an interview time. You are still free to withdraw from the study at any time and without giving a reason and any data you have supplied can be destroyed.

What will happen to me if I take part?

You will be asked to sign a consent form before taking part. A semi-structured interview will then take place.

The interview will take approximately 30 minutes in total, and will be audio-recorded with your permission. This interview will be conducted by Michael Mawhinney and can be done at your workplace, or at Oxford Brookes University.

The interview is designed to explore your thoughts and feelings on the care of patients receiving oral cancer treatments. It is therefore not a test of your skills or knowledge regarding these treatments, rather your thoughts and perspectives.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part in this study. However, the information you provide will be used to inform how people taking oral medication for their cancer are cared for.

What are the possible disadvantages of taking part?

We have sought to minimise the cost of participation, but appreciate there is time involved in participating in the interview. There may be a risk of distress if you have had negative experiences or encounters with patients taking oral medication for their cancer.
The interviewer, Michael Mawhinney, is also a registered nurse and therefore has a professional duty to report malpractice in the unlikely event this is discovered. In such an eventuality, the incidence of malpractice would be reported to the Haematology Oncology Matron.

Will what I say in this study be kept confidential?

All information collected about participants in this study will be kept strictly confidential subject to legal limitations. The data will be de-identified, and therefore, your name will not be used. Data collected from you will be assigned a random number and will only be able to be traced to you by the researcher. Your data will be kept at Oxford Brookes University in accordance with the University's policy on Academic Integrity for a period of 10 years, after which point it will be destroyed.
If you give permission to be interviewed (see consent form) your comments may be used in "quotation marks" in the final student thesis or published in academic journals. These comments would not be traceable to you and would remain de-identified.

What should I do if I want to take part?

If you wish to participate in this study, please contact Michael Mawhinney to arrange a time for interview. Contact details found at bottom.

What will happen to the results of the research study?

Once the results of this study have been anonymised they will be analysed and reported as a PhD thesis. They will be discussed at research conferences and reported to NHS [redacted] Publications from the research will also be published in appropriate health care and nursing journals.
A summary of findings will also be provided to participants.

Who is organising and funding the research?

This research is being conducted by a PhD student at Oxford Brookes University under the supervision of Professor Eila Watson and Dr Verna Lavender. This study has been funded by the Department of Applied Health and Professional Development via an Oxford Brookes University PhD studentship.

Who has reviewed the study?

This study has been discussed and reviewed with a consumer research group, which includes patients of a local NHS Trust. It has also had approval from the Faculty Research Ethics Committee at Oxford Brookes University and been granted NHS R&D permission.

Contact for Further Information

Should you have any further questions about the study, please do not hesitate to get in touch with Michael Mawhinney, contact details can be found below.

Tel: 01865 482 697
Fax: 01865 482 775
Email: michael.mawhinney-2015@brookes.ac.uk

If you have any concerns regarding how this study has been conducted please contact the Chair of the Faculty Research Ethics Committee at Oxford Brookes University on heabbott@brookes.ac.uk

Thank you
A sincere thank you for taking the time to read this information sheet.

Appendix 15 – Health professional topic guide

(a) The objectives of the study:
- To evaluate the current pre-SACT education clinic by identifying health professionals' perspectives and experiences of providing this service.
- To identify health professionals' perspectives and experiences of providing care to patients receiving oral SACT who are not directly involved with the pre-SACT education clinic.
- To explore the role of a nurse/pharmacist lead pre-SACT education clinic.
- To inform the development of national health policy regarding the care and safety of patients receiving oral systemic anti-cancer treatments
- To identify strategies to improve the care given to patients receiving oral systemic anti-cancer treatments.

(b) The literature review undertaken about:
- The role of HPs in safely managing the care of patients taking oral SACTs.
- The experience of patients taking oral SACTs.
- Interventions regarding the safe management of patients taking oral SACTs.

It is difficult to have a final set of questions at this stage until part one of the PhD project is fully complete as new information or questions to ask may come to light, however the topic guide for the semi structured interviews will include:

Questions about *oral SACTS* will explore:

- HPs views regarding oral SACTs.
- What training the HPs have had regarding oral SACT.
- HPs experience in caring for patients taking oral SACTs.
- How HPs describe the risks associated with oral SACTs.

Questions about the *management of care* of patients taking oral SACT will explore:

- What education, training and experience HPs feel staff involved with patients taking oral SACT require.
- HPs views and experience with the pre-chemotherapy education clinic .
- The use of patient held diaries.
- The level of support required for patients families/carers.
- What services HPs feel are required for patients.
- HPs views on resources for patients e.g. written information, clinic appointments, follow up.
- HPs views on introducing a telephone follow up service .
- HPs suggestions for improving the care given to patients receiving oral SACT.

Appendix 16 – Health professional interview schedule

Introductions:

- *Before we begin, can I confirm you have received the information about this study? … So you are aware this is voluntary and you have consented to participate?*

- *This session will be audio-recorded, written into a transcript and then the recording erased.*

- *If required, may we use some quotes from this interview in the final report of the study. Are you happy for things you have said during the interview to be used in this way?*

- *Please be aware we can stop the interview at any time. The interview covers several different topics. I will ask some questions about your experience, so there is no right or wrong answer.*

- *Before we begin, do you have any questions?*

Background:

- Can you tell me a little about your career to date? Have you always worked within oncology?
- Can you tell me about your current role?
- What training have you had for this role?

Oral SACT:

- How would you describe oral SACTs
- Can you tell me about your experiences with oral SACT?
- Where has your current knowledge of oral SACT come from?

Oral SACT patients:

- What would you describe are the risks associated with oral SACT? (toxicities/complications/unscheduled care)
- Have you had any experience caring for someone who has had issues with taking oral SACT?
- How do you think families and carers should be supported?

Staff views:

- What services do you think are needed for patients receiving oral SACT?
- Michael to give overview of oral education clinic:
  "OUH runs a nurse and pharmacist lead pre-chemotherapy education clinic. Patients prescribed oral SACT will attend this clinic for an appointment where a nurse or pharmacist will introduce them to their new medication and educate about safety. The appointment lasts around 45-60 minutes and covers drug specific side effects, safe handling, untoward events etc."
- What do you think about this set up of a clinic?

Roles of staff:

- Can you tell me a bit about the staff who look after patients prescribed oral SACTs?
- What education, training and experience you think these staff need?

Patient held diary:

- What are your thoughts on the patient held diary?
- Can you think of any experiences where you have found the diary helpful?
- If you could edit the diary, what would you change and why?

Resources:

- **(Clinic staff only)** What are your thoughts about resourcing of and capacity for supporting patients receiving oral SACT?
- How often do you think HPs should make contact with patients on oral SACT? Why do you think this?
- What would your thoughts be around the introduction of a telephone follow-up service?

Conclusions:

- Can you suggest any ways of improving the care of people prescribed oral SACT?
- Have you anything to add that you think perhaps I haven't covered or would be helpful?

"Thank you very much for your time and for agreeing to take part in this study, your comments have been really valuable."

Appendix 17 – Themes and sub-themes derived from coding health professional interview data

Patient Education

- Providing education
- Information overload
- Consultation style
- Content
- Continued education
- Tailored
- Knowledge deficits
- Education inducing stress

Families and Carers

- Education with families and carers
- Assisting with patients care
- Effect of educated families and carers
- Support for families and carers

Clinical Role

- GP
  - Communication
  - Relationship with GP
  - Education
  - Primary care
  - Practice nurse
- Pharmacy
- Physicians
- Nursing
- Multi-disciplinary working
- Clinical nurse specialist
- Pharmacy technician
- Health professional gender
- Patient interactions with HP's

Healthcare provision

- Patient follow-up
- Telephone follow-up
- Triage
- Patient diaries
  - Patient use of diary
  - Use in assessing toxicity

  - Positives
  - Suggestions for change
  - Negatives
  - HP perceptions of diary
- Services required
- Future services
  - Technology
- Unscheduled care
- Challenges
- Patient assessment
- HP perceived needs for patients receiving oral SACT
- Medication record cards
- Resources
- Support services
- Acute oncology
- Quality of care
- Telephone assessment
- Consenting patients
- District general hospitals
- Healthcare at home

Oral Education Clinic

- HP views of clinic
- Educator requirements
- Negatives
- Capacity and resourcing
- Impact
- Suggested improvements
- Burden of attendance
- HP understanding of oral education clinic
- Clinic delivery
- Telephone education
- Positives
- Missed opportunities
- Face to face education
- Monitoring patients
- Group education
- Managing difficult patients
- Oversight of oral education clinic
- Role of education clinic practitioners
- Administration

Oral SACT

- Description
- Risks
  - High risk patients
  - Managing high risk patients
- Adherence and compliance
  - Medication reminders
- HP perceptions of oral SACT
- Drug specifics
  - Independent monitoring
- Difficulties of oral SACT
- Patient perceptions of oral SACT
- Disadvantages of oral SACT
- Advantages of oral treatment
- Storage
- Packaging
- Errors
- Supportive medications
- Allocating SACT
- Associated errors
- Disadvantages of IV SACT
- Supply of oral SACT
- Dosage

Patient Experience

- Treatment toxicity
  - Acute
  - Delayed reporting
    - Reasons for delayed reporting
  - Low level
  - Difficulty in assessing
  - Toxicity timeline
- Patient perceptions
- Patient control
- Attitude toward oral SACT
- Patient choice
- Patient empowerment
- Preference toward oral SACT
- Delays
- Patient independence
- Polypharmacy
- Utilising healthcare services
- Changing patient perceptions
- Psychosocial needs
- Patient emotions
- Patient isolation
- Patient qualities

HP Training and Experience

- Professional training and experience
- Maintaining knowledge
- Training needs
- HP knowledge of oral SACT
- Knowledge deficits

Appendix 18 - Individual characteristics of respondents reporting a negative response regarding discussion of concerns and asking questions

Individual characteristics																			
Did you feel you had the chance to discuss your concerns and feelings about taking the oral anti-cancer medicine?																			
		Cancer and treatment			Socio-demographics							Validated measures *(sample mean)*							
Response to Q1B30	**ID**	**Cancer**	**Oral SACT**	**Number of side effects**	**Gender**	**Age**	**Marital status**	**Dependents**	**Employment**	**Education**	**Co-morbidities**	**SIMS Q1 (*12.86*)**	**SIMS Q2 (*12.69*)**	**MMAS-8 (*median 7.45*)**	**BMQ – Necessity (*21.12*)**	**BMQ – Concern (*14.7*)**	**CTSQ – ET (*53.68*)**	**CTSQ – FSE (*66.37*)**	**CTSQ – SWT (*81.08*)**
Not really	P223	CML	Bosutinib	15	F	48	M	Yes	W	D	1	6	6	7	22	14	25.00	37.50	42.86
Not at all	P306	Breast	Afinitor and exemestane	3	F	65	D	No	W	C	1	2	10	7	19	18	50.00	68.75	96.43
Not at all	P046	Breast	Missing	29	F	64	M	Yes	W	B	0	5	7	6	25	15	70.00	25.00	78.57

KEY: *Marital Status* D=divorced, M=married, W=widowed; *Education* A=secondary level, B=further education, C=university, D=postgraduate, E=PhD; *Employment* R=retired, W=widowed, U=unemployed

Appendix 19 – Sub-group analysis of perceived confidence

Subgroup analysis of perceived confidence by gender, long standing conditions and age																
		Q1B42					Q1B43					Q1B44				
		Positive		Negative		Sig. (χ^2)	Positive		Negative		Sig. (χ^2)	Positive		Negative		Sig. (χ^2)
		N	%	N	%		N	%	N	%		N	%	N	%	
Gender	Male	37	**80.4%**	9	**19.6%**	*P=0.9.89, df=1*	38	**82.6%**	8	**17.4%**	*P=0.161, df=1*	41	**93.2%**	3	**6.8%**	*P=0.294, df=1*
	Female	29	**80.6%**	7	**19.4%**		25	**69.4%**	11	**30.6%**		31	**86.1%**	5	**13.9%**	
	Total	66	**80.5%**	16	**19.5%**		63	**76.8%**	19	**23.2%**		72	**90.0%**	8	**10.0%**	
Long standing conditions	No chronic conditions	24	**72.7%**	9	**27.3%**	*P=0.360, df=3*	23	**69.7%**	10	**30.3%**	*0=0.318, df=3*	27	**87.1%**	4	**12.9%**	*P=0.551, df=3*
	1 other chronic condition	23	**88.5%**	3	**11.5%**		23	**88.5%**	3	**11.5%**		24	**92.3%**	2	**7.7%**	
	2 other chronic conditions	10	**90.1%**	1	**9.9%**		9	**81.8%**	2	**18.2%**		11	**100.0%**	0	**0.0%**	
	3 or more chronic conditions	10	**76.9%**	3	**23.1%**		9	**69.2%**	4	**30.8%**		11	**84.6%**	2	**15.4%**	
	Total	67	**80.7%**	16	**19.3%**		64	**77.1%**	19	**22.9%**		73	**90.1%**	8	**9.9%**	
Age	31-49	4	**80.0%**	1	**20.0%**	*P=0.835, df=3*	4	**80.0%**	1	**20.0%**	*P=0.952, df=3*	4	**80.0%**	1	**20.0%**	*P=0.186, df=3*
	50-69	23	**76.7%**	7	**23.3%**		23	**76.7%**	7	**23.3%**		24	**82.8%**	5	**17.2%**	
	70-89	32	**84.2%**	6	**15.8%**		30	**78.9%**	8	**21.1%**		37	**97.4%**	1	**2.6%**	
	90+	1	**100.0%**	0	**0.0%**		1	**100.0%**	0	**0.0%**		1	**100.0%**	0	**0.0%**	
	Total	60	**81.1%**	14	**18.9%**		58	**78.4%**	16	**21.6%**		66	**90.4%**	7	**9.6%**	
Diagnosis	Oncological	43	**76.7%**	13	**23.3%**	*P=0.214, df=1*	41	**73.2%**	15	**26.8%**	*P=0.255, df=1*	50	**89.3%**	6	**10.7%**	*P=0.705, df=1*
	Haematological	23	**88.4%**	3	**11.6%**		22	**84.6%**	4	**15.4%**		23	**92.0%**	2	**8.0%**	

Appendix 20 - Comparing SIMS responses in Questionnaire 1 and Questionnaire 2

Table Title																
Question	Too much			About right			Too little			None received			None needed			
	Q1 %(n)	Q2 %(n)	Diff (n)	Q1 %(n)	Q2 %(n)	Diff (n)	Q1 %(n)	Q2 %(n)	Diff (n)	Q1 %(n)	Q2 %(n)	Diff (n)	Q1 %(n)	Q2 %(n)	Diff (n)	
What it's called	3.9(2)	2.0(1)	-1	88.2(45)	96.1(49)	+4	-	-	-	-	-	-	7.8(4)	2.0(1)	-3	
What it's for	-	-	-	88.2(45)	92.2(47)	+2	5.9(3)	5/9(3)	0	-			5.9(3)	2.0(1)	-2	
What it does	-	-	-	70.6(36)	68.6(35)	-1	15.7(8)	23.5(12)	+4	7.8(4)	5.9(3)	-1	5.9(3)	2.0(1)	-2	
How it works	-	-	-	66.7(34)	64.7(33)	-1	15.7(8)	27.5(14)	**+6**	13.7(7)	5.9(3)	-4	3.9(2)	2.0(1)	-1	
How long to act	-	-	-	43.1(22)	43.1(22)	0	19.6(10)	37.3(19)	**+9**	33.3(17)	17.6(9)	**-6**	3.9(2)	2.0(1)	-1	
To tell if it's working	-	-	-	39.2(20)	43.1(22)	+2	23.5(12)	35.3(18)	**+6**	33.3(17)	21.6(11)	**-6**	3.9(2)	-	-	
How long to take	-	-	-	66.7(34)	58.8(30)	-4	13.7(7)	13.7(7)	0	13.7(7)	25.5(13)	**+6**	5.9(3)	2.0(1)	-2	
How to take	2.0(1)	-	-	96.1(49)	98.0(50)	+1	2.0(1)	2.0(1)	0	-	-	-	-	-		
How to get a new supply	2.0(1)	-	-	80.4(41)	80.4(41)	0	5.9(3)	13.7(7)	+4	11.8(6)	5.9(3)	-3	-	-		
The side effects	11.8(6)	7.8(4)	-2	84.3(43)	88.2(45)	+2	3.9(2)	2.0(1)	-1	-	2.0(1)	-	-	-		
The risks of side effects	5.9(3)	3.9(2)	-1	86.3(44)	86.3(44)	0	3.9(2)	5.9(3)	+1	3.9(2)	3.9(2)	0	-	-		
If you get side effects	3.9(2)	-	-	90.2(46)	90.2(46)	0	5.9(3)	5.9(3)	0	-	3.9(2)	-	-	-		
Can drink alcohol	-	-	-	52.9(27)	45.1(23)	-4	3.9(2)	11.8(6)	+4	35.3(18)	33.3(17)	-1	7.8(4)	9.8(5)	+1	
Medicine interactions	-	-	-	80.4(41)	68.6(35)	**-6**	7.8(4)	19.6(10)	**+6**	11.8(6)	11.8(6)	0	-	-		
If feeling drowsy	2.0(1)	-	-	70.6(36)	74.5(38)	+2	2.0(1)	13.7(7)	**+6**	21.6(11)	11.8(6)	-5	3.9(2)	-		
Effect on sex life	-	-	-	37.3(19)	45.1(23)	+4	7.8(4)	11.8(6)	+2	41.2(21)	33.3(17)	-4	13.7(7)	9.8(5)	-2	
If forget a dose	2.0(1)	-	-	84.3(43)	90.2(46)	+3	2.0(1)	2.0(1)	0	11.8(6)	7.8(4)	-2	-	-		

Appendix 21 - Individual characteristics of respondents reporting a negative BMQ differential score

Individual characteristics																			
ID and differential		Cancer and treatment			Socio-demographics							Validated measures *(sample mean)*							
ID	BMQ Differential	Cancer	Oral SACT	Number of side effects	Gender	Age	Marital status	Dependents	Employment	Education*	Co-morbidities	SIMS Q1 (*12.86*)	SIMS Q2 (*12.69*)	MMAS-8 (*median 7.45*)	BMQ – Necessity (*21.12*)	BMQ – Concern (*14.7*)	CTSQ – ET (*53.68*)	CTSQ – FSE (*66.37*)	CTSQ – SWT (*81.08*)
P185	-7	Colorectal	Capecitabine	0	M	70	M	No	R	A	0	16	-	-	11	18	-	-	-
P246	-5	Renal	Mitotane	0	M	53	M	No	W	B	0	10	12	8	20	25	60.00	68.75	75.00
P012	-4	Melanoma	Dabrafenib and trametinib	4	M	59	M	No	U	B	3	9	6	8	19	23	30.00	87.50	67.86
P170	-3	Renal	Sunitinib	15	F	76	W	No	R	B	0	-	11	8	19	22	70.00	56.25	82.14
P268	-3	Breast	Exemestane and everolimus	14	F	51	-	No	W	C	0	-	13	5.25	16	19	60.00	12.50	41.67
P001	-2	Breast	Exemestane and everolimus	12	F	-	M	No	R	D	1	9	-	8	17	19	55.00	37.50	46.43
P312	-2	Colorectal	Capecitabine	8	F	39	M	No	W	E	0	12	8	7	18	20	60.00	37.50	28.57
P075	-1	Prostate	Enzalutamide	6	M	85	M	No	R	B	3	3	12	7	17	18	35.00	68.75	89.29
P079	-1	CML	Dasatinib and hydroxycarbamide	8	F	54	M	No	W	-	2	-	-	6.75	16	17	35.00	56.25	66.67
P084	-1	Myeloma	CTD	10	M	86	M	No	R	E	0	-	16	6	22	23	70.00	43.75	92.86
P264	-1	Glioma	Temozolomide	11	F	75	M	No	R	B	3	-	10	6.75	17	18	35.00	56.25	67.86

KEY: *Marital Status* D=divorced, M=married, W=widowed; *Education* A=secondary level, B=further education, C=university, D=postgraduate, E=PhD; *Employment* R=retired, W=widowed, U=unemployed