**Ollscoil na hÉireann, Corcaigh**

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# A Mixed-Methods Evaluation of Novel Services for Vulnerable Patient Groups in Ireland.

**This thesis is submitted by**

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# Declaration

“This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism.”

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# Abstract

**Introduction:** Rising healthcare costs present a challenge to healthcare systems around the world. In Ireland, healthcare spending accounts for greater than a quarter of government expenditure. Cancer patients and older persons are two patient population groups that account for a large portion of healthcare utilisation and both groups are continuously increasing in number. Safe, cost-effective innovations are needed to provide care for these population groups while maintaining an adequate level of spending. This thesis sought to evaluate novel interventions that target cancer patients and older persons in Ireland, assessing both cost and quality of the interventions.

**Methods:** This thesis examined the cost and quality of the introduction of the novel services in Cancer and Older Person services i.e. Community Oncology Nursing Programme in the West of Ireland, the monitoring of oral anti-cancer therapies (OATs) nationally and the Optimising thERapy to prevent avoidable hospital Admissions in Multi-morbid older people (OPERAM) trial in Cork. These interventions were chosen as examples of recent innovations in the care of vulnerable, costly patient groups. Diverse local, regional and national Irish healthcare settings were evaluated, using a mix of economic evaluation and qualitative principles, as part of this thesis. Methodologies such as literature reviews, economic evaluations (cost-effectiveness analysis and cost comparison analysis), and qualitative analysis (using the thematic analysis) helped provide evidence and inform the recommendations.

**Results:** The full service pathway of cancer care provision in the hospital and community settings were mapped at a high-level. This was the first step of a

Time-Driven Activity-Based Costing (TDABC) model of cost evaluation. Both internal and external evaluation of the service was carried out. Inefficiencies were noted in the process flow, although these were unable to be addressed due to financial and time restraints.

The cost of providing cancer care in the community, that being in primary care centres or the patient's own home, were compared to providing the same care in an oncology day ward. Both the Irish health payer and societal perspectives were evaluated. From the healthcare provider perspective, the day-ward was a significantly cheaper option by an average of €17.13 per patient (95% CI €13.72 - €20.54, $p<0.001$). From the societal perspective, the community option was cheaper by an average of €2.77 per patient (95% CI -€3.02 – €8.55), although this was statistically a non-significant finding. Sensitivity analyses indicate that the community service model may be significantly cheaper from the societal perspective.

Semi-structured interviews with patients, community and hospital nurses involved in cancer care in the West of Ireland were analysed using thematic analysis. Four themes of improved patient experience, nurse-patient relationship, the importance of location and roadblocks to further implementation of the programme emerged. All interviewees expressed their belief that the introduction of the programme was a positive for patients.

The cost and qualitative impact of the monitoring of OATs was assessed. The median consultation time was 33 minutes, costing an average of €22.10 per consultation, using Clinical Nurse Specialist salary figures and €26.51 per consultation, using Advanced Nurse Practitioner salary figures. The

associated patient cost was €14.06 using the Human Capital method to calculate costs incurred from lost work productivity. Themes of the effect of Covid-19 on the service, expanding and complicated care package requirements, the need for dedicated oral clinics and the future of the service emerged from the interview data.

Care of the older person in Ireland also equates to a significant cost to the Irish Healthcare system. A clinical decision support system, used to apply the STOPP/START version 2 criteria to older persons in hospital across Europe, was assessed for cost-effectiveness. The data within this thesis analysed the cost-effectiveness and costs of the Irish data using simple difference and Seemingly Unrelated REGression (SUREG) models. The intervention showed no significant improvement in quality of life. By simple difference, the average difference in total costs was €757 per participant in favour of the intervention group, this was not a significant finding (p=0.790). In the SUREG model the intervention showed a cost saving of €1477 per participant, not a significant difference. (p=0.341).

**Conclusion:** The novel findings of this thesis offer insight into the effectiveness of the services and the potential for alternative methods of care delivery to be incorporated into national policy. The Irish healthcare system is in the midst of a reformation as part of the Sláintecare strategy, and the findings of this thesis are supportive of its drive towards a shift to primary care. The findings of this thesis provide specific information for policy makers on the examined interventions, and provides a roadmap for future research of novel evaluations targeting the vulnerable population groups assessed here.

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Lastly, I'd like to thank anyone brave enough to read this thesis. Enjoy!

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# List of Abbreviations

5-FU – 5- Fluorouracil

ADR - Adverse Drug Reaction

ANP – Advanced Nurse Practitioner

ATC - Anatomical Therapeutic Chemical

BMI – Body Mass Index

CDSS- Clinical Decision Support Systems

CEAC – Cost-Effectiveness Acceptability Curve

CHEERS - Consolidated Health Economic Evaluation Reporting Standards

CHO - Community Healthcare Organisation

CI – Confidence Interval

CNS - Clinical Nurse Specialist

COREQ - Consolidated criteria for reporting qualitative research

COVID-19 – CoronaVirus Disease 2019

DRG - Diagnosis Related Groups

ED - Emergency Department

EORTC - European Organization for Research and Treatment of Cancer

EQ-5D - European Quality of Life 5 Dimensions

FACT-G - Functional Assessment of Cancer Therapy

FEMPI - Financial Emergency Measures in the Public Interest

FUP – Follow-up

GLOBOCAN - Global Cancer Incidence, Mortality and Prevalence

GSEM - Generalised Structural Equation Modelling

HIQA - Health Information and Quality Authority

HSE - Health Service Executive

HSE-CPU – Health Service Executive Corporate Pharmaceutical Unit

HTA - Health Technology Assessment

IARC - International Agency for Research on Cancer

ICD-10 - International Statistical Classification of Diseases and Related Health Problems 10th Revision

ICER - Incremental Cost-Effectiveness Ratio

IQR - Interquartile Range

ISPOR - International Society for Phramacoeconomics and Outcomes Research

MMAS-8 - Morisky Medication Adherence Scale

NCCP - National Cancer Control Programme

NCD - Non-Communicable Disease

NCPE - National Centre for Pharmacoeconomics

NCPS - National Clinical Programme for Stroke

NCRI - National Cancer Registry of Ireland

NHS – National Health Service

OAT - Oral Anti-Cancer Therapy

OECD - Organisation for Economic Co-operation and Development

OPD - Outpatient Department

OPERAM - Optimising thERapy to prevent avoidable hospital Admissions in Multi-morbid older people

PICC - Peripherally Inserted Central Catheter

PIP - Potentially Inappropriate Prescribing

QALY - Quality-Adjusted Life Year

QoL – Quality of Life

SENATOR - Software ENgine for the Assessment & optimisation of drug and non-drug Therapy in Older peRsons

SHiM - Structured History taking of Medication

STOPP/START - Screening Tool of Older Persons Prescriptions/Screening Tool to Alert doctors to Right Treatment

STRIPA - Systematic Tool to Reduce Inappropriate Prescribing Assistant

STRIPA-A - Systematic Tool to Reduce Inappropriate Prescribing Assistant application

SUREG - Seemingly Unrelated Regression

TDABC - Time-Driven Activity-Based Costing

WHO - World Health Organization

# Chapter 1. Introduction

## 1.1 Rising medical costs

Financial issues have always challenged the world's health systems, and this pattern can be expected to continue. Global health costs are currently rising at an unsustainable rate, exceeding inflation rates in prosperous countries (1). Global health spending was calculated at close to $9 trillion in 2019, and is projected to exceed $10 trillion for the first time by around 2022 (prior to the previously unknown economic impact of the COVID-19 pandemic) (2). Examples of contributing factors include expanding and aging populations, an increasing number of people with chronic, long-term conditions, costlier infrastructure and medical technology investments and rising labour costs. Many of the world's health systems are struggling to maintain financial sustainability in an uncertain and changing environment. In 2019, the British National Health Service (NHS) hospital ran a deficit of £960 million; overall, the underlying financial deficit of hospital trusts at the end of 2019 was £5 billion, compared to £4.3 billion in 2018 (3).

## 1.2 Rising costs in Ireland

In Ireland, there has been a marked increase in health spending within the last decade. Between 2013 and 2018, annual health spending increased by around €2.6 billion, representing a 19% increase (4). From 2016 onwards, the annual Department of Finance Budget provided increased annual allocation and on average provided an additional €431 million annually to healthcare. Despite this increase, the health sector continued to overspend and the annual supplementary funding provided ranged from €195 million to around €645 million in a given year. Spending growth over this period was primarily driven

by increased expenditure in the acute hospital setting through increased staff numbers and a growth in pharmaceutical spending. The Irish Health Service Executive (HSE) has significantly increased staff recruitment since 2013 with total numbers increasing by 13% from 2013 to 2017(4). Simultaneously pharmaceutical spend decreased from 2012 to 2014 as a consequence of the introduction of a number of Financial Emergency Measures in the Public Interest (FEMPI) measures and other policies to reduce pharmaceutical prices (5). These decreases have been offset primarily by increases in spending on so-called High-Tech medicines. These more expensive medicines are managed through a reimbursable scheme and may only be initially prescribed by a consultant medical doctor (6). Expenditure on the High-Tech drugs scheme has continually increased over the period with High-Tech drugs scheme expenditure increasing by €231 million or 70% over the period 2011-2017 (7). The continued growth in High-Tech drugs is driven by the introduction of new medicines and increased utilisation of existing medicines.

The Department of Public Expenditure & Reform forecasted for a health sector budget/expenditure of over €17 billion in 2020, making up over a quarter of the overall national budget (8). Ireland's health spending per capita is now €3,364 per annum, the highest figure in the nation's history. This is a significant increase when viewed from a worldwide perspective. While average health spending per capita across Organisation for Economic Co-operation and Development (OECD) countries increased to €2,770 over the period from 2011-2017, it has been at a slower pace than the increase in Ireland's healthcare spending per capita (9).

Ireland's future health system planning has been set out by the Sláintecare Report, a cross-party consensus report aimed at delivering significant health reform (10). Sláintecare promises reform proposals which, if delivered, will establish a universal, single-tier health service where patients are treated solely on the basis of health need and the reorientation of the health system '*towards integrated primary and community care, consistent with the highest quality of patient safety in as short a time-frame as possible*' (11). While this strategy is expected to provide wide-ranging health benefits and ultimately reduced out-of-pocket healthcare payments for Irish citizens, the funding required for its implementation is significant. The report details the need for a guaranteed expansion of health funding by €380-€465 million per year, in years one to six, and at lower levels thereafter for expanded entitlements and funding of additional capacity to deliver universal healthcare. It also proposes implementing transitional and legacy funding arrangements of €3 billion over 6 years, in order to boost reinvestment into one-off system changing measures, training capacity and capital expenditure. The continued expansion of the country's health budget may inflict strain on other areas of society, making it imperative to implement the most effective and efficient initiatives possible.

## 1.3 Vulnerable population groups

The reality of public health spending is that certain patient groups require more significant health expenditure than others. This can be due to their numerical size relative to other groups or the cost per patient in treating their medical

condition. The health expenditure for these costly groups can impact the provision of services to the wider population. As a result, there is an increased focus on health initiatives for these groups in order to both improve the clinical outcomes of these vulnerable, those being patient groups with increased reliance on healthcare utilistaion, population groups as well as freeing up scarce resources for society as a whole by introducing initiatives that may be cost-reductive. Two such costly groups in any western population are (i) cancer patient populations and (ii) older populations.

### 1.3.1 Cancer

Cancer has long represented one of the most significant health problems in the world, and is expected to rank as the leading cause of death and the single most important barrier to increasing life expectancy in every country of the world in the 21st century. According to estimates from the World Health Organization (WHO), cancer is the first or second leading cause of death before 70 years of age in 91 of 172 countries (12). Cancer incidence and mortality are growing worldwide (13). This is due to growth in population, population aging and an increase in cancer risk-factors in the worldwide population. The Global Cancer Incidence, Mortality and Prevalence (GLOBOCAN) 2018 estimates produced by the International Agency for Research on Cancer (IARC) estimated 18.1 million new cancer cases and 9.6 million cancer deaths in 2018 alone (14). Spending on all medicines used in the treatment of patients with cancer reached nearly $150 billion in 2018 (15). This figure does not take into account other financial impacts of cancer care. Cancer patients across the world have increased medical costs such as doctor

visits and hospital stays, and face additional bills such as utilities, and travel as well as potential loss of income (16-18). There is legitimate concern around these rapidly increasing cancer treatment costs. Healthcare providers will have to identify if this increased spending is feasible, given their budgetary constraints. Accurate, and timely economic analyses are needed to provide these decision makers with the information needed.

Outside of these financial concerns, cancer patients suffer from a number of harmful sequelae resulting from their condition. Cancer, along with its treatments, has been shown to be a debilitating condition, having a long-term negative impact on a patient's physical and psychological condition (19). Cancer patients have an increased risk of developing anxiety and depression (20, 21). Cancer has been shown to negatively impact on quality of life (QoL) in the long-term (22). Cancer and its treatments negatively impacts its sufferers socially, by reducing fertility (23) and by causing other social difficulties such as a feeling of shame or stigma attached to the condition in some cases (24). Cancer patients have been shown to have fears of uncertainty and cancer recurrence, which can affect their mental health (25).

Cancer treatments have improved dramatically in recent years. The development of targeted cancer treatments has led to more precise and less harmful treatment options. Precision medicine is allowing cancer treatments to transition from the "*blunt*" chemotherapy option to an approach where doctors can choose treatments that are more likely to successfully treat a person's cancer based on the detailed genetic information of that person's specific cancer. Treatments such as immunotherapies have attracted

increased attention in recent years (26), with arguably the most successful branch of this treatment being monoclonal antibody therapies (27). These treatments bring improved clinical outcomes to many cancer patients, but are more expensive and one of the primary reasons for the rapid rise in cancer treatment costs previously discussed in this section.

Outside of pharmacological treatments, health agencies and other bodies have attempted other methods to improve the patient experience for cancer sufferers. The British NHS recently published its national cancer transformation strategy (28). The strategy discusses how to improve cancer detection, treatment and, of critical importance to the strategy, the patient experience. One of the primary targets of the strategy is to "*establish patient experience as being on a par with clinical effectiveness and safety" (28).* By implementing more services in the community around quality of life (QoL) metrics, physical condition, mental wellbeing and other lifestyle factors such as return to work and travel, the NHS is highlighting that sending patients into remission is only one part of treating cancer in a patient (28).

### 1.3.2 Cancer in Ireland

Ireland has a per-capita cancer incidence above the OECD average (29). There were 30,272 new cancer cases in 2018, with 9,621 cancer deaths (30). Cancer was responsible for over half (50.8%) of non-communicable disease (NCD) deaths. Cancer cases are expected to double over the next 25 years due to population aging and growth (31). Despite this projection, the National Cancer Registry of Ireland (NCRI) found that Ireland is making good progress in terms of survival improvements for all cancers (32). The findings are

presented graphically below in Figure 1.1. When comparing 5-year survival with 6 other high-income countries (Australia, Canada, Denmark, New Zealand, Norway and the UK), Ireland ranked 4th. Ireland showed the biggest improvements in survival (comparing 2010-2014 with 1995-1999) of any of the seven countries for oesophageal and stomach cancers, the 2nd highest improvement for rectal and lung cancers, the 3rd highest improvement for colon cancer and the 4th highest improvement for ovarian cancer. The report does note that Ireland is still some distance from matching the best performing countries across all metrics.

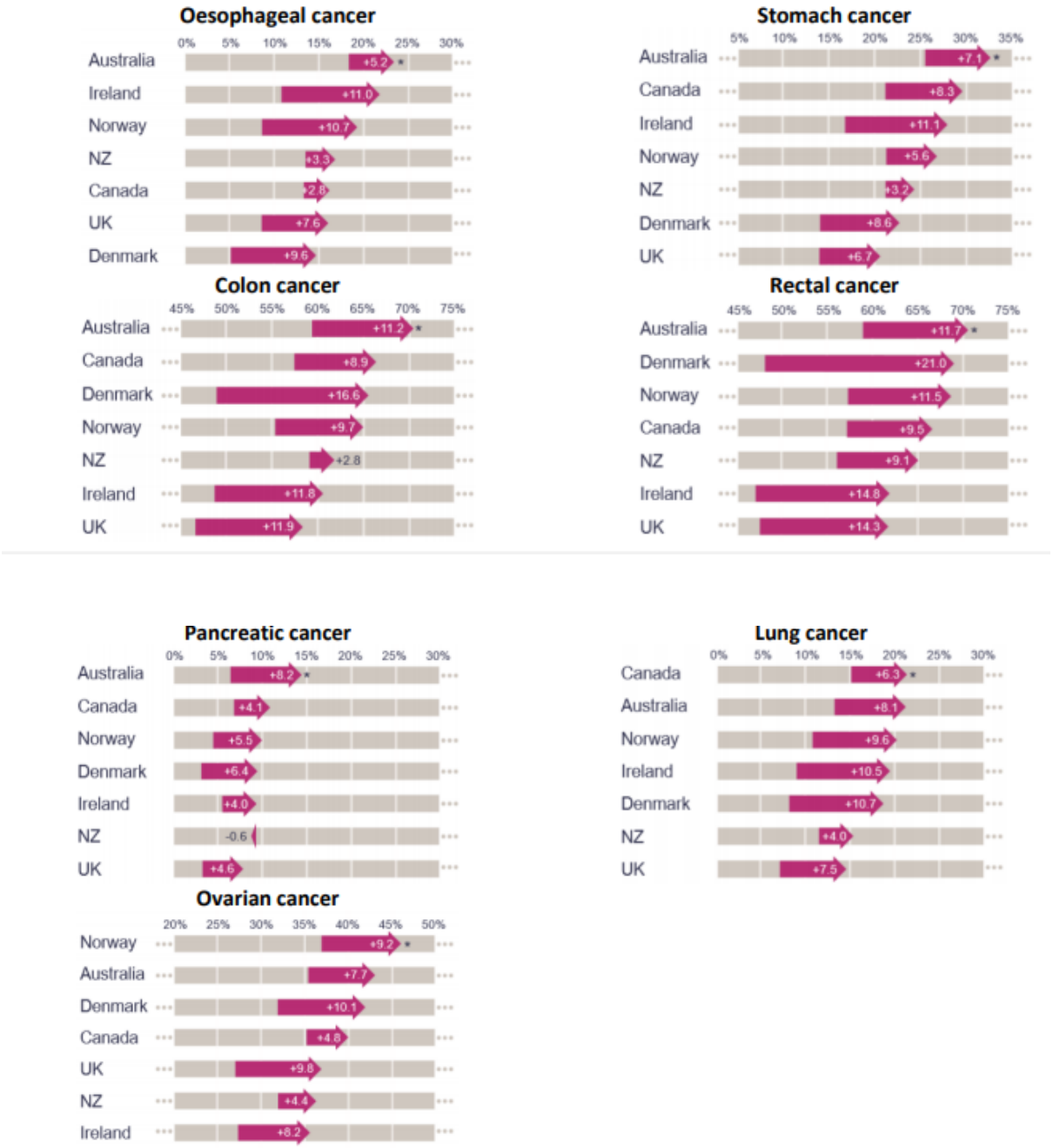



**Figure 1-1 5-YEAR NET SURVIVAL CHANGES: 1995-1999 TO 2010-2014 (SURVMARK-2) (taken from NCRI 2019 annual report)**

The first Irish national cancer strategy, called "*Cancer Services in Ireland: A National Strategy*" was published in 1996 (33). This document sought to bring coherence to the national cancer strategy, by developing cancer services and infrastructure and by appointing a range of cancer specialist boards. A 15%

reduction in premature (under 65 years) cancer mortality was achieved by 2003. From there, the second strategy followed in 2006, called "*A Strategy for Cancer Control in Ireland*" (34). This led to an increase in cancer centres, equal access to high quality treatment, the development of rapid access clinics and developments in cancer screening (35). Shortly after this publication, the National Cancer Control Programme (NCCP) was established. The NCCP aims "*to establish a comprehensive system of cancer control, primarily covering prevention, early detection, treatment and follow-up*" (36). The NCCP also sets standards and guidance for the delivery of cancer care and ensured the monitoring and oversight of cancer services throughout Ireland. In 2017, the National Cancer Strategy was developed, the principal areas of focus of this strategy are (37):

- prevention and early diagnosis,
- safe, high quality and patient-centred care,
- improved service delivery,
- addressing inequalities,
- supporting those living with and beyond cancer,
- increased measurement of outcomes and
- innovation and modernisation.

Central to these achieving these aims is the idea of timely access for all patients to safe, high quality care promised. This is in line with the Sláintecare health reform plan detailed in section 1.1. Budget 2020 in Ireland promised at

least €8 million in funding for the continuation of the National Cancer Strategy (8).

The Irish Cancer Society recently published "*The Real Cost of Cancer*" report (38). It discusses the financial hardships endured by Irish cancer patients and notes that the average cost of cancer is estimated to be €756 per month, rising to over €1,000 per month in some cancer cases. These increases in costs arise from medication, managing side effects, additional medical expenses, increased day-to-day living costs, costs associated with treatment, changes in personal care costs, and one-off household purchases. This financial hardship along with the worsened physical and mental health outlined in section 2.1 highlight the need to find the best and most efficient care for these patients.

### 1.3.3 Older persons

Providing health care to the expanding aging population is a key concern for governments and health systems globally. Overall life global expectancy is projected to increase from an estimated mean of 73.7 years in 2018 to 74.7 years by 2023 (39). The number of people aged over 65 will be more than 686 million, making up 11.8% of the total global population. This aging population trend generates considerable financial concern for already stretched governmental health budgets in many countries, particularly those with rapidly aging demographic trends. Outside of the reduction in state finances that results from an aging population with lower ability to generate income tax revenue, older persons represent a significantly more expensive population group.

Older persons (≥ 65 years old) present a more complex patient population due to its association with chronic multimorbidity. Because of this complexity, older person's healthcare costs are more expensive. Older persons are more likely to have multiple comorbidities (multimorbidity) and associated polypharmacy, both of which are associated with an increased risk of adverse drug reactions (ADRs), increased hospitalisations, increased use of primary care services, frailty and death (40-44). Older persons generally experience a decline in physical function and are more likely to suffer from cognitive decline than younger people (45, 46). Polypharmacy engenders inappropriate prescribing which in turn heightens the risk of ADRs (47). There have been significant efforts made to reduce the harm of potentially inappropriate prescribing (PIP) in older persons, through PIP criteria such as STOPP/START criteria, Beers criteria and the Medication Appropriateness Index (48-50). Quite apart from the personal risk posed by polypharmacy to older patients' personal safety, the excessive expenditure on healthcare in general and medication in particular in older people is substantially greater than in the young and middle aged sections of most populations (51, 52).

Interestingly, there has been debate about the actual impact of an aging population on health expenditure. Some analysts and policy makers view population aging as the major cause of the rapid growth in health expenditure. Others argue that population aging may have a minimal impact on the growth in health expenditure. This is based on three competing theories;

(i) expansion,

(ii) compression and

(iii) postponement of morbidity.

The expansion hypothesis assumes that an increase in life expectancy will increase the period of time lived with morbidity or disability (53). As the population ages, more and more people will be living with reduced function and increased cost of healthcare. The compression hypothesis assumes that this same period will shrink with improved healthcare (54). While the postponement hypothesis assumes an increase in life expectancy will coincide with the period with morbidity or disability being delayed to an older age, the duration will remain constant (55). Adults in the future will experience the same problems they experience now, only at a constant level of some years later than they do currently. A recent report analysing the health expenditure of EU countries, Japan and Singapore found that the projected effect of an aging population may not be as profound as might have been feared (56). Nevertheless, finding clinically effective and reasonably priced healthcare solutions for a growing population should be seen as a priority for health systems around the world.

### 1.3.4 Older persons in Ireland

Currently, life expectancy at birth in Ireland is high compared to other OECD countries at 82.3 years, up from 80.5 years in 2010 (57). Irish females are expected to live an average of 3.8 years longer than Irish males (57). Adults over the age of 60 years made up 15.3% of the total population in 2006, this increased to 18.4% in 2016.The 60+ population in Ireland now stands at approximately 860,000 and is projected to keep growing by 28,500 people per year to 1.15 million, or 23% of the total population, by 2026. Additionally, the

number of individuals over the age of 80 has increased by 45% between 2011 and 2021, from 130,598 (2.8% of the population) to 189,051 (3.5% of the population) (58).

The Planning for Health report published in 2017 highlighted that the growth in the elderly population is causing extreme resource demands and that Ireland was struggling to create appropriate quality infrastructure to provide healthcare for our ageing population. The report details the resource utilisation of older persons in Ireland (58). For example, older persons attend a GP practice on average 7 times a year compared to 15-64 year olds, who attend on average between three and five times a year. Similarly, half of all older persons attending an Emergency Department (ED) are admitted compared with one in five people aged 18-64 years being admitted (58).

The HSE has made attempts to improve care for the older persons in Ireland. Financial aids such as free GP visits to all adults aged 70 years and older, the Fair Deal scheme for nursing home affordability and respite grants are some of the methods the government has sought to reduce the cost burden on older persons and their healthcare (59). Recently, multidisciplinary frailty teams have increasingly become an integral part of older person care in Ireland. These teams provide comprehensive multidisciplinary assessments and resultant detailed care planning to ensure a patient's healthcare and social needs are met in a timely and holistic manner (60). The National Clinical Programme for Stroke (NPCS) was established in 2010 (61). It aims to improve the quality, access and cost-effectiveness of stroke care for adults of

all ages. These initiatives show the ongoing management plan for older person care in Ireland.

Of particular note in the initiatives set out for the care of older persons in Ireland was the set-up of the National Clinical Programme for Older Persons in 2010. It is a joint initiative between the HSE and the Royal College of Physicians of Ireland. It aims to provide quality care across all healthcare settings, while allowing for the continuing independence and dignity of older people (62). Some of its key measurable targets included within the National Clinical Programme for Older Persons are:

- Reduce delayed discharges in the acute hospital system.
- Decrease average length of stay for adults aged 65 years and over.
- Development of community health and social services to meet population needs.
- Reduce risk of inappropriate re-admission following discharge.
- Decrease risk of re-attendance at ED.
- Reduce % of inappropriate admissions to acute and long term care.

As with other developed nations, Ireland must continue to focus on the provision of safe and effective care for the older persons in the population in the face of a continually aging demographic shift.

## 1.4 Health economics

### 1.4.1 Introduction to health economics

With rising healthcare costs in the intermediate to long term, governments face the task of allocating a limited health budget to a diverse group of medical conditions across their country's population. Governments must therefore have a method for deducing how to get the most health gain outcomes using as few resources as possible.

Governments are under constant pressure to meet the demands of their population's healthcare, and given the reality of a limited budget, difficult decisions must be made. The concept of opportunity cost in healthcare refers to the potential loss of benefits, in terms of monetary or health gain, when an inferior technology is chosen (63, 64). Governments must be aware of these opportunity costs when selecting health interventions. They must have a method(s) for deducing the most cost-effective interventions, i.e. those interventions that yield the most health gain with the least associated cost.

A rapidly growing area of literature in healthcare is economic evaluation. This research aims to quantify the health gain and costs associated with a new health technology or intervention, and use these data points to compare the new innovations to existing and comparable health services. Broadly speaking, there are four main analysis types in health economic-evaluations (65):

1. Cost-minimisation/comparison – This involves simply comparing the costs of two or more interventions. This type of analysis would be used

when it is known that the clinical differences between the interventions is negligible or non-existent.

2. Cost-benefit – This is used to describe the pure monetary benefits of a new intervention. Given the inherent clinical nature of healthcare interventions, this is not as common as the other analyses.

3. Cost-effectiveness – This describes the clinical benefits of an intervention in terms of natural units (e.g. decrease in mmHg of blood pressure) per unit cost.

4. Cost-utility – This is a derivative of cost-effectiveness studies and can be considered the gold standard for cost-analysis. It describes the benefits in terms of utility units (e.g. quality-adjusted life years (QALYs)) per unit cost. This is the predominant analysis for government agencies when making decisions on introducing technologies to their health system.

Outside of the perspective from which the study will take place, which will be discussed later in this section, the choice of which analysis to use depends on the question being posed. In Chapter 3 of this thesis, a cost-comparison study was used to compare the costs incurred in two different settings for cancer care. The clinical outcomes in both settings had previously been demonstrated to be equal, therefore a simple cost-comparison could be used. In Chapter 6, a more complete cost-utility analysis was used to determine the cost-analysis of the OPERAM intervention. This required both cost and health utility parameters to determine its effectiveness compared to current standard of care. The health utility used is QALYs, which attempts to quantify both the life

years gained by a new intervention and also the quality of those years on a 0-1 relative scale (66). The quality portion of QALYs is calculated using a QoL measurement instrument, a popular example being the EQ-5D questionnaire (67). These questionnaires use country-specific population responses to determine a single number QoL measure. Derived from these QALYs, a concept inherent in cost-utility analyses is an Incremental Cost-Effectiveness Ratio (ICER). This is calculated by the formula (65):

$$ICER = \frac{Cost_A - Cost_B}{QALY_A - QALY_B} \qquad \text{(Equation 1.0)}$$

The benefit of using an ICER is that it acts as a universal and standardised method of cost-effectiveness determination. It allows for comparisons between otherwise distinct interventions (65). Criticisms of the method usually revolve around its use of QALYs as a determination of health status. Apart from the ethical consideration of putting a value on human quality of life, QALYs have several other shortcomings, including lack of consideration of a patient's age (older individuals are assumed to have lower QALYs since they do not have as many years to influence the calculation), social status, willingness to pay (behavioural economics) and their calculation using standard gamble of visual analogue scales (68). The United States' Affordable Care Act went as far as prohibiting the use of QALYs as a determination of health status, in the passage of the Act that stated: "The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII" (69).

Nevertheless, QALYs still represent the standard for overall health determination for cost-effectiveness analyses in most countries, primarily due to a lack of a better alternative.(70) Other limitations of ICER calculation emerge when either the intervention results in a reduction in health status or cost, or both. This is because there will now be either be a “negative” ICER, or a positive ICER resulting from a double negative. None of these can be directly compared to the standard ICER. Chapter 6 of this thesis deals with such an occurrence.

Governmental health agencies will use the ICER metric to determine whether a medicine is cost-effective at the listed price and thus if it will be reimbursed and selected for use within their countries. This method of economic evaluation is the most widely used way of selecting for new interventions or technology within a health budget. Most countries have an acceptable ICER level that the new intervention or technology must satisfy. In Ireland, this ICER is €45,000/QALY (71). This figure was used as an equivalent to the UK’s Stg£30,000/QALY ICER (72). Some countries, including USA and Germany do not use ICERs, and instead the price is negotiated between the pharmaceutical company and the statutory health insurance providers (73, 74). The decision to reimburse or not to reimburse a new intervention or technology is often a politically fraught one. While there is often a multitude of factors taken into account when making such a decision, economic evaluations offer a best practice and can help make the best informed decision possible.

When beginning an economic evaluation, another important aspect is to choose from whose perspective the evaluation is taking place. While evaluations can in theory take place from any perspective involved in the intervention, the two most commonly used perspectives are the health payer perspective and the societal perspective (75). The health payer perspective only includes direct costs which are incurred by the health service providing the intervention. The societal perspective aims to take into account the costs incurred by society as a whole, and includes indirect costs such as loss of productivity and travelling expenses, in addition to direct healthcare costs. While some government agencies can prefer the narrow viewpoint of direct costs, Sanders *et al.* recommended for the sake of consistency and comparability that analysts should report "*reference cases*" from 2 perspectives— the health care sector perspective and the societal perspective.(76) This was also corroborated by an International Society for Phramacoeconomics and Outcomes Research (ISPOR) Special Task Force report (77).

### 1.4.2 Economics evaluations in Ireland

Prospective economic evaluations in Ireland began in earnest with the establishment of the Health Information and Quality Authority (HIQA) in the Health Act 2007. HIQA reports to the Department of Health and also engages with the Department for Children and Youth Affairs. HIQA undertakes Health Technology Assessments (HTAs) to inform national-level policy decisions and national health service decisions. It provides guidance on economic evaluation

on all HTAs including pharmaceuticals, procedures, medical devices, broader public interventions and service delivery models (78).

The National Centre for Pharmacoeconomics (NCPE) is the agency involved in the HTAs of pharmaceuticals in Ireland. The NCPE was established in 1998 with funding by the Department of Health. The NCPE conducts HTAs for the HSE Corporate Pharmaceutical Unit (HSE-CPU), which is the interface between the HSE and the pharmaceutical industry in relation to medicine pricing and reimbursement applications and the operation of the national pricing framework agreements. The NCPE assesses evidence for the cost-effectiveness of technologies for use by patients in Ireland the Community Drugs Schemes (79). The NCPE staff use the ICER method of cost-effectiveness calculation mentioned in Section 1.4.1. They then make a recommendation to the Department of Health, stating whether or not the evidence supports the decision to reimburse the technology within the Irish healthcare system, at the current price. There are guidelines in place regarding timelines and thresholds for reimbursement. A clear pathway and decision-making process is available for this economic evaluation of pharmaceuticals (80). Economic evaluation for services in Ireland is not as readily defined a process however.

When assessing the possible introduction of a new service, it is important to conduct a proprietary analysis for the country in question. There is an acceptance that economic evaluations can vary significantly in results from region to region and country to country, due to multiple factors such as patient preference, existing services and unit costs (81, 82). It is important that Irish

health services evaluation is underpinned by Irish data. While it can be useful to examine the effectiveness and cost-effectiveness of novel services in other countries, Ireland presents its own unique circumstances that should be measured in any evaluation. A simple demonstration of this is the need for different value sets for QoL measures, such as EQ-5D. Until recently, Irish values sets were calculated using the UK dataset. A recent Irish dataset has now been made available, which should lead to more accurate QoL reporting (83).

### 1.4.3 Cost determination

There are two general approaches to determining costs in health care: (i) top-down costing (gross costing) and (ii) bottom-up (micro-costing). A top-down approach estimates the cost of an individual service on average, usually using readily available data such as average costs. These studies represent a simple method of measuring costs and are relatively easy to undertake in terms of man hours to perform. However, they are noted for sometimes being imprecise, and cannot provide the level of detail for each cost category that can be the most revealing aspect of cost evaluation (65). Consequently, there has been a recent shift towards using the more precise cost calculation method using the bottom-up approach, which is discussed further in this section.

In Ireland, hospitalisation costs are gathered using Diagnosis Related Groups (DRGs) in an approach called Case-mix (84). Case-mix categorises each hospital's caseload into discrete groups. This allows the comparison of activity and costs between different hospitals. Each patient admitted to a Case-mix

hospital has their age, gender, diagnoses, procedures and discharge status coded in an internationally acceptable coding system. It attributes costs to cases on the basis of empirical studies of actual hospital cost behaviour. Inpatient hospital costs in these groupings can be found on the HSE's Inpatient Ready Reckoner, which is a national directory of hospitalisation costs (85).

While this approach to costing is recognized to be more precise than the top-down approach, a bottom-up approach (micro-costing) is the gold standard for cost evaluations (65). Micro-costing generates a more precise estimate, by identifying all resources used in the intervention and then the unit costs of the resources are multiplied by the quantities used. It attempts to measure costs and benefits of service as accurately as possible, by including all fixed and variable costs of care at local prices. It gives a more accurate reflection of costs than the often used macro-costing methods. Studies comparing the cost estimates made by micro-costing studies versus macro-costing studies, whereby average costs are identified per treatment group (65), have shown that micro-costing methods produce superior results (65, 86, 87). Micro-costing can be used to account for unobserved costs such as patient time foregone, opportunity costs of relatives' work time lost etc. The main benefit of micro-costing is a high level of precision with regard to a local service or patients, from which important financial policy decisions can be deduced. This method allows the valuation of new technologies and services with a high degree of accuracy as to the true cost of the service. Micro-costing can be an arduous process, and may not be suitable for all costing studies. Considerable man hours that may be better spent on other aspects of the study may be wasted by accounting for all costs in a project (65). A top-down approach may

be sufficient when the level of precision does not need to be high, or when extrapolating average costs may be an acceptable method of cost calculation. Another drawback of micro-costing is its limited generalisability (65). Micro-costing studies often examine local processes and costs that may be specific to the location or nature of the process being examined. This is why economic evaluations will often carry out their own costing study instead of relying on previously published data.

## 1.5 Lean healthcare

Health systems have been described as economically bloated and inefficient, and operating at sub-optimum levels (88). An inefficient and poorly designed health system can lead to errors and reduced patient safety (89, 90). Health systems around the world are seeking to identify methodologies to tackle these issues. While economic evaluations and health economics may aid in allowing health systems to choose the most cost-effective treatment option, there is a need to improve flow in health systems. One of the most globally renowned methods of improving process flow within an organisation is lean management, a concept first pioneered in the Toyota Production System in Japan (91).

### 1.5.1 Lean manufacturing

The concept of lean manufacturing began in the Japanese motor company Toyota in the late 1940s. Seeking to emulate the mass-production capabilities of automotive companies such as Ford, Toyota set out to design an efficient production system. They built their system on the principle of a desire to have

production work in a continuous flow, with a focus on constant improvement and a respect for its workforce (91). This would result in an organisation that is continuously learning and provides high quality services at lower costs (92). The principles of lean manufacturing are chiefly:

(i) The identification of value.

(ii) The elimination of waste.

(iii) The generation of flow.

These principles lead to a more efficient and robust, or less error-prone, process that is of benefit to the customer (91). With the focus on worker engagement and critical thinking, lean thinking leads to a more knowledgeable, empowered and flexible workforce with high levels of teamwork (93). This lean thinking model of the Toyota Production System has proven so successful that it has been adopted in the fields of health, aerospace and consumer products, among several others (92). The western manufacturing community was introduced to lean thinking by Womack *et al.*, "*The Machine that Changed the World*" (94). The book, written as a response to the known gaps in performance between Toyota and western country carmakers using mass production systems, explores the infrastructure and practices that support lean production in order to facilitate a translation to non-Japanese and non- automotive industries (94).

### 1.5.2 Lean techniques

Melton, in her assessment of the benefits of lean thinking (94), summarised the "*how to lean*" process as follows:

i. Collect data.

ii. Analyse data.

iii. Design the change.

iv. Make the change.

v. Measure the benefits.

There are several techniques or tools that can be useful in achieving a lean process. Some of the most notable examples include Kaizen, Kanban and 5S (95-97).

Outside of these famous techniques, process mapping is a lean technique that is used to help identify value adds and non-value adds of a process. This technique will be discussed in more detail later in this chapter.

### 1.5.3 Lean in healthcare

Lean has become the standard for efficiency and excellence in the manufacturing industry. Given this success, it is only natural that it would be introduced in health systems. The goal of a health system is to ensure that care of a high quality, safety and efficiency. Womack and Jones, the authors of the 2007 book that introduced the western world to lean concepts, advocated for the use of lean in healthcare (98). They put forward the key to implementing lean thinking in medical care is to put the patient at the front of thinking, and include time and “comfort” as key performance measures of the system. Much like the Toyota system, they argue that having multi- skilled teams taking care of the patient and the active involvement of the patient in the process are critically important. The NHS has long been a proponent of

lean thinking (99), and have used lean in combination with Six-Sigma principles (100). Six-Sigma is a process improvement design approach used to reduce the likelihood of errors (101). It takes a different approach to lean in process design but is often used synergistically with lean (102). Several health systems have shown a large benefit in adopting lean, resulting in large waste reduction and major cost savings (103-106).

However, recently there have been criticisms of lean in healthcare, with some asserting that there is a focus on the “tools” of lean rather than the patient (107). Lean has also faced challenges when it comes to tensions between clinicians and service leaders around the social organisation of healthcare work (108). A review of lean in healthcare found that while results appear initially promising, there may still be concerns about the challenges and barriers of implementing lean in healthcare (109).

It is clear that aspects of lean and other industrial engineering practices can prove valuable in the evaluation of health services, particularly when used as an overview tool to simplify complex services. Jimmerson *et* al demonstrated lean’s use in providing solutions to flow issues at a large hospital (103). Issues as simple as a lack of paper for heart monitor printers to larger issues including patient transfer between departments were tackled by adopting lean techniques. There was universal success in increasing process flow, with some departments reducing turnaround time by half its length prior to the adoption of lean. The adoption of lean in an in-patient pharmacy department aimed to tackle workflow issues resulted in an annual cost-saving of $289,256 (104). Following the implementation of lean techniques, there was a reduction

of missing doses, errors, and patient-specific waste by 30%, 50%, and 30%, respectively. The number of outdated drugs decreased by 20%, medication inventory cost was reduced by $50,000 and pharmaceutical waste was reduced by 40%.

## 1.6 Process mapping

Process mapping has been described as an "*entire approach that leads to a holistic understanding of the process under review" (110)* Although it has its roots outside lean thinking, process mapping has become an integral part of the lean "*toolkit*", and is used with lean practice given its strengths in data collection and process re-design by identifying value additive and non-value additive processes (111-113). It involves documenting activities of a process in a detailed graphical format. Process mapping has long been an important technique in service assessment and improvement (114). It has the advantage of communicating roles and responsibilities to team members, providing a useful "*what-if"* guide and improving all-round efficiency (110). In recent years, it has become a key component of popular techniques such as Six Sigma and lean thinking (115, 116)..

### 1.6.1 Process mapping in healthcare

Process mapping has recently been used to examine and improve healthcare processes. It may also allow health policy decision makers to view the management of a medical condition in the form of sequential events, and by doing so, gaining an insight into both the patient and healthcare staff

experience (118). Process mapping has demonstrated clinical benefit in improving efficiency and reducing unnecessary or ineffective care (113, 119).

A recent review of the literature by Antonacci *et al*. examined the findings of eight quality improvement projects from different healthcare settings within the NHS (120). Inductive analysis on interviews of participant's experience of using process mapping was carried out. There were eight key benefits related to process mapping reported by the participants i.e.

i. Gathering a shared understanding of the reality
ii. Identifying improvement opportunities
iii. Increased empathy
iv. Engaging stakeholders in the project
v. Defining the project's objectives
vi. Learning
vii. The simplicity of the exercise
viii. Monitoring project progress

Five factors related to a successful process mapping exercise were identified;

(i) simple and appropriate visual representation
(ii) information gathered from multiple stakeholders
(iii) facilitator's experience and soft skills
(iv) basic training.
(v) iterative use of process mapping throughout the project.

There are limitations to process mapping. It can be a costly and lengthy exercise. Manual process mapping takes resources in the form of money and time. There is a team directly responsible for producing the map, as well as

the employees who are brought away from their work to be contribute their knowledge to the project (121). Process mapping often relies on the memory of the person describing the process, and any gap in that recollection can lead to a gap or error in the process map (121). One way of remedying this is the "*walk the journey*" method of data collection, where the entire process is observed by the mapping team. This technique has been recommended for use in process mapping exercises in healthcare, with the added advantage of experiencing the patient journey and improving patient empathy (122).

### 1.6.2 Time-driven activity-based costing

Another use of process mapping is that of a costing approach, where the sequential events derived from process mapping can be used in time-driven activity-based costing (TDABC). TDABC uses two parameters (123);

(i) the unit cost supplying capacity, and

(ii) the time required to perform the activity.

In 2011, Kaplan and Porter set out a seven step approach to TDABC in healthcare settings (124), presented in Table 1.1 below. TDABC model has been shown to be successful in process assessment and costing activities across a variety of disciplines, including emergency medicine, paediatrics, neurology and oncology (125-128). TDABC has been shown to be particularly accurate in costing activities where the main driver of cost is time, as is the case in the costing studies of Chapter 3 and 5. In their systematic review of TDABC studies in the literature, Keel *et al.* found TDABC was used in both operational improvement and also to inform reimbursement policy (129).

TDABC was found to be a generally simple procedure, yet more accurate than traditional activity-based costing. They noted that other than defining the medical condition and care delivery value chain, all other steps set out by Kaplan and Porter are mandatory for a proper TDABC analysis. The emerging theme was that TDABC is a growing discipline and should be slowly incorporated into existing systems to provide the best cost assessments possible (129).

**Table 1.1 Seven steps of TDABC in healthcare.**

| Step | Process |
|---|---|
| Step 1 | Select the medical condition. |
| Step 2 | Define the care delivery value chain. |
| Step 3 | Develop process maps of each activity in patient care delivery. |
| Step 4 | Obtain time estimates for each process. |
| Step 5 | Estimate the cost of supplying patient care resources. |
| Step 6 | Estimate the capacity of each resource, and calculate the capacity cost rate. |
| Step 7 | Calculate the total cost of patient care. |

Footnote: Steps 2 and 3 of this model are delivered by the use of Process Mapping. In order for a precise costing model to be achieved, each event in the process must be detailed and a cost allocated.

Chapter 2 and Chapter 3 of this thesis describe the use of this process mapping and TDABC model to evaluate a community oncology nursing programme in Galway and Mayo. Chapter 2 uses process mapping to gain a close-up view of the service both in the hospital and in the community, and identifying time points that are needed for a costing study. Chapter 3 continues this TDABC model to complete a cost-comparison analysis between delivering care in the hospital versus the community.

## 1.7 Aims and objectives

The primary aim of this thesis was to assess the quality and cost-effectiveness of novel services aimed to improve the health outcomes of older patients with multimorbidity and cancer patients, two vulnerable patient groups whose healthcare costs are rapidly rising.

The author of this thesis was the primary investigator for all research presented in this thesis. The author was responsible for devising research strategy and implementing methodologies required to complete the research work. The five chapters described below, provide the main evidence for this thesis. The conclusions and recommendations forthcoming from this thesis are based on the findings of chapters 2 – 6 (inclusive). The contents of Chapters 3 and 4 are published in academic peer reviewed journals at the time thesis submission, and the contents of Chapter 5 are under review. The author of this thesis is listed as the lead author on all external publications generated from work presented in this thesis manuscript.

The specific objectives for each chapter were as follows:

**Chapter 2: A Process Mapping Exercise to Evaluate Hospital and Community Models of Cancer Care Delivery**

The objective of this chapter was to use the industrial technique of process mapping in the context of oncology care in the West of Ireland in both secondary care and primary care settings. The objectives were to:

i. assess the functionality of the service and seek possible improvements in its delivery, and
ii. gain a complete understanding of the processes and characters of oncology care, and to use this information to design data-collection sheets for a TDABC study.

**Chapter 3: A Cost Comparison Study to Review Community versus Acute Hospital Models of Nursing Care delivered to Oncology Patients.**

This chapter aimed to determine the cost viability of delivering cancer care by nurses in the community as part of a primary care package in contrast to secondary care support. The primary objective of this chapter was to quantify the costs associated with providing care in each setting and to compare them in order to explore the viability of expanding the service nationally i.e. if this service was cost-effective for national roll-out.

**Chapter 4: A qualitative analysis of patients and healthcare professionals' opinions of community and acute hospital nursing oncology models of care in the west of Ireland**

This chapter aimed to assess the impact of the new Community Oncology Nursing Programme has had on patients and their care, as well as examining its viability through the viewpoint of the nurses delivering the programme. The objectives of this chapter were to determine the attitude of those involved in a novel community oncology nursing care programme, i.e. both the patients and nurses involved in the community and hospital setting, through interview assessment.

**Chapter 5: A Mixed-Methods Analysis of the Monitoring of Oral Anti-Cancer Therapies**

This chapter aimed to assess the cost of the monitoring of oral anti-cancer therapies, as well as to assess the lived experiences of the nurses responsible for this care and their views on how the service operates and can be improved. The objectives of this chapter were to:

i. quantify the time spent by nurses monitoring individual patients and the associated costs
ii. interview nurses responsible for the monitoring of oral anti-cancer therapy and identify the facilitators, challenges and future of the service

**Chapter 6: An economic evaluation of the OPERAM (Optimising thERapy to prevent avoidable hospital Admissions in Multi-morbid older people) randomized controlled trial in an Irish hospital**

This chapter aimed to determine the cost-effectiveness of an automated medicine optimisation programme aimed at older persons with polypharmacy. The objectives were to:

i. quantify the costs associated with delivering the intervention.
ii. measure all medical associated costs incurred by the patients receiving the intervention and the control group of usual care over the course of a year-long follow up.
iii. measure the health utility change associated with receiving the intervention.
iv. determine the cost-effectiveness of the intervention by comparing the costs and health utility changes between the intervention and control group.

Introduction (Chapter 1):

The rising costs of healthcare are placing an ever-increasing strain on the world's health systems. Cancer patients and older persons are two of the most vulnerable and costly patient cohorts. This thesis aimed to assess both the costs and the patient impact of novel health services that target these patient groups. Chapter 1 provides a narrative review of the current status and trends of these population groups globally and in Ireland.

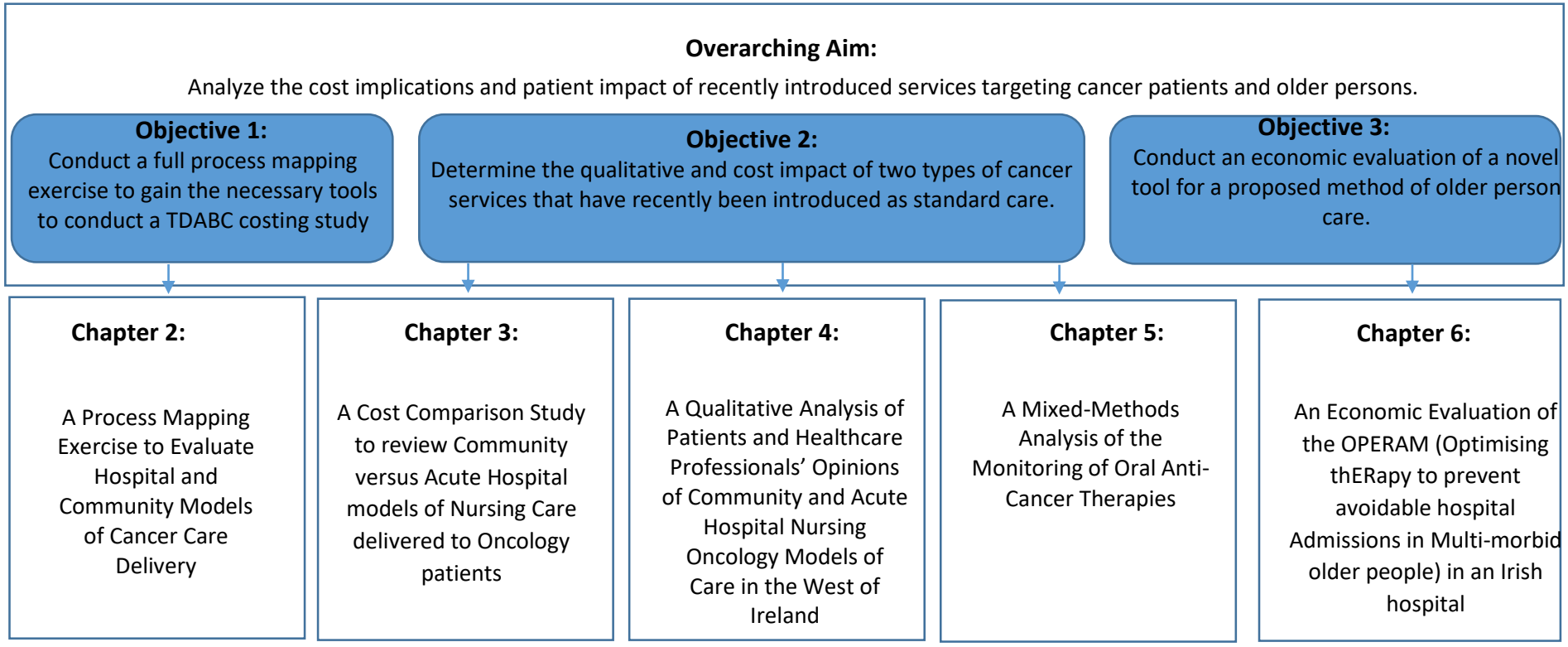



**Figure 1-2 Thesis outline**

## 1.8 Ethical considerations

While every attempt was made to minimise the amount of data collected, the methodology in this thesis necessitated the collection of both patient and staff data. The collected data was anonymised wherever possible. Ethical consideration was given to all studies in this thesis, and ethical approval was sought from the relevant authorities when needed. The individual ethical considerations and details of approval are given in each chapter.

# Chapter 2. A Process Mapping Exercise to Evaluate Hospital and Community Models of Cancer Care Delivery.

## 2.1 Abstract

**Introduction:** Process mapping has long been used in the industrial engineering sector as a method of service evaluation and enhancement and has recently been adopted in healthcare system improvement projects. It provides a simple graphical overview of the process being examined, detailing all steps in the process flow. Time-driven, activity-based costing uses process mapping to identify which key steps need to be timed and costed. The process mapping exercise allows for both internal and external service evaluation. It can serve as the first step in a time-driver activity based costing exercise.

**Methods:** A process mapping exercise was performed to evaluate the process flow of cancer care in the hospital day-unit and in the community, to identify any inefficiencies in care delivery and to form the basis of a cost-comparison study of the two settings The key stakeholders in each of the examined processes were asked to describe the process from beginning to end, describing all the characters in the process and their relationships. The "*walk the journey"* methodology was followed to gain further insight.

**Results:** Top level process maps were drawn, and from these time recording sheets of the key measurables were designed.

**Conclusions:** The process mapping exercise provided a method for both external and internal evaluation of the provision of cancer care in the hospital and community settings. The recording sheets provided by this exercise will

form the basis for a time-driven activity-based costing study to follow in Chapter 3.

## 2.2 Introduction

Evidence based medicine is the central pillar of all modern healthcare systems. It can be defined as "*the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients*" (130). It provides us with the innovation of new medicines and diagnostics, backed by scientific evidence and is a key component of a modern properly functioning healthcare system. The other is evidence-based management, which provides the organisational strategies, structures and change management practices that enable physicians and other healthcare professionals to provide evidence-based care in a timely and efficient manner (131).

There is evidence to suggest that operational problems underlie some of the quality issues found in healthcare systems. Examples include the improper supply of materials and information across organisational boundaries (89) and incomplete or improper clinical data collection (90). This leads to time and resource misuse and wastage and an overall less efficient healthcare system. Improper implementation of operational systems can also have an adverse effect on patient safety (132). Given these deficiencies, the adoption of evidence based management systems is key to delivering effective treatment for patients (133, 134). This has led to the examination of tools used in industrial engineering applied to a healthcare setting, such as Lean thinking and Six Sigma (100, 106, 135, 136).

Another tool adapted from industrial engineering is Process Mapping, which was introduced in Chapter 1. It aims to provide a high-level overview of a process or service, and to identify each stakeholder and their inter-linking roles. It has proven useful in healthcare settings where policy makers are searching for ways to improve the efficiency of their healthcare systems (120, 122, 137). By engaging and communicating with all members of a team involved in a process, such as the delivery of healthcare to a patient, it provides the benefit of being able to answer questions regarding various scenarios which may arise throughout the care process (114).

Process mapping can be used as part of a Time-Driven Activity Based Costing (TDABC) model, as previously described in Chapter 1. By providing a simple overview of the process being examined, the maps drawn can be used to identify the necessary measurable needed to accurately assess the time, and therefore the cost, involved.

In 2010, a community oncology nursing programme was developed in respond to service pressures within Acute Medical Oncology Departments in the west and northwest of Ireland. The programme enables community nurses to provide shared nursing care to oncology patients at home and in primary care centres. The nurses first completed a specifically tailored Level 9 University-accredited education course (138). A pilot program of this initiative has been evaluated and was found to have had a positive impact on:

(i) patients, through a reduced burden of travel and an overall improvement in quality of life, and

(ii) community and acute hospital-based oncology services,

showing enhanced integration of patient care (139).

A cost-minimisation study was not undertaken in the initial evaluation as there was only a small number of patients involved in the pilot evaluation of this programme. Hence, it was deemed necessary to complete a cost-comparison analysis of this new programme, before further roll-out was implemented nationally (Chapter 3).

Initial scoping meetings were carried out by the research group with the National Cancer Control Programme (NCCP) and key stakeholders in the hospital as well as with public health nursing managers in the study area. It was agreed, that in order to achieve a full assessment of the service and in this manner provide accurate costing, the TDABC model should be used. It was agreed that an external industrial engineer (with extensive experience in the field of TDABC) would be engaged to aid in steps 2 and 3 of the TDABC model as defined in Table 1.1. This chapter aims to describe the steps involved in the process mapping exercise and also to serve as the basis of the cost-comparison analysis detailed in Chapter 3.

**Table 1.1 TDABC seven step model**

| Step | Process |
|---|---|
| Step 1 | Select the medical condition. |
| Step 2 | Define the care delivery value chain. |
| Step 3 | Develop process maps of each activity in patient care delivery. |
| Step 4 | Obtain time estimates for each process. |

| | |
|---|---|
| Step 5 | Estimate the cost of supplying patient care resources. |
| Step 6 | Estimate the capacity of each resource, and calculate the capacity cost rate. |
| Step 7 | Calculate the total cost of patient care. |

### 2.2.1 Aims

This chapter describes the application of process mapping in the context of adult oncology care in the West of Ireland in both secondary and primary care settings. The ultimate aim was to gain a complete understanding of the processes and characters of adult oncology care, and to use this information to design data-collection sheets for a TDABC study.

This chapter offers a methodology for steps taken to perform a process mapping exercise.

## 2.3 Methods

### 2.3.1 Study sites

#### 2.3.1.1 Hospital

The oncology day unit that participated in the process mapping and costing as part of this study was located in a 521-bed University Teaching Hospital in the West of Ireland, providing a range of specialities. Oncology services include chemotherapy treatment, adjuvant therapies, 5-fluorouracil (FU) pump infusions and disconnections, catheter insertion and intravenous infusion line

dressings among several others**.** The oncology day unit itself is made up of 18 patient treatment chairs/couches, and is operated by staff nurses and clinical nurse managers working alongside a multi-disciplinary team within the acute care setting; this would be typical of an outpatient department (OPD) oncology service in Ireland.

#### 2.3.1.2 Community

The community service that participated in this study was costed in two counties in the West of Ireland i.e. Galway and Mayo. For either county, a trained district general nurse is responsible for a given area's population. Patients in this area are given care in either Primary Care Centres located in that area, or where appropriate, in the patient's own home in circumstances e.g. if a patient is unable to travel to hospital due to illness or other restricting factors.

### 2.3.1 Process Mapping

The Process Mapping exercise was performed in line with previous recommendations (122). The time period for this study was January 2019 to July 2019. Process maps were designed independently in both settings, although both followed the same methodology. Process mapping was done only for oncology services that were common to both the ambulatory day unit and community oncology care, as the ultimate aim was to compare the cost of providing these oncology support services across both settings. The particular services that were examined were 5-FU (fluorouracil) pump disconnections, PortaCath® flushes, the care of Peripherally Inserted Central Catheter (PICC) lines and Hickmann lines, head-to-toe full oncology assessment and other

auxiliary oncology services such as medication administration, medication management and blood sampling.

The lead author and an experienced industrial engineer met with key stakeholders in the provision of the oncology services in the following locations:

(1) in the day unit/out-patient department (OPD) of the University Teaching Hospital,
(2) Galway primary care, and
(3) Mayo primary care.

The characters of each process were identified. The staff involved in the process, including management, directors and frontline staff, described from the first step of the patient journey until its end, identifying each individual event in the process and who was responsible at each event level. From this, an initial high-level process map was drawn up to provide the authors with an overview of the process. The "*walk the journey*" format, as proposed by Trebble *et al.* in their guide to process mapping in healthcare (122), was followed, directly observing the patient pathway and interviewing relevant staff members from beginning to end of the patient care journey. Final process maps were designed and validated by the key stakeholders.

Using the process maps to identify each event in the oncology care process, the authors began designing data observation sheets that would capture every possible cost in the process. The initial data collection sheets were shared with the relevant stakeholders in each site, for review and consultation. Changes were made after care process examination and discussion with key

stakeholders in the clinical sites. A trial / pilot study period was agreed where the data collection sheets would be distributed to the relevant sites and tested to determine if a scenario might arise that could not be quantified on the data collection sheet. Following this pilot study period, the data collection sheets were adjusted, distributed to all the relevant stakeholders and were finalized and agreed by all. The data collection sheets were validated by observing the relevant stakeholders using the data collection sheets in a real-life scenario. The final data collection sheets were distributed as part of a cost-comparison of the oncology service provided in the oncology day unit versus the service provided in the community.

### 2.3.2 Ethical considerations

Ethical approval was sought and granted from the clinical research ethics committees of both the local hospital network and primary care network in the relevant regions.

### 2.3.3 Software

The process maps were created using Microsoft Visio 2019. Data collection sheets were created using Microsoft Excel 2016.

## 2.4 Results

### 2.4.1 Development of process maps

The healthcare professionals and support staff who participated within each of the respective study settings are detailed in Table 2.1. It was through discussion and mapping the workflow of these individuals that the development of the final high-level process maps was achieved, these are illustrated in Figure 2.1, Figure 2.2 and Figure 2.3 below.

**Table 2.1 Characters of oncology service in day ward and community settings.**

| **Oncology day ward** | **Community** |
|---|---|
| Patient | Patient |
| Nurse | Community public health nurse |
| Clerical officer | Liaison public health nurse |
| Appointments officer | Clerical officer |

### 2.3.4 Determination of cost parameters

In the oncology day unit, the data points and variables required for a cost analysis to be undertaken were identified as follows:

(1) patient travel time to the hospital,

(2) patient waiting time in the day unit,

(3) time duration of oncology treatment service,

(4) type of oncology service provided, and

(5) patient costs incurred from the journey to the hospital.

Given that nurses may be called away from the patient to complete other duties, time lost to these "*interruptions*" was also deemed to be an important parameter to be collected and measured. There was initial consideration given to inclusion of further stratifications such as time spent measuring vital signs and time spent writing clinical update notes, but these were assimilated as part of one umbrella term of "*duration of oncology service*" and were thus excluded.

In the community setting, the key time measurables identified were as follows:

(1) nurse travel time,
(2) patient travel time,
(3) patient waiting time,
(4) time duration of specific oncology service provided,
(5) time spent on administration duties before or after performing the specific intervention and,
(6) time lost to interruptions (as with the oncology day unit).

Other parameters required for the cost analysis to be undertaken were (i) patient travel costs and (ii) nurse travel distance. Nurse travel distance was used because the travel expenses are based on distance travelled according to the public sector expense rates.(140) Other useful data points recorded were:

(1) location of the oncology service (in the patient's home or primary care centre),
(2) type of oncology service provided,

(3) referral source, and

(4) whether the intervention took place in regular working hours (8.00 am to 5.00 pm).

As with the hospital setting, additional stratifications of the full community-based oncology service were deemed unnecessary.

The final data collection sheets for use in costing of the oncology interventions are shown in Figure 2.3 and Figure 2.4 below. These final versions were delivered after the successful pilot testing week at all sites. In the day unit setting, it was noted that there was no indication of patient costs. It was initially intended that this would be determined at the oncology day unit reception upon patient arrival, but the nurse team found it to be disjointed and preferred to provide detail of all inputs on one single data sheet. In the community setting, the nurses felt that additional details regarding the source of referral, as well as increased detail about the type of service being carried out should be provided, such as whether the service was within regular hours or was on the weekend or if it was outside their usual jurisdiction.

Process flow was deemed to be satisfactory overall upon further consultation with the stakeholders. The mean (+/- SD) patient waiting time was 8.04 minutes (+/-4.52) in the oncology day unit and 0.41 minutes (+/-0.28) in the community. Recommendations were also made around redesigning the oncology day unit in order to reduce both patient and nurse transit time during service provision. However, these were deemed unlikely to be completed given financial and operational constraints currently imposed by the

government upon the Health Service Executive in Ireland, arising from the Covid-19 crisis.

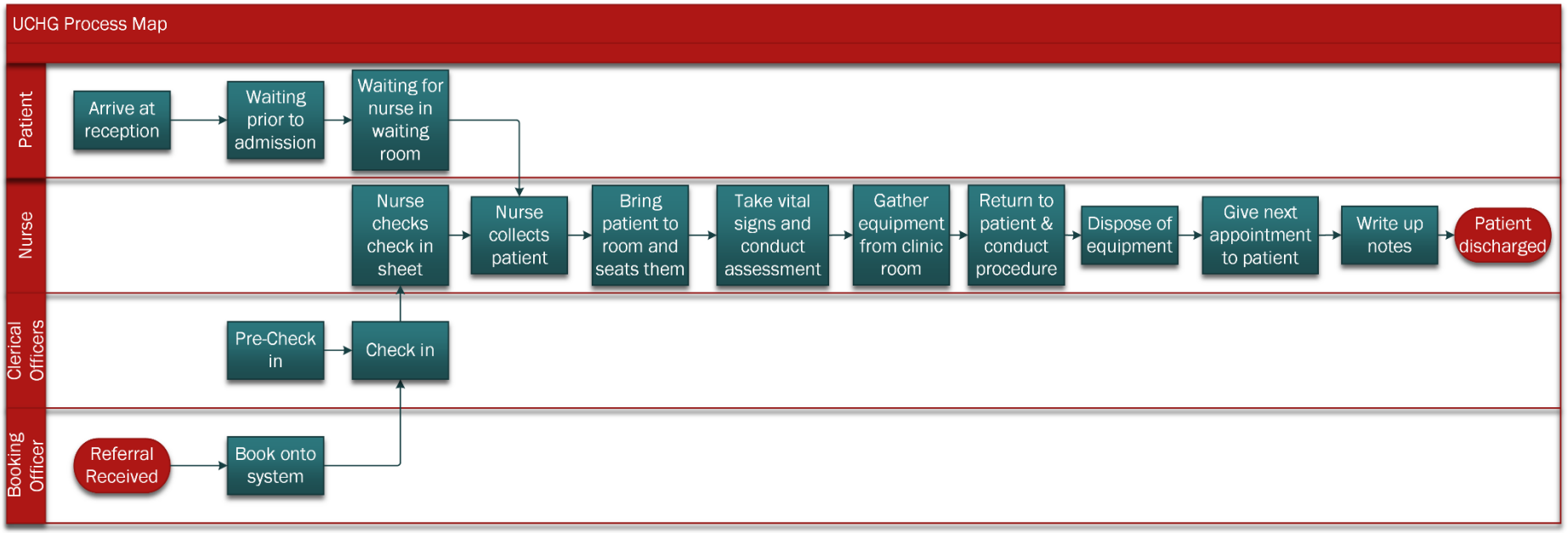



**Figure 2-1 Oncology day unit process map**

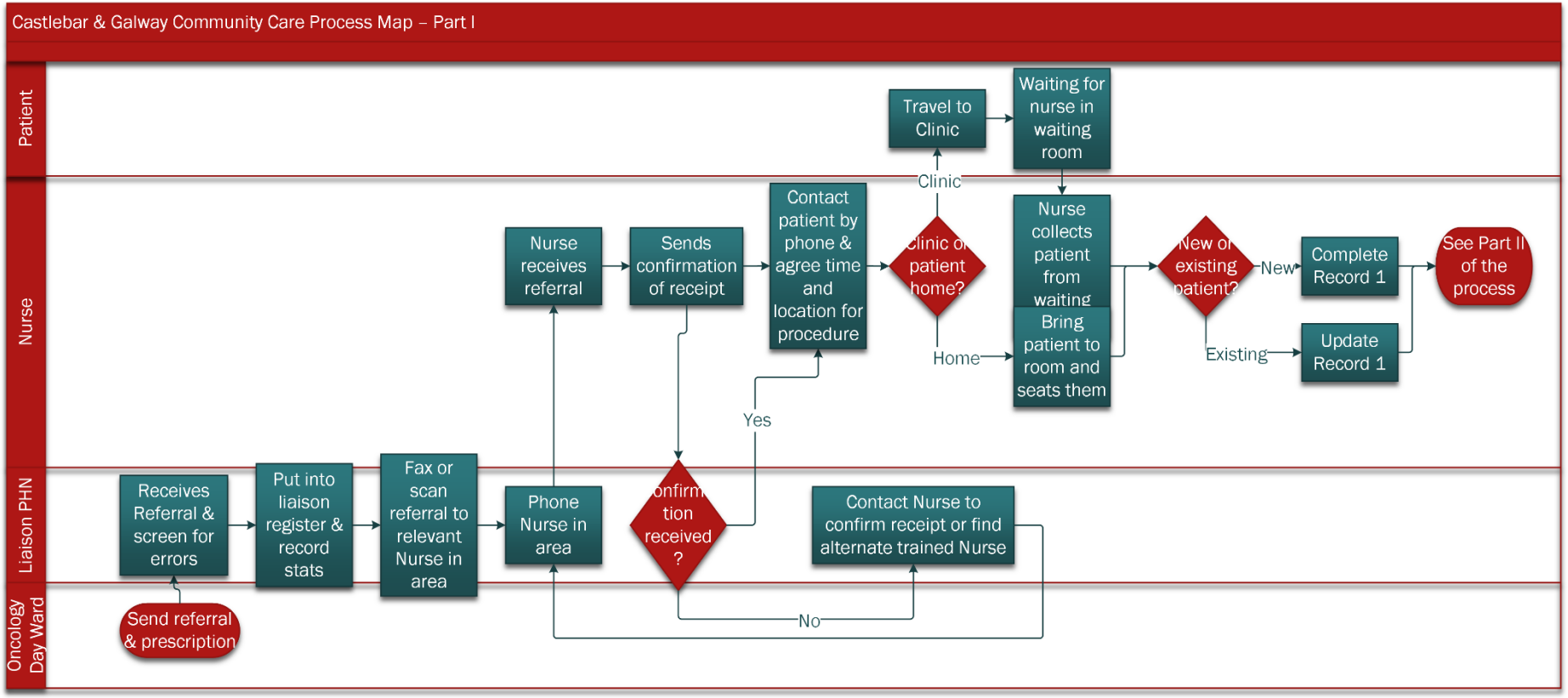



**Figure 2-2 Community oncology care process map.**

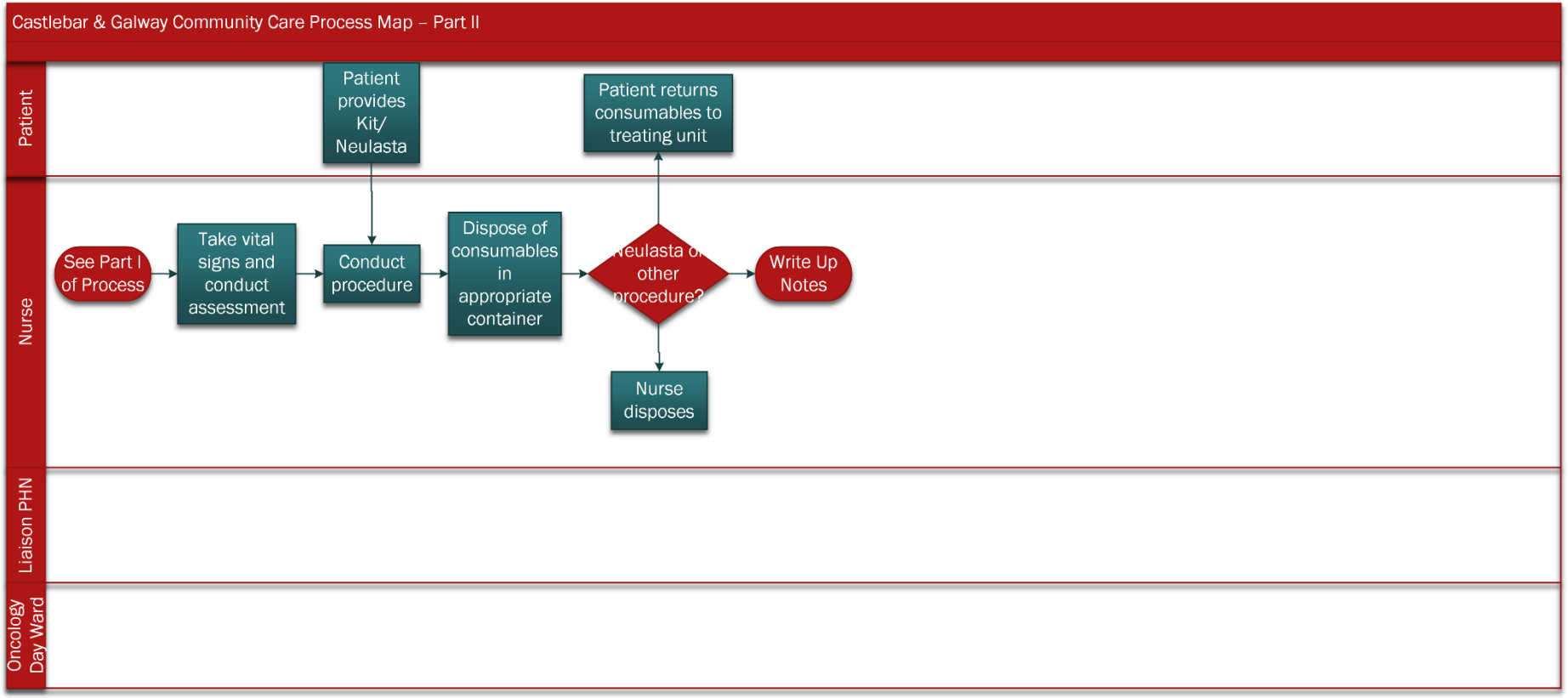



**Figure 2-3 Community oncology care process map continued.**

Data Collection Sheet

| Patient travel time (Hours&Mins) | Patient wait time (Hours&Mins) | What time did Patient check in? | Time collected from waiting room | Time discharged by Nurse | Lost care time due to interruptions |
|---|---|---|---|---|---|
| hh:mm | hh:mm | hh:mm | hh:mm | hh:mm | hh:mm |

| Patient Parking Costs | Patient Travel Costs |
|---|---|
| | |

| Procedure Date | DD-MMM-YYYY |
|---|---|

Please check which of the following procedures were conducted:

| 5FU Disconnection | PICC Line Dressing | PortaCath Flush | Hickmann 1 | Hickmann 2 | Hickmann 3 |
|---|---|---|---|---|---|
| | | | | | |

| Dressing |
|---|
| |

| | Yes | No |
|---|---|---|
| Any problems identified outside standard procedure? (Y/N) | | |

**Figure 2-4 Oncology day unit data collection sheet.**

Data Collection Sheet

| Nurse travel time **from previous location** (Hours&Mins) | Nurse travel distance **from previous location/call** (Kms) | 1) Home 2) Clinic (Please Circle) | 1) Mon - Fri 2) Out of Hours 3) Weekends 4) Other Area Cross Cover (Please circle) | REFERRAL SOURCE: 1) Public 2) Private (Please circle) |
|---|---|---|---|---|
| hh:mm | | | | |

| Patient travel time to Health Centre (Hours&Mins) | Patient waiting time (Hours&Mins) | Time taken for Nursing Intervention? (Hours&Mins) | Lost care time due to interruptions (Hours&Mins) | CLIENT COHORT: 1) Oncology Chemotherapy / Palliative 2) Oral Chemotherapy 3) Radiotherapy 4) Supportive Therapy (Please circle) |
|---|---|---|---|---|
| hh:mm | hh:mm | hh:mm | hh:mm | |

| Patient travel costs | Time for this Oncology follow-up documentation & referrals (Hours&Mins) |
|---|---|
| | hh:mm |

| Procedure Date | DD-MMM-YYYY |
|---|---|

Please check which of the following procedures were conducted:

| Full Oncology Nursing Assessment | 5FU Disconnection | PICC Line Dressing | PortaCath Flush | Hickmann 1 | Hickmann 2 |
|---|---|---|---|---|---|
| | | | | | |

| Hickmann 3 | Dressing | Neulasta / Neupogen / Injections | Referrals to other disciplines due to Oncology needs. | Other |
|---|---|---|---|---|
| | | | | |

| | | | | Yes | No |
|---|---|---|---|---|---|
| Any problems identified outside standard procedure or any of the above? (Y/N) (If Yes please describe below) | | | | | |
| | | | | | |

**Figure 2-5: Community oncology data collection sheet.**

## 2.4 Discussion

This study detailed the oncology auxiliary service pathways in an oncology day unit and in a community setting. Given the lack of familiarity of the authors with the clinical pathway details prior to the process mapping, this was a key step in the time points needed for a TDABC study. This TDABC model has been used to allocate accurate costs in both healthcare and industry. Kaplan *et al.* used process mapping and TDABC to investigate costs of the Benign Prostate Hyperplasia care pathway in inpatient and outpatient settings (141). The approach for the present study was similar, in that it mapped the patient pathway in different settings for a particular patient population. TDABC has been used previously in outpatient services (142) and in primary care (143), with both studies commenting on the strength of the methodology.

This study followed the guidance of Trebble *et al*. i.e. with process mapping in healthcare (122). The results of the present study align with other process mapping exercises in the literature. In their examination of neurosurgery and urology services, McLaughlin *et al*. found that the process mapping exercise was effective in engaging healthcare providers, both within and outside the same department of the organisation, in the assessment of the process and in providing an ideal platform for an accurate cost assessment where the true cost of each activity could be examined (125). Antonacci *et al.'s* review of process mapping in healthcare improvement projects similarly found benefits arising from process mapping exercises. They highlighted the benefits resulting from aiding healthcare provider engagement as well as simplicity in detailing the pathway of the service provided, which can help to identify any design changes necessary (120). In helping to design these process maps,

the oncology team members in each setting were given an opportunity to critically evaluate the service, through the research team providing the results of the process mapping exercise to the key stakeholders who were able to examine and offer their critique. Steering committee meetings provided opportunity for discussion of the process maps and their consequences for the service and the basis for the next step of the cost-comparison analysis of the two settings (Chapter 3). In the community setting, there was no immediate concern regarding the efficiency of the process, although the unavoidable limiting step of nurse travel was acknowledged. There is value in the present exercise in that it allowed for an internal examination of the process by those involved at the respective sites which would be valuable in any future work around improving the efficiency of the patient pathway.

The process mapping informed the team of all inputs that would be required of an observation sheet designed to accurately measure the time spent by the relevant actors in the provision of an oncology service in the dedicated hospital day unit or in the community. The finalised observation sheets formed the basis for accurate capture of time recordings for non-emergency ambulatory oncology services carried out in a hospital setting and primary care setting (Chapter 3), i.e. in primary care centres as well as through home visits. Time recordings will be multiplied by a unit cost per time to calculate the cost of that time, as specified in the Irish guidelines for economic analyses (144). The observation sheets will allow for the recording of nurse time and patient time and cost separately, and this will allow for accurate calculation of care costs both from a health-payer perspective, using only nursing times and costs, and

from a societal perspective, using all costs. This is the preferred method for cost reporting (76, 77).

### 2.4.1 Limitations

The process maps designed in this study were high level maps only. Some of the finer details in the pathway may be hidden behind more global events. This can include some of the tasks the nurses carry out such as the individual steps taken when treating the patient. However, given that process mapping is a tool designed for brief examination of the service and for construction of observation sheets for further data collection, this was not an issue.

Process mapping can be limited by insufficient or inaccurate data input. This was addressed by thorough examination of the process maps by those involved in the service on an everyday basis. The authors also followed the patient journey throughout the process in order to gain a full understanding of the service and all its variables.

## 2.5 Conclusion

The process mapping exercise provided a unique opportunity for both an external and internal examination of the cancer care process in the oncology day unit and in the community. By simplifying the respective processes into a graphical form, it allowed for the main time variable components of the process to be identified such that they could be incorporated into a data observation sheet that can be used for the cost-comparison study to follow (Chapter 3).

# Chapter 3. A Cost Comparison Study to Review Community versus Acute Hospital Models of Nursing Care delivered to Oncology Patients

## 3.1 Abstract

**Purpose**: Ireland's Sláintecare health policy plan is placing an increased focus on primary care. As part of Sláintecare's oncology plan, a community oncology nursing programme was developed to train community nurses to deliver care in the community. While the initial pilot was proven to be clinically safe, no cost evaluation was carried out. This study aims to compare the costs of providing cancer support services in an ambulatory day-ward setting versus cancer care in the community.

**Methods**: 183 interventions (40 in the day-ward and 143 in the community) were timed and costed using healthcare professional salaries and the Human Capital method.

**Results**: From the healthcare provider perspective, the day-ward was a significantly cheaper option by an average of €17.13 (95% CI €13.72 - €20.54, $p<0.001$). From the societal perspective, the community option was cheaper by an average of €2.77 (95% CI -€3.02 – €8.55), although this was statistically a non-significant finding. Sensitivity analyses indicate that the community service model may be significantly cheaper from the societal perspective.

**Conclusions**: Given the demand for cost-viable options for primary care services, a community-based programme may represent a national option for cancer care in Ireland when viewed from the societal perspective.

## 3.2 Introduction

Cancer is one of the leading causes of morbidity and mortality across the world. An estimated 18.1 million new cancer diagnoses and 9.6 million cancer deaths were reported by the Global Cancer Observatory in 2018 estimates (14). Cancer prevalence is expected to double by 2035(14) and with that both the costs and demands of oncology services will increase proportionately. As a result, healthcare providers such as the Health Service Executive (HSE) are seeking ways to either (i) directly reduce costs of cancer care, or (ii) reduce cancer costs by moving the provision of cancer care interventions from the secondary care setting to the primary and community care sectors (145-147), as well as to ease the difficulties placed on patients facing long journeys for their cancer care (148).

Nurse-led interventions have become increasingly common as a way of enhancing the cost-efficiency of care and improving resource-utilisation in the healthcare system. As an increasingly specialised profession, there are many opportunities for nurses to expand and develop their roles within all sectors of healthcare provision. The literature reports that nurse practitioners are in general clinically effective (149) and cost-effective (150) in healthcare provision and role expansion. Increased training for nurses has allowed for new enhanced services to be provided for patients' benefit, with the healthcare provider and society also benefiting. Specialist cancer nursing interventions have shown enhanced patient outcomes, experiences and improvement in cancer management, in terms of both clinical and cost outputs (151-153). Patients value the communication, experience and personal education they

receive from nurse specialists while receiving care, which oncology nurses in particular have been shown to demonstrate (154).

The present study was conducted in a catchment area of 22,572km$^2$. This leads to long journeys and poses problems for patients looking to access services located centrally in hospitals. Cancer patients deal with many challenges in receiving their care, such as disruption of work, social life, psychiatric comorbidities (155) particularly depression (156), anxiety (20) and diminished quality of life (157). There is also a demonstrated strain on family caregivers looking after those who receive cancer care (158). Ideally, cancer patients should be provided with every possible opportunity to improve both the quality and accessibility of their cancer care. One such method is introducing oncology care to the community setting. Initiatives in the USA (146), Australia (145) and the United Kingdom (148) focused on moving oncology services from secondary to a primary care setting have shown success, in terms of patient preference, quality of care and cost. A recent study in the USA has shown decreased care cost for those patients receiving oncology care in the primary care setting rather than in secondary care setting (159).

In 2010, a community oncology nursing programme was developed in response to hospital service pressures within acute Medical Oncology Departments in Ireland. The programme enabled community nurses to provide shared nursing care to acute oncology patients at home and in primary care centres. The nurses first completed a specifically tailored Level 9 University-

accredited education course. A pilot programme of this initiative has been evaluated and found to have had positive impacts on (i) patients themselves, through a qualitatively demonstrated improvement on quality of life, and (ii) community and acute hospital-based oncology services, showing enhanced integration of patient care, both assessed qualitatively (139). The programme was introduced to HSE Community Healthcare Organisation (CHO) Area 2 in 2014 (160) leading to an ever-increasing demand on the community oncology service since then. Table 3.1 below indicates the number of community oncology interventions in the Galway city catchment area in the last 3 years. The large increases in services provided between January and June 2019 can be attributed to an increase in the level of trained nurses, allowing for further roll-out of safe primary care services. Costings were not undertaken in the initial evaluation as there was a relatively small number of patients involved in the pilot evaluation of this programme. Hence, it was deemed necessary to complete a cost-comparison analysis of this new programme, before further roll-out of the programme nationally.

**Table 3.1 Number of community oncology services in Galway**

| Time period | 5-FU pump disconnections | Other oncology services | Total |
|---|---|---|---|
| **January 2017 – June 2017** | 349 | 693 | **1042** |
| **July 2017 - December 2017** | 369 | 657 | **1026** |

| | | | |
|---|---|---|---|
| **January 2018 – June 2018** | 330 | 715 | **1045** |
| **July 2018 – December 2018** | 388 | 762 | **1150** |
| **January 2019 – June 2019** | 435 | 1353 | **1788** |

Ireland is in the process of implementing a 10-year plan for health reform policy called Sláintecare. The aim is to establish a universal, single-tier health service for all citizens as well as re-structuring the health system "towards integrated primary and community care that is consistent with the highest quality of patient safety in as short a time-frame as possible" (11). There is a central aim to move health services into primary care where possible. The community oncology programme examined here aims to provide both a safe and viable method of delivering cancer services in the community instead of providing the same care within an oncology day-ward of an acute hospital. To the best of the author's knowledge, this was the first study of its kind.

## 3.3 Methods

This study utilised a micro-costing approach to calculate costs in the hospital and community settings, both from the healthcare provider's perspective and the societal perspective in Ireland during the latter months of 2019. Micro-costing is a type of costing method involving the direct enumeration and costing out of every input consumed during an intervention (161). It has

become the method of choice in costing due to its precise nature. Studies comparing the cost estimates made by micro-costing studies versus gross costing studies, whereby average costs are identified per treatment group (65) have shown that micro-costing methods produce superior results, especially in the context of the present study that takes place in a hospital and where the main driver of cost is labour-related costs (86, 87, 162, 163).

### 3.3.1 Guidelines

In order for this study to be carried out with the quality set out in the literature, this paper was reported in accordance with the International Society for Phramacoeconomics and Outcomes Research (ISPOR) Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines for reporting health economic evaluations (164). This is the most widely used set of reporting guidelines in health economics research.

### 3.3.2 Study sites

**Hospital**

The oncology day ward that was costed as part of this study is a University teaching hospital in the west of Ireland, with 521 beds providing a range of specialities. Patients are assessed, managed and treated with a variety of interventions including chemotherapy, adjuvant therapies, 5-Flurouracil (5-FU) pump disconnections, catheter insertion supportive care and dressings.

**Community**

The community service was costed in two counties in the west of Ireland (Galway and Mayo). For either county, a community nurse who has completed

the community oncology education programme is responsible for a given area and population. Patients in this area are given care in either Primary Care centres located in the given area, or in the patient's own home depending on individual circumstances.

### 3.3.3 Intervention

Several oncology interventions have been deemed suitable for delivery in the community. Governance over the patient population and the interventions which can be delivered in primary care rests with the consultant and his/her cancer team in secondary care. The nurses carried out interventions such as 5-FU pump disconnections, PortaCath flushes, the care of Peripherally Inserted Central Catheter (PICC) lines and Hickmann lines, head-to-toe patient assessment and other auxiliary oncology services such as medication administration, medication management and blood sampling. These services were carried out under HSE best practice and values guidelines, in accordance with the community oncology nursing programme resource book.

### 3.3.4 Process mapping

The process mapping exercise was described in full in Chapter 2. This was the first step in the time-driven activity-based costing method followed by the present chapter.

### 3.3.5 Cost comparison analysis

The costs examined in this study can be summarised as follows:

**Table 3.2 Summary of comparisons**

| | |
|---|---|
| Health payer x Hospital costs | Health payer x Community costs |

| | |
|---|---|
| Societal x Hospital costs | Societal x Community costs |

Both the healthcare provider and societal perspectives were calculated, based upon available costs and measurements taken in 2019. Direct and indirect costs were calculated. Direct costs included healthcare professional time, expenses and consumable cost. Indirect costs included patient productivity time lost, travel costs and overheads. The currency used in all cases was Euros (€).

To calculate time-related costs, active time spent by nurses on carrying out tasks related to the patient's oncology care were recorded using a direct observation approach with a stopwatch. Patient-related time costs were calculated from total time spent waiting as well as travel time, using patient self-reported times. For nurses travelling to patients' homes, nurse travel time was recorded using an observation sheet and stopwatch. The HSE healthcare professional pay scale (as per 2019) was used to cost the times observed. The midpoint of the relative professions pay scales (165) was used and adjusted according to guidelines for economic evaluations in Ireland (71) including pension payments, social insurance and overheads. The hourly consultation rate was calculated by dividing the midpoint salary by the number of weeks worked per year and the number of hours worked per week. The number of weeks worked per year is 48 and the number of scheduled hours per week is 39. Public health nurse pay rates were applied to the community observations, and staff nurse rates were applied to the in-hospital day ward observations. Patient time-related costs were calculated using the Human Capital Method

(166). The average national hourly income as of 2019 Q2 (€23.81) was used (167). This method has been used previously to calculate in detail productivity loss in cancer (168, 169). No discounting was needed given that the data collection was carried out over a 3-month period. Similar methods of time-related cost calculation have been used by the study team previously (170, 171).

The procedures that were costed were the head-to-toe patient assessment, 5-FU pump disconnection, PICC line dressing, PortaCath flush, Hickman lines and some miscellaneous procedures. Nursing experts were consulted on the consumables used in each of these processes. The costs of consumables were determined by invoices issued from the finance department of the hospital involved in the programme in 2019. The resource utilisation and unit costs of consumables were used to calculate the total consumable cost for each process. This is outlined in Table 3.2. The cost of consumables used in the community are the same as those used in the hospital.

**Table 3.3 Consumables used in single procedure**

| Items | Pump discon-nection | Port Flush | PICC dressing | Hickman Dressing | | |
|---|---|---|---|---|---|---|
| | | | | Single lumen | Double lumen | Triple lumen |
| **Heparinised Saline 10 units per ml** | 1 | 1 | 2 | 1 | 2 | 3 |
| **Sterile posiflush syringe** | 1 | 2 | 4 | 3 | 4 | 6 |
| **Syringe luer lock** | 1 | 2 | 4 | 3 | 4 | 6 |
| **Sani Cloth** | 2 | 3 | 6 | 4 | 6 | 8 |
| **Sterile Dressing Pack** | | 1 | 1 | | | |
| **NeutraClear Needle Free Connector** | | 1 | 2 | | | |
| **Filter Needle** | 1 | 1 | 2 | 1 | 2 | 3 |
| **Gloves Surg Gammex** | | 1 | 2 | 2 | 2 | 2 |
| **Dressing Opsite IV 3000** | | | 2 | 2 | 2 | 2 |
| **Gripper Needles** | | 1 | | | | |
| **Gauze square** | 2 | | | | | |
| **Opsite post op 6.5v5cm** | 1 | 1 | | | | |
| **Chemotherapy gloves** | 2 | | | | | |

Total cost of a procedure was calculated from the public healthcare payer's perspective (HSE), by summing the total consumable cost and healthcare professional costs (procedure time, travel time, travel expenses), and the societal perspective cost, which was calculated by summing the cost of patient time and expenses to the health payer's cost.

No patient outcomes data were recorded in this study. This is because the pilot study for the Community Oncology Nursing Programme demonstrated no clinical difference in providing care in the two settings (19). During the evaluation period, there were no adverse events reported among the patients who were treated at home by the oncology PHNs. There were no emergency phone calls made by the PHNs to the mobile phone number that had been specifically available for consultations and enquires as well as emergencies. While there was no quantitative assessment of change in patient quality of life, a qualitative assessment found an emphasis on the improvement of quality of life for patients treated in the community when compared to being treated in the hospital day-ward. The training provided by this programme is crucial to the viability of this project. The majority of community nurses carrying out the interventions in the community would have had no formal education in specialised oncology care prior to completing this programme. Without this programme, any cost study would need to detail clinical values for a cost-effectiveness study to be completed. Given that there was no identified difference in clinical outcomes, comparing the costs incurred in both settings is sufficient to determine the viability of this intervention.

The costs in both settings were analysed using Kolmogorov-Smirnov and Shapiro-Wilks methods to check for normality. Parametric data were compared using an independent sample two-tailed t-test, with α level of 0.05 to test for significance. Levene's test for variance equivalence was used, and equal variance was not assumed if a significant result was found. For the cost-comparison analysis, the cost of consumables was excluded to remove it as a confounder i.e. the consumables used for each procedure do not vary between hospital and community settings. As there were some procedure types only undertaken in the community setting, a cost-comparison analysis for only procedures carried out in both settings was completed. The cost of community interventions in the two counties was compared using an independent samples t-test.

### 3.3.6 Sensitivity analysis

Although most day ward procedures are carried out by staff nurses, a portion of procedures are carried out by clinical nurse specialists. The costs incurred using a clinical nurse specialist hourly rate at levels of 5%, 10% and 15% involvement were calculated (165).

Given that many cancer patients are too unwell to travel alone, a sensitivity analysis was undertaken to examine the impact of another person accompanying the patient on the social cost (without consumables) of the intervention. The cost of this accompanying person was calculated using the same Human Capital Method as the patient cost. To examine the variable effects of a patient being accompanied, 20%, 40%, 60%, 80% and 100% of the sample in all settings were analysed as if another person had accompanied

them. For interventions carried out in the patient's home, no increase in cost was incurred, as there would be no need for an accompanying carer. The difference in cost between secondary and primary care interventions in this group was analysed using independent samples t-test.

### 3.3.7 Ethical considerations

Ethical approval was granted from the clinical research ethics committees of both the local hospital network and primary care network in the region (Saolta University Health Care Group C.A 2084) (see Appendix E - Chapter 3 Ethics approval letter).

### 3.3.8 Software

Analysis was carried out using IBM® SPSS Statistics Version 24 and Microsoft® Excel 2016. Process maps were created using Microsoft® Visio 2019.

## 3.4 Results

Table 3.3 below details the cost of consumables as provided by the finance department used in each procedure identified in the process mapping exercise e.g. the costliest procedure was a Hickmann 3 dressing at €11.98.

**Table 3.4 Cost of procedures**

| Procedure | Cost (€) |
|---|---|
| 5FU pump disconnection | 3.32 |
| PICC line dressing | 8.31 |
| PortaCath flush | 7.11 |
| Hickmann 1 dressing | 5.77 |
| Hickmann 2 dressing | 8.37 |
| Hickmann 3 dressing | 11.98 |

The consumables used for each procedure do not vary between hospital and community settings. As such, it was excluded from the cost comparison analysis.

### 3.4.1 Healthcare professionals' cost

The midpoint annual salary for staff nurses is €38,546, resulting in an adjusted salary of €53,868 and an hourly consultation rate of €28.76. The annual salary midpoint for public health nurses is €54,888, resulting in an adjusted salary of €76,110 and an hourly consultation rate of €40.66.

### 3.4.2 Cost comparison analysis

A total of 183 procedures were analysed over the study period (between 14th April and 1st August 2019), 40 carried out in the hospital setting and 143 in the community. Ideally, an equal number of interventions would have been assessed across both settings but this was not feasible due to the lesser

number of interventions that occur in the hospital. The number of each type of intervention is shown in Table 3.4.

**Table 3.5 Number of interventions analysed**

| | Hospital | Community | Total |
|---|---|---|---|
| **5-FU disconnection** | 18 | 65 | 83 |
| **PICC line dressing** | 2 | 9 | 11 |
| **PortaCath Flush** | 18 | 7 | 25 |
| **Hickmann 1** | 0 | 0 | 0 |
| **Hickmann 2** | 0 | 8 | 8 |
| **Hickmann 3** | 0 | 9 | 9 |
| **Multiple procedures** | 2 | 13 | 15 |
| **Neulasta/Neupogen injections** | 0 | 26 | 26 |
| **Other** | 0 | 5 | 5 |
| **Missing** | 0 | 1 | 1 |
| **Total observations** | 40 | 143 | 183 |

As shown, some interventions were recorded only in the community setting. As such, an analysis of procedures recorded in both settings was deemed necessary.

Descriptive statistics of observations in each setting are shown in Table 3.4. The means and standard deviations of the data are shown. Given that for the purpose of this analysis waiting time and travel time can be grouped together, these are combined in the variable additional time.

**Table 3.6 Descriptive statistics of observations**

| | Hospital | | Community | |
|---|---|---|---|---|
| **Procedure time (minutes)** | 15.93 (9.95) | | 26.79 (14.99) | |
| **Additional nurse time (minutes)*** | 0 (0) | | 10.39 (13.22) | |
| **Additional patient time (minutes)*** | 45.03 (33.31) | | 10.35 (12.38) | |
| **Nurse travel costs (€)** | 0 | | 1.17 (2.02) | |
| **Patient travel costs (€)** | 7.70 (7.24) | | 0.833 (1.67) | |
| **Total cost (health payer) (€)** | Not including consumables | Including consumables | Not including consumables | Including consumables |
| | 7.83 (5.46) | 13.51 (5.32) | 24.90 (15.11) | 30.02 (14.99) |
| **Total cost (societal) (€)** | Not including consumables | Including consumables | Not including consumables | Including consumables |
| | 32.46 (19.47) | 38.14 (19.29) | 29.69 (15.38) | 34.81 (15.22) |

**travel time + waiting time*

The cost of procedures from the healthcare payer's perspective was analysed. Equal variance was not assumed. The hospital setting was shown to be an average of €17.07 (95% CI €14.02 - €20.12, $p<0.001$) less costly per procedure. When selecting only procedures done in each setting, equal variance again was not assumed and the hospital setting was an average of €17.13 (95% CI €13.72 - €20.54, $p<0.001$) less costly per procedure.

For the societal perspective, equal variance was assumed. The community setting was cheaper by an average of €2.77 (95% CI -€3.02 – €8.55) per procedure, although this was a non-significant result (p=0.347). When selecting only procedures done in each setting, a similar result was found, with the community setting being cheaper by an average of €3.47 (95% CI -€2.84 - €9.75), once again a non-significant difference (p=0.278).

### 3.4.3 Home care versus primary care

The cost of providing the interventions in the primary care centre was significantly lower when compared to interventions in the patient's own home, from both the healthcare payer's and societal perspective. Equal variance was assumed in both comparisons. The primary care centre cost was an average of €15.36 (95% CI €10.83 - €19.89, p<0.001) from the healthcare payer's perspective and an average of €7.59 (95% CI €2.44 - €12.73, p=0.004) from the societal perspective.

Comparing the cost of only interventions carried out in the primary care centre versus those in the hospital, the hospital was found to be cheaper by an average of €5.69 (95% CI -€1.09 - €12.47) from the healthcare payer's perspective, but this was not a significant difference (p = 0.098). From the societal perspective, the primary care centre was cheaper by an average of €11.15 (95% CI €8.49 - €13.89) (p<0.001).

Table 3.6 below details the location of interventions carried out in the two counties. Comparing the cost of interventions in the two counties, interventions carried out in County Mayo was shown to be an average of €6.96 (95% CI

€1.88 - €12.02) cheaper from the health payer's perspective and €5.34 (95% CI €0.34 – €10.36) cheaper from the societal perspective (p=0.008 and p=0.034 respectively) than in County Galway.

**Table 3.7 Location of community interventions**

| | Primary Care Centre | Patient's home | Missing | Total |
|---|---|---|---|---|
| **Galway** | 22 | 39 | 1 | 62 |
| **Mayo** | 34 | 38 | 0 | 82 |
| **Total** | 56 | 87 | 1 | 144 |

### 3.4.4 Sensitivity analysis

The salary midpoint of a clinical nurse specialist was €54,462, resulting in an adjusted annual salary of €76,706 and an hourly consultation rate of €40.97 i.e. a 41% increase in staff costs in the hospital setting compared to community. The cost from the societal perspective of clinical nurse specialists carrying out 5%, 10% and 15% of procedures resulted in the community care delivery being cheaper by €2.92 (95% CI -€2.82 – €8.76, p=0.331), €3.10 (95% CI -€2.61 – €8.96, p=0.317) and €3.22 (95% CI -2.42 – €9.08, p=0.302) respectively. None of these findings, however, were statistically significant.

The cost of accompanying supporters of patients examined at rates of 20%, 40%, 60%, 80% and 100% of interventions is detailed in Table 3.7. Equal variance was not assumed for comparisons.

**Table 3.8 Cost of patient accompaniment**

| % of patients | Mean social cost | Difference in cost |
|---|---|---|

| being accompanied | Hospital | Community | |
|---|---|---|---|
| 0 | 32.46 (15.38) | 29.69 (15.38) | 2.77 (p=0.432) |
| 20 | 35.69 (21.22) | 31.32 (15.67) | 4.37 (p=0.115) |
| 40 | 43.63 (31.98) | 34.97 (16.01) | 8.66 (p=0.025) |
| 60 | 49.50 (32.55) | 35.04 (16.76) | 14.46 (p=0.016) |
| 80 | 52.31 (32.87) | 36.99 (17.39) | 15.33 (p=0.008) |
| 100 | 55.36 (33.20) | 39.45 (19.85) | 15.90 (p=0.006) |

At all rates above 40%, there was a significant difference in mean cost, ranging from €8.66 (95% CI €0.96 - €16.36, p=0.03) at 40%, to €15.90 (95% CI €7.61 - €21.20, p<0.01) at 100%.

## 3.5 Discussion

This study showed that there is a significant cost increase in providing this service in the community from the health payer's perspective, with a mean difference of €17.07 (p<0.001). This was expected given the increased staff costs from traveling in the community. Nurse travel time was the primary driver in this cost increase, with average nurse travel time in all community interventions being 13.22 (+/-10.39) minutes, equating to €9.09 (+/-€7.14) in salary cost. The travel costs incurred also played a role in the increase. The average procedure time was significantly longer in the community (p<0.001), even when examining similar procedures only. This may be due to the additional public health role of the nurses delivering the oncology care, as described in the community oncology handbook.

This study captured the societal perspective by calculating the loss of productivity via the Human Capital method as well as the health care payer perspective. Sanders et al. recommended that for the purpose of consistency and comparability, analysts should report “reference cases” from two perspectives— the health care sector perspective and the societal perspective (76). This was also corroborated by an ISPOR Special Task Force report (77). When using the societal perspective, this study found that there was no significant difference in the cost of delivering the oncology services between the two settings. A statistically non-significant cost reduction of €2.77 (p=0.278) when delivering interventions in the community was discovered. The primary reason for this change compared to the health payer’s perspective is the reduction in patient travel time. The patient travel time is reduced by an average of 35 minutes (95% CI 27.97 minutes – 41.38 minutes). This finding may be as important as the cost-saving from the health payer’s perspective, given that a central aim of the Irish Government’s Sláintecare healthcare policy is an accessible, single-tier and affordable healthcare system for all, with an increased focus on patient-centred care (11).

The analysis of the different primary care settings showed the expected result that the primary care centre was a cheaper option for the health payer, being an average of €15.36 ($p<0.001$) than the patient’s home. The primary care centre was found to be an average of €5.69 (95% CI -€1.09 - €12.47) more expensive than the hospital from the health payer’s perspective but this was not significant (p=0.098). This may be because the community nurses were recorded in some instances to be travelling back to the centre after dealing

with a home visit. From the societal perspective, the primary care centre was significantly cheaper than the hospital, by an average of €11.15 (95% CI €8.49 - €13.89, p<0.001). It is important to note that as part of any oncology primary care package, home visits will be a necessity. Given their clinical status, certain patients will require a home visit. This finding does show that from a societal perspective, interventions given in a primary care centre close to a patient's home represent a significant cost reduction, before considering the improvement in access to services from the patient's viewpoint.

While all analyses indicated that providing the intervention in the community resulted in a significant cost increase for the health payer, the sensitivity analyses demonstrated that there is a possibility that providing cancer care in the community represents a less costly alternative from the society perspective. Frailer cancer patients are often accompanied for travel requirement and physical support reasons. This study found that in a scenario where a randomly selected 40% of the patients in both settings were accompanied by another person, a significant cost reduction of €8.66 (95% CI €0.96 - €16.36, p = 0.03) was observed. This trend continued and became clearer the more patients were accompanied for their treatment. Unfortunately, the study did not record if someone had travelled with the patient or not.

When viewing from the societal perspective, these are welcome findings for the development of oncology care in Ireland. Providing oncology support services in the community is in line with the aims of Sláintecare healthcare policy, and this study shows that this represents a viable economic option. By

moving these services away from oncology day unit within busy acute hospitals, there should be benefits for all. The freed-up space in the hospital oncology service would allow for more of the treatments that can only be provided in the day unit, such as chemotherapy. In addition to the economic benefits, there may be a quality of life benefit for the cancer patient by providing some of these interventions in the community, due to a reduced risk of infection associated with travel to hospital (172). Patients have stated their preference for receiving oncology care in their own home (145). The reasons include avoidance of travel and parking problems, reduction in hospital-associated anxiety, feeling of comfort in their own home and not burdening their carers and family.

Given that these oncology support interventions can be provided in a cost-effective manner, there may be scope for expanding the duties of community nurses to include other oncology services. The UK has for quite some time allowed for chemotherapy to be administered as part of the list of services available in primary care (173). Even if only the less complex interventions were handled in the community, this would further reduce the demands on the oncology day units in acute hospitals. There is also a preference amongst both patients and nurses for blood samples to be collected in the community to streamline the chemotherapy administration process, as will be discussed in Chapter 4.

All interventions analysed were from two counties of Galway and Mayo in the West of Ireland. One of the counties is particularly sparsely populated (Mayo).

The average distance to healthcare facilities can be up to seven times larger in rural areas than urban areas (174). Table 3.8 below shows the population density of the counties in the study compared to other Irish counties.

**Table 3.9 Population densities in Republic of Ireland**

| **County** | Population | Population density | Rank (of 26) |
|---|---|---|---|
| **Mayo*** | 130,507 | 23.3 | 25 |
| **Galway*** | 258,808 | 40.2 | 14 |
| **Dublin** | 1,347,357 | 1459.2 | 1 |
| **Louth** | 128,884 | 155.4 | 2 |
| **Kildare** | 222,504 | 131.0 | 3 |
| **Cork** | 542,868 | 72.3 | 5 |

** Study counties*

This study used time recordings across community and hospital settings to compare the cost of delivering oncology support services. Other studies in this area have shown some differing results, albeit with different methodologies and focuses. Rischin et al. used direct and indirect costs based on services received and found that the average chemotherapy treatment was $83 AUD more expensive to deliver in the community than in hospital (145). Gordan et al. discovered a significant decrease in cost per patient per month when delivering care in community oncology clinics compared to hospital clinics, primarily driven by the increased cost of chemotherapy and provider visits in hospital-based clinics (159).

### 3.5.1 Limitations

The only costs estimated in this study were the costs incurred in the carrying out of the oncology interventions. The cost of training in the Community

Oncology Nursing Programme is not included in this analysis. If this cost were included, it would favour the hospital setting over the community setting. However, given that this is a lifelong qualification, it may be biased to include the cost of training when analysing the sample of interventions recorded. If it were included, the average cost per intervention carried out by a trained community nurse over the duration of their career would be negligible.

Ideally, a larger number of interventions would have been analysed for more robust results. These would ideally have come from the hospital setting to get more equitable sample sizes to compare, and thus provide more precise comparisons. However, where possible, these support services were carried out in the community to free up needed space in the hospital oncology day unit. Consequently, an imbalance in the proportion carried out in the community compared to the hospital was expected.

The sensitivity analyses were needed due to a lack of information regarding the type of staff who carried out the intervention and uncertainty as to whether the patient was accompanied by another person. The sensitivity analysis attempting to assess the impact of patients being accompanied to the hospital by carers only assessed physical accompaniment to the hospital. While the journey to the community centre may be less arduous than travel to a main hospital, it is possible that the patient could be accompanied by a carer in that circumstance.

## 3.6 Conclusion

This study has shown that providing oncology support services in the community in Ireland may be a viable economic option when viewed from the societal perspective. The community oncology nursing programme has demonstrated safety in its provision of these interventions in the community, indicating that the services that these trained community nurses provide may be a cost-effective service. Given that previous studies have shown the preference for community interventions among patients and with Ireland's increasing focus on building a health system focused more on primary care, an enhanced community oncology programme may provide an option in reducing the oncology demands in hospital.

# Chapter 4. A Qualitative Evaluation of Community and Acute Hospital Nursing Oncology Services in Ireland.

## 4.1 Abstract

**Purpose**: Cancer patients are a particularly vulnerable population group, facing particular physical, mental, logistical and financial challenges. This fact, as well as Ireland's increased focus on primary care with the Sláintecare healthcare plan, has led to the development of the Community Oncology Nursing Programme, where community nurses are trained to provide cancer care outside of hospital. the present study sought to explore the lived experiences of the patients and nurses involved in this programme in order to examine its impact on patients as well as determine facilitators and roadblocks for future development.

**Methods**: A qualitative examination of the service was carried out by interviewing cancer patients receiving care as part of the programme as well as the nurses delivering care, both in the community and hospital day-ward. Thematic analysis was used.

**Results**: Themes of improved patient experience, nurse-patient relationship, the importance of location and roadblocks to further implementation of the programme emerged. There was a universal belief that the programme offered benefits to cancer patients and improved their care to some extent.

**Conclusions**: The Community Oncology Nursing Programme has been well received by both nurses and patients. The service provided by community

nurses as part of this programme offers benefits to patients and an improved cancer service.

## 4.2 Introduction

Cancer is one of the leading causes of morbidity and mortality across the world with an estimated 18.1 million new cancer diagnoses and 9.6 million cancer deaths reported in 2018(14). Cancer, along with its treatments, has been shown to be debilitating, worsening the patient's physical and mental well-being(19-21). Cancer patients face long term difficulties in a range of physical and mental domains. Cancer has a long term impact on quality of life (QoL), and is associated with problems of anxiety, depression and infertility as well as social difficulties such as a feelings of shame or stigma attached to the condition (22-24, 175, 176). Cancer patients have been shown to experience fears of uncertainty and recurrence, contributing to poorer their mental health in a proportion of cases (177). Patients face additional financial burdens, with Irish cancer patients facing a reported average income drop as high as €1,527 per month, as well as additional medical and home bill expenses (38). Travel time and distance has been shown to influence a patient's decision to decline treatment, particularly in rural areas which are an hour or more away from a treatment facility (17).

Primary care is becoming an increasingly important component in cancer care delivery. A recent report in The Lancet highlighted the expanding role of primary care in cancer control and management. Primary care has a diverse set of roles in cancer care, ranging from screening and early detection, to end of life care (178). Primary care was found to have a continuous role in care

for cancer patients. This report showed that the strengths of primary care, especially the development of continuous therapeutic relationships with the patient, is particularly evident in cancer care.

There is general agreement that home-based chemotherapy is the preferred option for patients receiving cancer treatment (145), and patients with advanced cancer have been shown to prefer home care for end of life treatment (179). Home care treatments have been shown to improve clinical outcomes for patients, including gastro-intestinal side effects, pain, fatigue, insomnia and anxiety (148, 180). Patients have also been shown to value the care provided by nurses in the community which provides them with psycho-social benefits,(181) an "*unsurpassable*" level of care (182) and increased communication during their treatment (154). Research has demonstrated that nurses have improved care abilities when dealing with patients in their own homes, due to better observation of surroundings and a more personal relationship with the patient and their primary carers/families (183).

A community oncology nursing programme was developed in Ireland in 2010 in response to service pressures in acute medical oncology departments. Ireland is in the process of implementing a 10-year plan for health reform called Sláintecare. The aim of the Sláintecare policy is to establish a universal, single-tier health service as well as re-structuring the health system "towards integrated primary and community care that is consistent with the highest quality of patient safety in as short a time-frame as possible"(11). Sláintecare aims to move health services into primary care where possible, with a focus on patient-centred care. The programme enables community nurses to

provide shared nursing care to acute cancer patients at home/in a community setting (i.e. via a primary healthcare centre). The nurses first complete a specifically tailored Level Nine (postgraduate) university-accredited education course (in collaboration with National University of Ireland Galway - NUIG)(138). The programme consists of didactic lectures, case scenarios, reflective learning and workshops. The nurses complete a clinical placement of 20 hours and a final assessment consisting of a multiple-choice question examination and a detailed case study presentation. Upon successful completion of this programme, nurses are then deemed competent to perform certain clinical interventions safely for cancer patients in their own home which would previously have been delivered in the acute hospital setting, such as 5-Fluorouracil (5-FU) pump disconnections, PortaCath™ flushes, the care of Peripherally Inserted Central Catheter (PICC) lines and Hickmann lines, head-to-toe full nursing assessment focusing on cancer and the consequences of its treatments, and other auxiliary cancer support services such as medication administration and medication management. A pilot program of this initiative (undertaken in the northwest of Ireland) has been evaluated and was found to have had a positive impact on patients, on community-based and acute hospital-based cancer services showing enhanced integration of care (184). However, community nursing services in Galway, Mayo and elsewhere face major challenges in responding to the increased demand of caring for these patients without the support of additional resources.

A concurrent cost-comparison study, comparing the hospital versus community setting was undertaken simultaneously to this study, which is reported in Chapter 3. However, this pure costing study does not show some

of the personal and professional benefits or drawbacks of this new community-based cancer treatment programme. Hence, a qualitative approach is proposed to elucidate the thoughts/opinions of those involved in the programme, as well as its impact on patients. This study aimed to capture the benefits and challenges of this programme, as well as to examine the facilitators and roadblocks for future rollout of the programme, potentially at a national level.

## 4.3 Methods

### 4.3.1 Ethical considerations

Ethical approval was granted from the clinical research ethics committees of both the local hospital network and primary care network in the region (see Appendix G – Chapter 4 Ethics approval).

### 4.3.2 Participants

Those involved in providing care and patients receiving care via the new community oncology nursing programme were invited to participate in this study. This included cancer patients in both the hospital day unit and in the community setting. The oncology day unit is part of a University teaching hospital in the west of Ireland, with 521 beds providing a range of specialities. Patients are assessed and managed according to their individual treatment needs. Interventions include chemotherapy, adjuvant therapies, 5-Flurouracil (5-FU) pump disconnections, catheter insertion supportive care and dressings. The community service is provided in two counties in the west of Ireland (Galway and Mayo). County Mayo is particularly sparsely populated, with a

population density of 23.3 individuals per $km^2$; by comparison, County Dublin has a population density of 1459.2 individuals per $km^2$.(185). For each county, a community nurse who has completed the community oncology education programme is responsible for a designated area and population. Patients in this area are managed in either primary care centres located in that area, or in the patient's own home depending on individual circumstances. Nurses in both settings were also invited to participate, including nurses in the oncology day unit at the relevant main hospital, clinical nurse managers, liaison public health nurses and primary care regional general nurses who have been trained as part of the programme and regional manager nurses.

### 4.3.3 Sampling Strategy

Purposive sampling (186) using a pre-defined matrix for maximum variation sampling of patients, and nurses in the hospital setting and public health nurses in the community. A sampling framework was used to ensure that there was as wide a variety as possible in interview participants. The sample framework is detailed in Table 4.1 below. Final sample size for interviews was determined using the method of sample size calculation for qualitative interviews described by Francis *et al* (187). This method involves setting out a minimum sample size for initial analysis, the initial analysis sample and a stopping criterion, specifying how many interviews will be conducted with no new ideas emerging. The initial analysis sample was decided to be 7 Interviews across nurse and patient interviews, and the stopping criterion was 3 new interviews with no new themes arising. Data collection was complete when thematic saturation was deemed to have occurred.

**Table 4.1 Sampling matrix for participants**

| **Nurse** | | **Patient** | |
|---|---|---|---|
| Hospital | Community | Hospital | Community |
| >10 years' experience | >10 years' experience | >60 years old | |
| <10 years' experience | <10 years' experience | 40-60 years old | |
| Accredited cancer qualification | Completed CONP* (or other accredited cancer qualification) | <40 years old | |
| No accredited cancer qualification | Not completed CONP* (or other accredited cancer qualification) | Urban Galway residence | Urban Galway residence |
| Experience in community | Galway urban based | Rural Galway residence | Rural Galway residence |
| | Galway rural based | Experience with CONP* | Urban Mayo residence |

| | |
|---|---|
| | Mayo urban based |
| | Mayo rural based |

| | |
|---|---|
| No experience with CONP* | Rural Mayo residence |
| Male | |
| Female | |

**Community Oncology Nursing Programme*

### 4.3.4 Recruitment

Participants, both patients and nurses, were identified with the help of the Clinical Nurse Manager in the oncology day unit and the Director of Public Health Nursing in both counties. When identified, participants were provided with Participant Information Leaflets and consent forms by a research nurse. Participants were invited to read the Participant Information Leaflet and given time to decide whether they wished to take part. Where possible, the Participant Information Leaflet was provided days or weeks in advance. If patients indicated willingness to participate, their contact details were given to the primary researcher to arrange the interview. Prior to the beginning of the interview, participants were given the opportunity to ask any questions relating to the study before signing the consent form. Participants were made aware of the reason behind the interviews, and the motivation of the primary researcher of using this research as part of a PhD thesis.

### 4.3.5 Data collection

Study participants were asked questions according to a topic guide (Appendix H attached). Three distinct topic guides were used, one for each type of

participant. The topic guides focused on the participants' thoughts on any benefits or drawbacks of the programme, how it could be improved and envisioning a scenario where the service was no longer available. More specific questions for each participant group were also included, such as thoughts on the training aspect of the service for those nurses who had undertaken the programme. Given that the topic guides shared broadly similar questions and discussion points, all participants were analysed as a single group. Topic guides were developed using the research group's own experience as well as direct input with experts in the process of cancer care. The topic guides were initially pilot-tested with one member of each participant group and were amended following feedback. These pilot test interviews were not included in the final study analysis.

Interviews were carried out face-to face by the primary researcher, who was trained in qualitative research methods from a university postgraduate training module. Audio recordings of these interviews were transcribed verbatim. Field notes were also taken to inform of non-auditory responses.

Interviews took place in locations that best suited the participants. For the hospital nurses and patients interviewed in hospital, interviews took place in a private room adjacent to the oncology day unit. Interviews in the community took place in a similarly suitable private room in the Primary Care centre. One interview took place in the patient's own home due to travel issues. All interviews were conducted one-to-one in private. All participants who were approached agreed to part in the study. No transcripts were requested by the

participants. The shortest interview was 8 minutes long, the longest was 26 minutes long. The median interview duration was 13 minutes.

### 4.3.6 Analysis

The interviews were audio recorded and transcribed by the lead author. The data was coded by the lead author and a portion of the anonymised data was also coded by a second researcher to ensure consistency of coding. All codings were found to be consistent across the two researchers. The data was analysed using thematic analysis, as set out by Braun and Clarke.(188) This method of qualitative analysis is a six step process; (i) familiarisation with the data, (ii) generating initial codes, (iii) searching for themes, (iv) reviewing themes, (v) defining and naming themes, (vi) producing the report.

### 4.3.7 Software

Audio recordings were made using a Dictaphone (Sony® ICD-PX240) and Mobile Device (OnePlus® Pro 7T) The transcribed interviews were analysed using NVivo® Version 12.

### 4.3.8 Guidelines

This study was written in accordance with the consolidated criteria for reporting qualitative research (COREQ) statement (189).

## 4.4 Results

18 interviews were completed. There were 6 patients, 3 male and 3 female. There were 5 hospital nurses and 7 community nurses.

Using thematic analysis detailed by Braun and Clarke(188), four major themes were generated from the data, with a number of categories which are detailed below. All participants were analysed as one group. While this may have been thought to hinder the ability to specifically analyse the discussion of individual cohorts, the themes and topics discussed were consistent across groups, apart from expected variations such as discussions regarding the logistics of the programme being discussed almost exclusively by community nurses.

**Table 4.2 Major themes and categories identified**

| **Themes** | **Categories** |
|---|---|
| Improved patient experience | • Patient Safety and efficiency<br>• Psychological impact<br>• Expense and freedom<br>• Improved community nurse capabilities |
| Nurse- Patient relationship | • Many community nurses already known to patients long-term (‘cradle to grave’), building on that relationship<br>• Education of nurses to ensure they are competent in meeting patients’ needs and giving patients confidence in their ability to assess and manage their care |
| The importance of location | • Urban versus rural<br>• West versus rest of Ireland |
| Programme roadblocks | • Increased caseload<br>• Difficulty in release of staff for training<br>• Absence of recognition on taking on new roles<br>• Specialisation not always beneficial<br>• Increased support in hospital<br>• Knowledge gap |

Table 4.3 gives a breakdown of the number of times the four themes were discussed by the individual participant groups.

**Table 4.3 Number of times themes were discussed by participant groups**

| Theme | Patient (n=6) | Hospital Nurse (n=5) | Community Nurse (n=7) |
|---|---|---|---|
| Improved patient experience | 6 | 5 | 7 |
| Nurse- Patient relationship | 6 | 4 | 7 |
| The importance of location | 5 | 5 | 7 |
| Programme roadblocks | 2 | 3 | 7 |

### 4.4.1 Improved patient experience

It was unanimously agreed by both patients and nurses interviewed, that the community service was of additional advantage to the patient. A number of reasons for this were put forward including patient safety and efficiency, psychological impact, and fewer expenses and greater freedom from having services delivered in the patient's community or own home.

#### *4.4.1.1 Patient safety and efficiency*

The hardship that patients go through during treatment was particularly noted, and nurses were keen to minimise this as much as possible. Nurses felt that patients were more comfortable in their own homes.

"*I think they feel a lot safer at home, they're often pretty sick and exhausted.... I think the recovery is much better once they have someone coming into their own home or into a local health centre*". **CN3**

Nurses were aware of the clinical impact of patients travelling to a hospital setting, noting the increased risk of infection for these susceptible patients.

"*We try and quarantine people, anyone with the superbugs and things like that. But there are other bugs and people come in with respiratory infections and they are exposed…. we've only two single rooms here so they are limited*" **HN3.**

**"***They're sick patients and neutropenic and you don't want them to be going into the hospital and picking up something else***" CN1.**

Moving the support services to the community allows for a more efficient service in the hospital, reducing time for treatment.

"*Certainly from the hospital point of view…. to be able to facilitate the likes of these disconnections and pumps and different things, enhances our job here …. allows for us to treat people quicker you know from the time of diagnosis that there is not that wait list*" **HN5**.

#### *4.4.1.2 Psychological impact*

Outside of the long travel times and the related difficulties in accessing the hospital service, patients faced psychological difficulties when confronted with the hospital environment. Patients already dealing with the psychological challenges of their condition are particularly vulnerable and nurses were aware that there may be increased anxiety in patients who travel to hospital.

"*A lot of patients get anxious having to come in here. You know just the whole idea of coming into hospital*?" **HN2.**

Patients often had negative memories of their time in hospital, both related to their cancer and for other more personal reasons.

> "*Well it just brings all your memories back of your diagnosis and operations and you're still there, you're not just finished in the hospital when you're going in and out. So it's not a pleasant experience a lot of the time, there's a lot facing you when you're going in*" **Pat1.**

> *"I suppose the hospital setting itself is a bit more daunting… it's just a mental picture we have, going back to when we were kids"* **Pat6.**

Nurses in the hospital noted that the appearance and location of the oncology day unit itself may have an impact. The day unit itself was described as uncomfortable for the patients, particularly while they were waiting.

> "*Even to access the ground floor, they go down a flight of stairs you know so. I just think we could do more to make it more pleasant for them, I think a lot of them might dread coming here, just because of the look of it and where it is*" **HN4**.

> "*The drawbacks for the patients would be probably because it's so busy and we've got an increase in patient number, the waiting area isn't big enough for a lot of patients even to wait around. Sometimes some of them are waiting on the steps waiting for treatment*" **HN5.**

Patients experienced longer waiting times in the hospital and felt more uncomfortable doing so.

> "*The waiting times can be a bit tedious and they can be very long sometimes… could be a wait of 3 or 4 hours…. And when you're waiting, there isn't a lot of room outside and just the room itself can be a bit uncomfortable. And when you're coming in you don't really want to be waiting around"* **Pat4.**

In contrast, attending the local health centre was familiar and easier for patients. Patients did not face the same mental barriers when accessing these facilities.

> "*A lot of them enjoy coming here, it's probably mentally easier for them I imagine. Because going into the hospital sometimes had negative connotations with it, whereas we are not as hospitalised as the hospital*"**CN4**.

#### *4.4.1.3 Expense and freedom*

Non-clinical outcomes such as the expense of travelling for patients was important. Related to this was the time and the fact that spending the day travelling to the hospital and long waiting times limited the patients and accompanying persons' freedom to work or carry out usual daily activities.

> "*When I'm going to the hospital I usually get a taxi… The community centre is only a short way away so it's not expensive, that's a big thing. Especially when you're older"* **Pat2.**

"*It's a day gone. For mothers it's a day gone from their kids, family at home*" **HN1**.

The time saving as well as the physical toll of car parking was important for the patients. Particularly ill patients being treated with chemotherapy could face a physically draining walk to access the day-unit, which was not the case in the community.

*"Well, [it is] much better for parking, much better for time in general. There's never a problem finding a spot here, you could be ages in the hospital"* **Pat1.**

*"Definitely it's physically easier, because there is a designated car park for patients in the hospital, but it's away from the front door, down a hill. So, if you are sick with having chemotherapy, you have to walk a good bit."* **CN4.**

A patient's ability to work might be affected by the increased time spent travelling to the hospital.

"*I think the fact that they're at home and are free to do their daily basis and can get to work if they need to. Because most of them will want to work…. So, when you take in travel time to the hospital and the long waits they'd have, and then it saves them from sitting in a sick bed when they're not actually sick. So, freedom of movement almost"* **CN6**.

Some patients would be less reliant on others to help them travel, sparing them from the guilt of burden that often arises from their condition.

"*I'd often not have the energy so I'd need someone else to bring me in and out which is a burden on them*" **Pat4**.

#### *4.4.1.4 Improved community nursing capabilities*

The training given to community nurses as part of the programme was universally lauded by those who had received it. As well as the obvious improvement in knowledge that the education provides, the course helped foster improved relationships between the two settings, allowing for better communication and improved patient care as a result.

"*I think your knowledge base really improves. I think we have a better relationship with our colleagues in the hospital compared to what we had. There's a lot more communication…. If I ever had a query for a patient it was easier to get through, I knew my way a bit better*" **CN3**.

The community nurses were more confident and felt more capable following their training. It allowed them to increase their knowledge of the condition and also to familiarise themselves with the patient journey through cancer treatment.

"*Once I did the programme, you visited all these sites and you saw exactly and you saw what was decided and what happened the patient in the hospital setting…. And for different therapies, what happened there and how a different therapy was delivered. And even just the different cancers, you know, how they manifest themselves in the body, and all of that was touched on in the course. It was excellent, for me it was a great learning*" **CN7.**

The training the nurses received as part of the community oncology nursing programme allowed them to appropriately assess and manage queries from the patients.

> "*And then when the patients come in and they might question something or might describe an experience they had in the house you'd be in a position to understand it more, because you've done placements in the different areas as well*" **CN6.**

### 4.4.2 Nurse-patient relationship

In all responses there was a noticeable bond formed between the patient and nurses in both settings. Many nurses felt a sense of duty of care when caring for the patients.

> "*When you're seeing the same person every few weeks you really do get a sense of what they're going through and how tough it is. And with that, you don't mind putting in the extra hour it might take to travel, you know if you're going into someone on the way home after you're supposed to finish. I'd have no problem doing that"* ***CN2*****.**

Patients were put at ease upon seeing a familiar face.

> *"You get to know them better, puts you more at ease and stuff like that. You see the same girl each time, so you get to know them a bit more. It helps when you know who's coming"* **Pat2***.*

Following the patient's journey from beginning to end of treatment provided a sense of satisfaction for nurses.

> "*You kind of get to see patients from the start of their diagnosis right through to completing their chemotherapy and so on. It's quite special really, it does make you appreciate the work that you're doing*" **HN5**.

The familiarity gained from repeated meetings provided benefits in the delivery of care.

> *"When you see them regularly, that's when you start to spot there's problems. They may be picked up sooner. That they're really starting to lose weight, that they're really struggling. That you can ring the unit and say I think this client needs to be reviewed*" **CN3.**

For patients, the ease of access to a local community nurse they knew enabled more direct and enhanced communication when needed.

> "*I can make a phone call to have it done in the morning. While if you go to (the day unit), you can't do that…. And if I have any questions, I can ring and I know they'll answer me quickly. I have the nurse's mobile number so I know if I'm ever not feeling well or need something, I can get her on the phone" **Pat6**.*

This was different to the arduous process of getting through to hospital staff.

> "*They will say to you that they can ask questions, they feel safer, they feel happier, that they have a link so even when we take off the pump,*

*the next day if there's a problem they have someone rather than trying to get through to the regional*" **CN3**.

### 4.4.3 The importance of location

#### *4.4.3.1 Urban versus rural*

The divide between patients in a rural setting compared to those in an urban setting was a central point in discussions. The long travel times from rural settings was a challenge for many of these patients, a challenge exacerbated by treatment side-effects such as nausea. The more immediate access to a local community centre and nurse was a benefit for these patients.

"*You'd be going nearly 100 kilometres to get to your furthest patient. So, if you're thinking of a sick patient travelling that distance, that's very hard on them…. And if you were up in Belmullet or somewhere like that, they have a nurse up there. Otherwise, the patients would be coming down to Castlebar. Even some of them travel to Galway, not even to Castlebar. And that's too much to be asking of them*"**CN7**

Cost was another factor.

"*We'd have a lot of people coming from various parts of the west and midland you know? So, it reduces down their commute, it reduces their cost and again it gives them a bit of security to think that they have a local centre that they can go to*" **HN2**.

Patients in rural areas have an increased reliance on others for travel due to public transport limitations.

> "*They might have to ask their families. A lot of them would rely on their families and their families might have to take time off work. Especially if public transport doesn't suit timewise. For instance, to Castlebar, to get a bus you'd be gone at 9 and a bus might not be coming back until 4 in the afternoon*" **CN7.**

> *"For me personally I don't drive so I have to advance lifts every time but I have a big family and they are all helping out… I suppose just the time it takes to get in, with traffic and getting all the way into the town it can be a long trip"* **Pat4**

Patients in locations closer to the hospital did not experience as much difficulty with travel as those in rural areas, but did note that they were fortunate in this.

> "*I think it's great for people who live further out. You know, I'd meet people inside in the hospital who've come from Belmullet and that's awful hard on them*" **Pat1.**

#### *4.4.3.2 'West versus rest'*

Community nurses were aware that some of the problems faced by them might not be the case across the country. The more sparsely populated West of Ireland provided greater challenges to care when compared to other parts of the country, particularly Dublin.

"*I suppose one thing is that it might be easier in other parts of the country. Like, for example, when I was in Dublin, it's much more compact and it might be easier to get to patients. And there's more staff there*" **CN6**.

Some community catchment areas in Galway and Mayo extend to islands, presenting a very particular challenge. Patients would have had to stay on the mainland due to travel restrictions back to their island homes.

"*I suppose when I started doing the course it was in Connemara, the difference for those clients was huge. Because you've got to remember they're travelling huge distances. When you work on the islands, it's even more so. A lot of these clients would have had to stay in town. When they have an oncology nurse on the island, they can stay home. So that was a huge benefit for them"* **CN3**

### 4.4.4 Programme roadblocks

The stakeholders universally found benefit in the programme, however some issues with its implementation and future prospects were raised.

#### *4.4.4.1 Increased caseload*

Community nurses experienced an increased caseload while undergoing the accredited course. Nurses said that completing the course presented challenges due to the extra work on an already busy schedule.

"*Well it could be a drawback for us because it increases our workload…. it is difficult to get away from the work to do the course*… t*here are some courses you can do here in the centre through the Galway Centre for*

*Education but it's not always possible to attend those. And then there is the oncology nurse course. But again, because our workload is so big, some of us wouldn't always be able to attend those courses*." **CN6**.

Others noted that upon completing the course, they would have extra oncology services added on to their own caseload.

"*Like if I was doing it for other nurses it's not like anything's being taken away from my caseload, it's just something that's added on for me*" **CN1.**

This increase in caseload, as well as a lack of places in the programme has meant that the roll-out in some areas has been limited, reducing the number of trained community nurses.

"*But there is only like 6 people, 6 PHN's that have done it this year now, there is more on board to do it. But, the roll-out of it in (here) has been pretty poor"* **CN4**

#### *4.4.4.2 Specialisation not always beneficial*

One community nurse felt that by doing the course she had been placed in a specific role and that consequently this may prevent other nurses from seeking this specialisation.

"*If you've been able to do a course and you're specialised in it, you're nearly holed into that area if they're short. There are palliative care teams that help with the oncology as well, whereas is we do just this it covers us for our registration. But, generally, what happens is if you do anything extra, you could be pulled into other areas*" **CN6.**

Others felt differently, thinking it was an advancement in career progression.

> "*For the nurse, it makes you more competent and expands your scope of practice. Any nurse that gets an opportunity to improve themselves, in knowledge and perspectives, should do it*" **CN7.**

#### *4.4.4.3 Increased support in hospital*

Nurses were noted to be more isolated in the community than in the hospital, presenting challenges. Where nurses in the hospital setting often had numerous colleagues, both nurses and other healthcare professionals, to have discussions and aid in queries, nurses in the community were often acting more on their own or in smaller groups.

> "*I think you'd have more of a support network in the hospital, compared to the community*." **CN4.**

Hospital nurses appreciated the extra security that came from being surrounded by supportive colleagues.

> "*There's a lot of us here so if we're ever stuck we can get someone around us to help, which is great when you're just starting. I know when I started you always like having the more experienced girls around to help out if you need it*" **HN1.**

For one patient, the hospital was a better location if something went wrong during their treatment.

> **"***I guess I feel safer in one way. Whereas at home I think if something went wrong or if it wasn't done right, whereas a hospital I am kind of*

*aware that it is done properly. If anything ever happened, well I'm in the right place*" **Pat 4**.

This could present particular problems in more isolated areas with fewer nurses. The limited allotment of places in the programme had left some nurses relying on the help of others to teach them certain skills.

"*You learned on the job. Whoever had been doing it (oncology care) demonstrated it to you*" **CN2**.

#### *4.4.4.4 Knowledge gap*

One community nurse was concerned that there may be a gap in knowledge between nurses in the two settings.

"*Since I became a public health nurse, I have noticed a big gap in knowledge compared to nurses working in the hospital and public health nurses. I would know a lot about oncology, but some public health nurses don't because they are very generalised, they look after a lot of different patients"* **CN4.**

One particular nurse was concerned that patients might not be as confident in community nurses as they were with hospital nurses.

"*Some patients might see us as more generalised not as specifically specialised in oncology nursing as they would be in the hospital. So, I think that sometimes they are a bit afraid of coming to us, because they think …… they might not know what they are doing*".

This nurse saw the community oncology nursing programme as a big step in helping to bridge the gap.

"*The community oncology programme would be massively beneficial to Public Health Nurses… if I had my way, I would make sure that they all had taken part in the community oncology nurse programme, because they really shouldn't be providing care for these patients if they don't know what they are doing*".

## 4.5 **Discussion**

This study provides an insight into the psychology of those involved in community cancer services in the west of Ireland, the patients and community nurses, as well as the thoughts of nurses in the hospital day units who have experience with treating these same patients. Most evident in this study was the universal belief that community-based cancer care provided additional benefit for the patients.

The development of a nurse-patient relationship over time has been well documented. Wright et al. (190) reported that the development of this relationship was the basis through which much medical care was given. Nurses focused their care based on their observations from this nurse-patient relationship. Nurses in this study noted that greater personal familiarity with their patients can lead to improved care due to faster recognition of problem symptoms such as weight loss. Griffiths *et al* (181) reported the value patients place on this relationship and the psycho-social benefits they receive from home visits in particular. Patients in this study found benefit in the increased familiarity they had with their primary care nurses, who they could contact more readily than the hospital nurses if they needed specific advice or support relating to any aspect of their cancer care. Being a shorter distance away and

having more contact options such as a mobile phone number meant that most patients had more immediate access to the nurses in the community. Both patients and nurses felt that seeing the same nurse each time was another key factor in improving bonds between patient and nurse in the community i.e. everybody agreed that continuity of nursing care was paramount to a better patient experience. None of the patients indicated any notable difference in knowledge or quality of care across the two settings and while one nurse in the community was concerned about a potential knowledge gap between nurses in hospitals compared to nurses in the community, they also identified the education and learning provided by the programme as a means of minimising this problem.

Given the previous findings showing that 23%-30% of cancer patients develop some form of significant psychological problem over the course of their treatment (21), it is logical that psychological support should be an integral part of cancer care. Both nurses and patients in this study noted the psychological impact of a journey to the hospital day unit on patients, superimposed on the physical challenges of travel for physically unwell patients. Patients' negative impressions of the hospital environment came from both their condition and prior personal convictions, such as negative thoughts from childhood of hospitals being intimidating places. Patients have been shown to prefer home care for various reasons such as less worry about childcare (191) and avoidance of journeying to hospital which can be emotionally draining (145, 192). Tralongo *et al*. (2011) reported that 90% of cancer patients found hospital admission to be more distressing than home care.

The fact that this study was carried out in two counties in the West of Ireland, Galway and Mayo put a particular focus on the challenges for patients in rural areas who have to travel to hospitals sometimes located more than 100km away from home. For these patients, travel avoidance had the most important value from the introduction of the community cancer treatment service. Nurses in both settings were aware of the physical and psychological impact of these long journeys; not surprisingly, they indicated that this service was of particular benefit to those in more rural areas.

Sláintecare, Ireland's current health reform policy, aims "towards integrated primary and community care that is consistent with the highest quality of patient safety in as short a time-frame as possible"(11). It aims to provide a health service accessible to all residents, showing the importance of primary care teams and cancer services in the more rural areas of the country.

Another aspect of Sláintecare is the increased focus on patient-centred care. The findings of this study indicate that patient-centred care is evident in both hospital and community settings. Both hospital and community-based nurses displayed clear empathy for the patients' difficulties and it is clear they want a cancer treatment service that takes account of the needs of both the patients and their families. All the nurses interviewed believed there was a benefit for the patient if their cancer care could be delivered in the community by trained community nurses and expressed that they believed that this is the service that should be offered as first choice.

For this programme to become successful and implemented as part of cancer care services nationally, the concerns raised by the community nurses in this

study will need to be considered carefully by health policy makers and those with responsibility for its implementation. Concerns raised by nurses interviewed included:

i. lower levels of support than their hospital counterparts.
ii. the need for addition of study days each year.
iii. extra cancer-oriented work superimposed on an already busy caseload.

The nurses acknowledged the value of the training course and the increased capabilities it provided them. However, there was concern that where only one nurse in a large catchment area might have cancer care training, that same nurse might be required to assist their colleagues in adjacent catchment areas should any issues arise, such as an unplanned absence. This could be particularly problematic given the long distances nurses already have to travel to facilitate care in their own area. This problem could be mitigated if more nurses were facilitated to participate in the cancer training programme and upskilled to a level of competence as cancer care nurse practitioners. Several nurses within HSE regional catchment areas have completed the programme, but often there is a reliance on other nurses who have more experience in cancer care to help teach them.

The original pilot study of the programme found that clinical outcomes for cancer patients treated in the community were not inferior to those of patients treated in the day unit (184). Patients should be made aware of these findings when undergoing care in the community to address concerns they may have about safety and efficacy of treatment in the community compared to the hospital. Other studies have reported similarly, with no worsening of quality of

life and no difference in safety between cancer care in the community compared to hospital (193). However, this non-inferiority of treatment outcome was contingent on the nurses in the community undergoing the necessary specialized training as part of the programme. It is logical, therefore, to propose that for the desired clinical outcomes in the community, there should be particular emphasis on greater participation in the programme among primary care nurses.

A concurrent study that compares the cost of providing cancer services in the community and hospital was undertaken as part of the evaluation of the community oncology nursing programme, reported in Chapter 3. This study found a significant increase of €6.86 ($p<0.001$) in the cost of travel for each hospital-treated patient for each intervention. Patients' journeys to hospital were found to be an average of 34.67 minutes longer when travelling to hospital ($p<0.001$) compared to when receiving care in the community. These findings indicate increased costs for patients travelling to hospital, and give clearer perspective to the concerns regarding arduous travel burdens for many of these sick patients. Increased travel time has been shown to impose financial, time and practical hardships on cancer patients (17, 194). Nurses interviewed in this study were keen to minimise avoidable patient difficulties as much as possible. Having cancer care delivered in the community has been shown to reduce the financial and travel hardship incurred by the patient, as well as any travel companions such as family and carers who often accompany cancer patients due to their illness (17).

### 4.5.1 Limitations

There was a risk of bias in the responses of the nurses in both settings, as they may have felt that it is important to put their work and environment in a positive light. To the authors' best judgement this was not the case, as many of the nurses were critical of their own environment and reflected positively on their opposite care setting. Patients may have been reticent to criticise some aspects of their care to avoid being seen to be overly critical or causing embarrassment. This was mitigated by ensuring them that all interviews were completely confidential i.e. that no detail of their interview would be shared with their attending cancer nurse or any other third party. Selection bias of interviewees was minimised by the use of a sampling matrix to ensure representation. There was no prior relationship between the primary researcher and any the interview participants. Some of the interviews with patients were shorter than expected, the shortest being 8 minutes in duration. While a number of short interval patient interviews may have led to a proportionally skewed response from some patient groups, the authors were confident that a sufficient level of detail was acquired from these interviews and were thus included.

## 4.6 Conclusion

The responses of both patients and nurses in this qualitative study showed that the community oncology nursing programme has benefits for the quality of care provided for cancer patients. Benefits included reduced risk of infection, reduced stress, increased freedom, reduced cost, reduced waiting time and reduced reliance on others such as family for transport and support. The previously reported therapeutic relationship developed between cancer

patients and cancer treatment nurses was clearly evident, and facilitated an increased insight into the patient's condition. Ireland's health reform plan, Sláintecare, is aiming for an accessible healthcare system that has an increased focus on primary care. For this aim to be realized (i.e. that cancer care should continue to be delivered in the community), there is a need for an increase in the number of nurses participating in the programme.

# Chapter 5. A Mixed-Methods Analysis of the Monitoring of Oral Anti-Cancer Therapies.

## 5.1 Abstract

**Introduction:** Oral anti-cancer therapies offer advantages over parenteral therapies in terms of their non–invasive nature and reduced intrusiveness. However, the shift from directly observed administration of these therapies to home administration means that continuous monitoring is needed. The oral anti-cancer therapy market is rapidly growing, with an ever-increasing number of new medicines available for the patients presenting with cancer illnesses. This study aims to (i) evaluate both the cost of providing monitoring consultations of oral anti-cancer therapies, and (ii) to assess the experience of cancer therapy nurses responsible for the monitoring and their opinions of the quality of the service.

**Methods:** This study provides a mixed-methods evaluation of the monitoring of oral anti-cancer therapies. Nurses were asked to record the time taken for them to perform their monitoring duties, and staff related costs were calculated using publicly available salary data. Patient-related costs were calculated using the Human Capital method. Nurses were asked to discuss their experience of monitoring oral anti-cancer therapies in semi-structured interviews. These interviews were subsequently analysed using thematic analysis.

**Results:** 201 recordings and their associated costs were documented. The median consultation time was 33 minutes, costing €22.10 using Clinical Nurse Specialist salary figures and €26.51 using Advanced Nurse Practitioner salary

figures. The associated patient cost was €14.06. Themes of the effect of Covid-19 on the service, expanding and complicated care package requirements, the need for dedicated oral clinics and the future of the service emerged from the interview data.

**Conclusion:** The monitoring service provided by nurses may be undervalued. The commitment to fully dedicated oral anti-cancer therapy clinics and an increase in staff to align with the ongoing increase in service demand is seen as vital for the continued safe and effective delivery of this specialist cancer service.

## 5.2 Introduction

Cancer, as one of the most significant health problems in the world, continues to increase in prevalence. According to estimates from the World Health Organization (WHO), cancer is the first or second leading cause of death before 70 years of age in 91 of 172 countries (12). Cancer incidence and mortality are growing worldwide (13). The Global Cancer Incidence, Mortality and Prevalence (GLOBOCAN) 2018 report estimated 18.1 million new cancer cases and 9.6 million cancer deaths in 2018 (14).

With these epidemiological data, cancer therapies have come under increased focus for pharmaceutical manufacturers. In 2019, 35.2% of research and development projects were cancer therapies, up from 34.1% in 2018, 32.6% in 2017 and 30.1% in 2016 (195). Oral anti-cancer therapies (OATs) have become more common as part of cancer care due to their improved targeting of cancer cells when compared to traditional chemotherapeutic agents. In recent years, the number of OATs being approved for patient reimbursement

in Ireland has outnumbered the more traditional parenteral therapies (196). OAT have contributed to a large increase in cancer survival and life expectancy from diagnosis in recent decades (197, 198). OAT administration provides more prolonged drug exposure compared with intermittent IV infusion, which may be important for some anti-cancer drugs with schedule-dependent efficacy (199, 200). Patients have stated a preference for oral anti-cancer therapies, due to their non-invasive and convenient nature (201, 202). A recent review of the literature found that 84.1% of patients have a stated preference for OATs rather than parenteral agents (203).

Despite these advantages, there are limitations on the use of OATs. Most notably, there is an increased risk of adverse drug reactions and adverse drug and food interactions when using these oral therapies (204, 205). QTc interval prolongation, CYP450 enzyme alteration, pH-dependent absorption and the interaction with the fat content of meals are some of the problems associated with these agents (205). Patient adherence to OATs represents another issue in medication management. A study on adherence with targeted OATs found an overall adherence rate of around 70% (206). Another study of women receiving 5 years of adjuvant tamoxifen for breast cancer showed that these patients filled their prescription 87% of the time the first year of treatment, decreasing to 50% by year 4 (207). If adherence is low, the health advantages conferred by OATs may not be as great as initially thought from clinical trial data (208).

With the issues outlined above, there is a need for the monitoring of those who are receiving OATs, both before and during treatment. Patients are monitored

at the beginning of each treatment cycle, usually every 3-4weeks, for recent warning symptoms, adverse events, derangement of haematological and biochemical blood results and toxicity checks (209). The need for regular monitoring associated with OATs places significant burden on the healthcare system(209). There has been notable success from using OATs, both financially and clinically, by reducing the time between the initial baseline visit and first follow-up monitoring to 1 or 2 weeks (209). However, this reduced waiting time for patients could place further strain on an already stretched service. To date, the extent of the impact of greater OAT availability on local secondary care oncology outpatient services and on healthcare staff has not been measured.

### 5.2.1 Aim

This study aims to examine the impact of increasing OAT availability on local secondary care oncology outpatient services and on healthcare staff using a mixed-methods approach. That is, to carry out an impact evaluation from a quantitative perspective measuring total time spent monitoring for each patient and the associated cost to the healthcare provider, and from a quantitative perspective using semi-structured interviews to evaluate the lived experiences of the nurses who are responsible for the monitoring and delivery of OAT in Ireland.

## 5.3 Methods

### 5.3.1 Study sites

Oncology day units in eight hospitals across Ireland were evaluated. Of these, one was in a private hospital, the rest were in public hospitals run by both voluntary organisations and the HSE. Two of the hospitals were in the South/Southwest Hospital Group of Ireland, four were in the Saolta Hospital Group in the West of Ireland and one was in the Dublin/Midlands Hospital Group. Two of the hospitals in the South/Southwest Hospital Group are the designated cancer centres for their respective regions, as well as one of the hospitals in the West of Ireland. This means that they treat a higher number of patients.

Two of the hospitals evaluated did not have dedicated oral anti-cancer therapy clinics and treated patients as part of the general chemotherapy service in their oncology day unit. Those hospitals with dedicated clinics ran them on specified days each week, although no hospital had a full-time OAT clinic.

### 5.3.2 Ethical considerations

Ethical approval was granted from the relevant clinical research ethics committees of all participating hospitals. Applications were submitted and accepted to the Saolta Hospitals Group Research Ethics Committee (C.A. 2521), the Clinical Research Ethics Committee of the Cork Teaching Hospitals (ECM 4 (c) 12/01/2021), the Clinical Ethics Committee of the Bon Secours Health System and the HSE South Eastern Area Research Ethics Committee (see Appendix J – Chapter 5 Ethics approval). One hospital did not require a full ethics application as no patient level data were being collected there.

### 5.3.3 Cost evaluation

Costs from both the health payer's and societal perspective were assessed. All costs recorded were from 2021 and were in Euros (€). No discounts were applied as the entire study was completed over a 3-month study period. Time-driven activity-based costing (TDABC) was used to assess overall costs based on the time taken to monitor each visiting patient. TDABC uses two parameters for calculation i.e. (i) unit cost, and (ii) time take to complete activity (123). A seven-step approach was used in healthcare settings to calculate the total cost of patient care, detailed in Table 1.1 from Chapter 1 (124).

**Table 1.1 Seven steps of TDABC in healthcare**

| **Step** | **Process** |
|---|---|
| Step 1 | Select the medical condition. |
| Step 2 | Define the care delivery value chain. |
| Step 3 | Develop process maps of each activity in patient care delivery. |
| Step 4 | Obtain time estimates for each process. |
| Step 5 | Estimate the cost of supplying patient care resources. |
| Step 6 | Estimate the capacity of each resource and calculate the capacity cost rate. |
| Step 7 | Calculate the total cost of patient care. |

Footnote: Steps 2 and 3 of this model are delivered by the use of Process Mapping. In order for a precise costing model to be achieved, each event in the process must be detailed and a cost allocated.

#### *5.3.3.1 Process mapping*

As part of the seven-step TDABC method, process maps were designed for each individual day ward practice. This involved consultation with process

leaders in the sites, these being the advanced nurse practitioners who run the OAT process. Ideally, and according to the literature, direct observation of the process by the lead investigator would follow, however this was not possible due to restrictions put in place as a result of the Covid-19 pandemic i.e. non-essential staff visiting healthcare settings. Therefore, instead of site visits, the lead author conducted detailed discussions with staff within each site and each map was signed off as correct by the respective process leader. Given that all study sites use the National Cancer Control Programme (NCCP) protocols(210), the process map was nearly identical in all sites, the only differences being logistical in nature such as IT system used and the location where the patient waited before the appointment. Figures 5.1 and 5.2 below shows a representative process map for all study sites. The process maps were designed at a top-level manner, aiding in outline each step in the respective processes. The process maps were designed for the regular, face-to-face consultations. For virtual consultations, the process would follow the same steps, however tasks not possible to carry out virtually, namely physical assessments and blood taking, were not performed. The blood samples may be taken by a GP or other healthcare practitioner and sent to the hospital for analysis. This was needed to identify resource utilisation, at the start of the costing study. From the process mapping exercise, a time recording template (Appendix K attached) was designed for the nurses in each site to record the time observations in as simple and efficient a manner as possible.

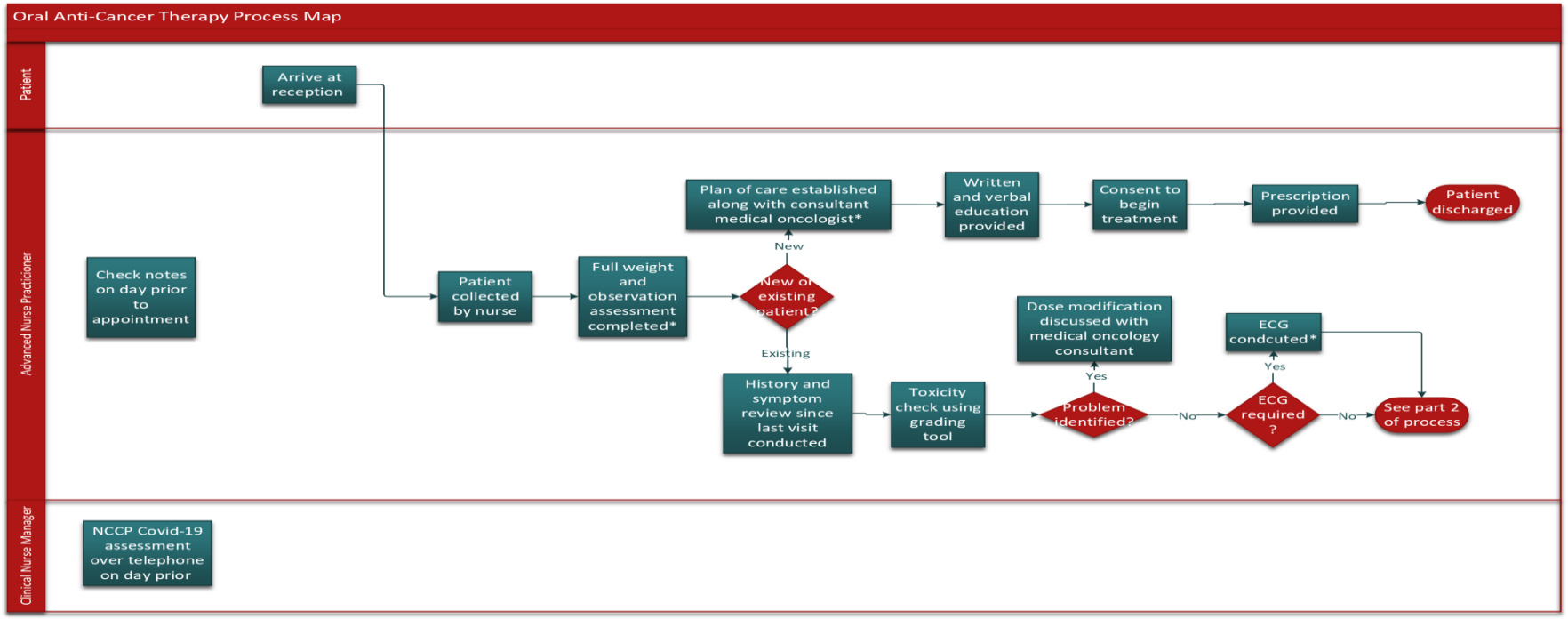



**Figure 5-1 Oral anti-cancer therapy monitoring process map part 1**

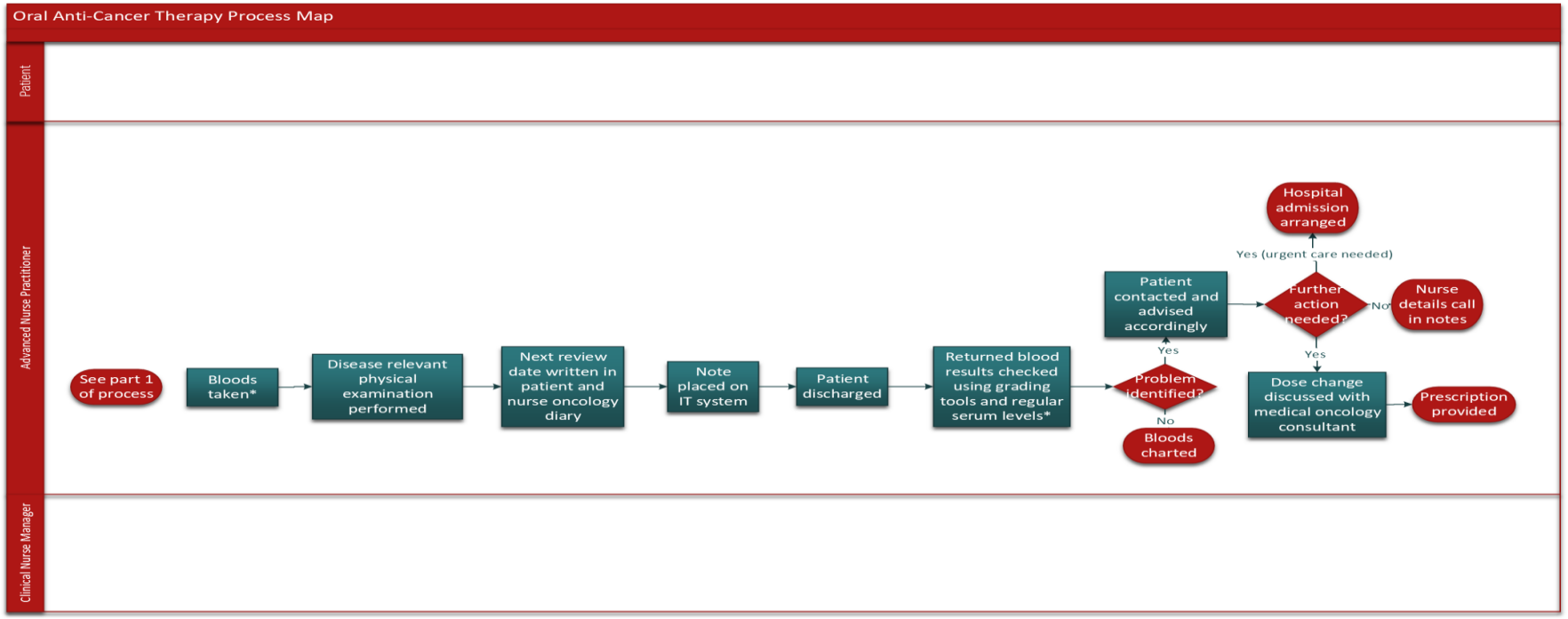



**Figure 5-2 Oral anti-cancer therapy monitoring process map part 2**

#### *5.3.3.2 Cost evaluation*

Time-related costs were calculated by measuring active time spent by nurses on carrying out tasks related to the monitoring patients' OAT's. Times were recorded using a direct observation approach by the practicing nurse with a stopwatch. Both face-to face (present in day unit) and on-line virtual consultations were assessed. Using the pre-designed recording template (see Appendix K – Chapter 5 data collection sheet), nurses recorded total time of care, which included time spent directly managing the patient as well as any other tasks related to the patient's care.

The most recent HSE healthcare professional pay scale (October 2020) was used to cost the times observed (211). All observations were performed by either a clinical nurse specialist (CNS) or and advanced nurse practitioner (ANP). The midpoint of the relative professions pay scales was used and adjusted according to guidelines for economic evaluations in Ireland (212), including pension payment, social insurance and overhead costs. The hourly consultation rate was calculated by dividing the midpoint salary by the number of weeks worked per year and the number of hours worked per week. The number of weeks worked per year is 48 and the number of hours per week is 39. Advanced nurse practitioner and clinical nurse specialist rates were applied to the time observations. Patient time-related costs were calculated using the Human Capital Method (213). The average national hourly income as of 2020 Q4 (€25.56) was used (214).

A sensitivity analysis examining the increased societal costs of patient travel was performed. An average patient travel time (38.42 minutes) to the hospital

day unit derived from a previous study (215) was applied to the face-to-face consultation costs. The extra societal cost was calculated using the Human Capital Method as previously discussed.

### 5.3.4 Qualitative

#### *5.3.4.1 Sampling Strategy*

Initial purposive sampling (186) of nurses responsible for OAT monitoring was carried out. Further participants were identified using snowball sampling. Final sample size for interviews was determined using the Francis *et al.* (2020) method of sample size calculation for qualitative interviews. This method involves setting out a minimum sample size for initial analysis, and a stopping criterion, specifying how many interviews will be conducted with no new ideas or themes emerging. The initial analysis sample was decided to be 7 Interviews as per the Francis *et al.* methodology, and the stopping criterion was 3 new interviews in which no new themes arising. Data collection was complete when thematic saturation was deemed to have occurred.

#### *5.3.4.2 Recruitment*

Participants were initially identified through contact with a gatekeeper with knowledge of OAT clinics in Ireland. There was a very limited number of potential participants given the small number of nurses with responsibility for the monitoring of OATs in Ireland. When identified, participants were provided with a Participant Information Leaflet. Participants were invited to read the information leaflet and given at least 14 days to decide whether they wished to participate. If invited oncology nurses indicated their willingness to participate, their contact details were given to the primary researcher to

arrange their interviews. Prior to starting the interviews, participants were given the opportunity to ask any questions before signing the consent form. Participants were made aware of the reason for the interviews, and the motivation of the primary researcher of using this research as part of his PhD thesis.

#### *5.3.4.3 Data collection*

Study participants were asked questions according to a topic guide (Appendix L attached). The topic guide focused on the participants' thoughts on any benefits or drawbacks of the service, facilitators or roadblocks to further development and their own personal experience in undertaking this responsibility. Topic guides were developed after reviewing the literature, using the researchers' own experiences as well as direct input from experts with experience in the process of cancer care. The topic guides were initially pilot tested with nurses with experience in monitoring patients on OAT, and were amended as needed following feedback. These pilot interviews were not included in the final study analysis.

Due to restrictions put in place by the Covid-19 pandemic, interviews were carried out remotely using Zoom® video conferencing by the primary researcher trained in qualitative research methods who also transcribed audio recordings of these interviews verbatim. Field notes were taken immediately post-interview to inform of non-auditory responses.

Interviews took place at times and venues selected by the participants. All interviews were conducted in private. All participants who were approached agreed to participate in the study. No transcripts were requested by the

participants. All participants allowed for the use of anonymised quotes from their interviews to be published. There was no prior relationship between the primary researcher and any of the interview participants.

### 5.3.5 Software

Cost data was analysed using Microsoft Excel® 2016. Process maps were created using Microsoft Visio® 2019. Interviews took place remotely using Zoom® video conferencing. Audio recordings were made using a Dictaphone (Sony® ICD-PX240) and Mobile Device (OnePlus® Pro 7T) The transcribed interviews were analysed using NVivo® Version 12.

### 5.3.6 Guidelines

This study was written in accordance with the COREQ statement (189).

## 5.4 Results

### 5.4.1 Cost analysis

#### *5.4.1.1 Healthcare professional cost*

The annual salary midpoint for an ANP was €64,571, resulting in an adjusted salary of €90,238 and an hourly consultation rate of €48.24. The annual salary midpoint for a CNS was €53,843, resulting in an adjusted salary of €76,110 and an hourly consultation rate of €40.19.

#### *5.4.1.2 Observations*

A total of 201 timed observations were recorded across 5 hospital sites; 179 of these were face-to-face consultations and 22 were virtual consultations. Three of the hospitals included in the qualitative aspect of the study elected

not to take part in the time recordings due to the staff members not being able to commit to the time requirements of the data collection. When analysed graphically, the distribution of time recordings was found to be non-parametric.

Descriptive statistics of the recordings are shown in Table 5.1 below. Figure 5.3 presents the data graphically in the form of a boxplot.

**Table 5.1 Descriptive statistics of time recordings of consultations with patients receiving OAT**

| | | Time (minutes) | | | | |
|---|---|---|---|---|---|---|
| **Process** | **N** | **Minimum** | **Q1** | **Median** | **Q3** | **Maximum** |
| **ECG** | 34 | 1 | 6 | 8 | 10 | 13 |
| **Physical assessment (PA)** | 179 | 2 | 9 | 11 | 15 | 34 |
| **Bloods** | 192 | 1 | 2 | 4 | 6 | 24 |
| **Issue resolution** | 70 | 1 | 7 | 10 | 15 | 62 |
| **Total time (including issue resolution)** | | 15 | 22 | 33 | 45 | 120 |

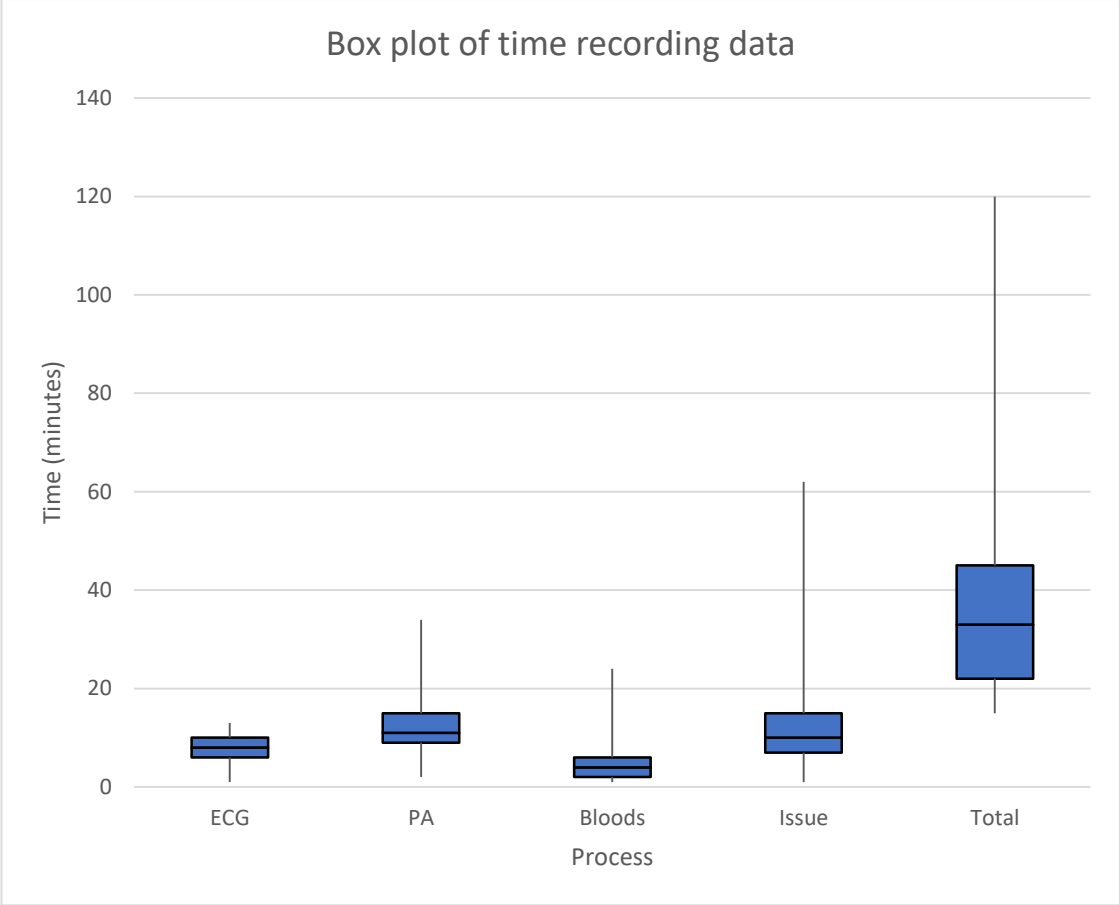



**Figure 5-3 Box plot of time recording data**

Of the 201 recordings, 34 included the performance of an ECG while the remaining 167 had no ECG performed; ECGs were undertaken selectively according to the potential cardiotoxicity of the prescribed OAT regimen. Nurses were able to identify whether an issue arose throughout the course of the observation, including medication toxicity issues, blood test results issues or any another unforeseen issues. 131 of the observations recorded passed with no patient issues being raised; the remaining 70 observations (34.8%) encompassed at least one patient issue. The disruption time due to these issues ranged from 1 minute to 62 minutes and the median disruption time where an issue arose was 10 minutes. The reasons for these issues ranged from expected problems as outlined in the process map (Figures 1 and 2), to

more unexpected problems, such as where the patient needed additional psychological support from the nurse.

#### *5.4.1.3 Cost analysis*

Using the healthcare professionals' consultation rate as the unit cost and applying them to the time recordings, the costs of CNS and ANP consultations were calculated (see Table 5.2).

**Table 5.2 Costs of consultations by healthcare professional type.**

| **Healthcare professional type** | **Cost (€)** | | | | |
|---|---|---|---|---|---|
| | Min | Q1 | Median | Q3 | Max |
| Clinical Nurse Specialist | 10.04 | 14.74 | 22.10 | 30.15 | 80.38 |
| Advanced Nurse Practitioner | 12.05 | 17.67 | 26.51 | 36.15 | 96.40 |
| Patient | 6.39 | 9.37 | 14.06 | 19.17 | 51.12 |

The time recordings by hospital type are shown in Table 5.3.

**Table 5.3 Time recordings by hospital type**

| Hospital type | Time (minutes) | | | | |
|---|---|---|---|---|---|
| | Min | Q1 | Median | Q3 | Max |
| Designated Cancer Centre | 15 | 22 | 33 | 45 | 105 |
| Not designated centre | 15 | 21 | 33 | 48 | 120 |
| Large hospital (> 400 beds) | 15 | 21 | 31 | 45 | 105 |
| Small hospital (<400 beds) | 15 | 22 | 33 | 45 | 120 |
| City hospital | 15 | 21 | 31 | 45 | 105 |
| Non-city hospital | 15 | 22 | 33 | 45 | 120 |

#### *5.4.1.4 Sensitivity analysis*

The extra cost incurred by patient travel per face-to-face consultation was found to be €16.37

### 5.4.2 Qualitative evaluation of interviews

In total, 11 interviews were completed. The interviews ranged from 16 to 43 minutes in length, with the median interview duration being 22 minutes.

Using thematic analysis detailed by Braun et al. (2019), four major themes emerged from the data, with a number of categories which are detailed below (Table 5.4).

**Table 5.4 Major themes and categories identified from interview analysis.**

| **Themes** | **Categories** |
|---|---|
| Effect of the Covid-19 pandemic | • Staff demands<br>• Patient fear<br>• Adapting the service |
| A challenging and expanding service | • Challenges of monitoring<br>• Communication with community<br>• More medicines and more demand |
| Dedicated oral clinics | • Clinic requirements<br>• Nurse attributes |
| The future of oral anti-cancer care | • A move to the community<br>• Nurse meetings<br>• Improved system databases |

Table 5.5 gives a breakdown of the number of times each theme arose across all interviews

**Table 5.5 Number of times themes identified in interviews**

| **Themes** | **Number of interviews identified** |
|---|---|

| | |
|---|---|
| Effect of the Covid-19 pandemic | 11 |
| A challenging and expanding service | 11 |
| Dedicated oral clinics | 10 |
| The future of oral anti-cancer care | 9 |

#### *5.4.2.1 Effect of the Covid-19 pandemic*

The topic of the Covid-19 pandemic and its effect on the individual nurses, patients and the overall service dominated the discussion. While presenting an increased pressure on the service as well as negatively affecting some aspects of patient care, there was also discussion on the lessons learned from the necessary adaptations made over the previous year and how these lessons can be utilized in practice even after the crisis point of the pandemic has concluded.

##### *5.4.2.1.1 Staff demands*

Due to the strain placed on the wider health service because of the pandemic, many nurses were redeployed as emergency staff to other areas of the hospital. The result was a reduction in the capacity of services such as the monitoring of OAT's.

> *"The biggest issue that happened to us is redeployment. So, within our hospital at the first wave back in March… clinical nurse specialists were redeployed to work in other areas…. So, nurse led services then just, they just collapsed, we had nobody to had the patients over to".* **N4**

Nurses felt that cancer patients' care suffered as a result of this change.

> *"That made me very busy and probably the oral treatment suffered a bit, because I couldn't give as much time or as much follow up to them".* **N1**

> *"But a lot of the services as well weren't available with Covid, like the support centres, so that was quite a big drawback as well for the patients".* **N11**

Some nurses noted that the pandemic affected their ability to receive information from other nurses performing similar duties and from pharmaceutical company representatives providing product information.

> *"And often you meet other nurses at study days or events and all that has been cancelled now because of Covid, everything is done online and virtual. So, you are not meeting people to see how they are doing things in their hospital".* **N4**

> *"Pre-Covid, a drug rep would have come into the hospital and they would have given you information, sometimes during an education session with staff. But I mean Covid now has put a spanner on the works [and] all that, I mean people can't come into the hospital".* **N8**

*5.4.2.1.2 Patient fear*

Beyond the difficulties faced by patients because of a reduced capacity service, nurses were aware that many patients, quite understandably given

their condition and potentially compromised immune status, were fearful of coming to hospital for treatment.

> *"Obviously, the biggest difficulties for everybody at the moment is the Covid pandemic. And we have patients who are who are older, prostate cancer gentlemen, who do not want to come into hospitals. They're very, very anxious about coming in".* **N7**

> *"The fear, patient fear of coming into hospital, they are frightened. I mean we had I suppose during the two huge waves of Covid, we had quite high in patient numbers in the hospital and patients were frightened, they did not want to come into clinic".* **N9**

The nurses commented that patients often felt lonely or isolated during the pandemic, and while they appreciated the improved relationship that was developed during consultations, they felt that some patients were using the sessions as a social connection opportunity and often reduced the time spent on the intended clinical monitoring.

> *"I think because they are not in contact with people on a day-to-day basis, the phone call is like a phone call with a friend… So, you are ringing and you are hearing all about everything and neighbours and the traffic and you are trying to kind of get the physical assessment done. No, but on the other hand it develops the relationship, so the benefit of that is when they do come into see you then they are kind of all happy, you know what I mean."* **N3**

Patients faced new challenges in traveling to the hospitals. Some patient's reliance on public transport or a volunteer driving service made travel difficult

during the COVID-19 crisis.

> *"Particularly [here] where you have such a large county, some might be travelling huge distances. And they'd rely on public transport or a volunteer service like the Irish Cancer Society. But that requires a volunteer driver calling to your home and then taking you to the hospital. And while the Irish Cancer Society have worked very hard to make sure that that's safe… I think people are still very reluctant and they don't want to get into a car with somebody else".* **N2**

*5.4.2.1.3 Adapting the service*

Because of the COVID-19 pandemic, many consultations that were previously done in person were changed to on-line virtual consultations, done by telephone or by video call. Some nurses admitted there was an adaptation period to the new method of monitoring.

> *"The virtual assessments started off, I found them quite daunting. In my head I thought they were going to be a lot quicker. I don't know why I thought that".* **N3**

Some nurses were positive about the change, while admitting there are some negatives, the overall shift has been positive, especially for the patients.

> *"We've had no difficulties with it. Everything's been perfect… I think for the patient as well, they really enjoy it… We haven't officially evaluated it, but they seem much more positive about it."* **N10**

Others felt that, while it was necessary, they would still prefer the traditional monitoring done through physical attendance. They felt that some duties were impossible to be done virtually, particularly physical assessments.

*"Well, it is quite difficult to assess patients over the phone… I suppose our patients we would know them quite well and we'd see them quite regularly. So, we would get a good feel of them on the telephone triage… But it's never as good as seeing someone, like face to face… It has been difficult with the virtual because you are just looking at blood results, you are not really looking at a patient. It has been challenging."* **N11**

Despite these pressures, the nurses were aware that their first responsibility was of patient care and safety, and emphasized that what is best for the patient is best for the service.

*"I don't think their care has been impaired in anyway. Like, there's been no incidents, their bloods are satisfactory, there has been no patient complaints. They say they are happy and I suppose we exist for the patients, not for what we perceive to be always for the best, because that can be quite paternalistic".* **N2**

*"The new approach that we have, it's more convenient for the patient because some of it is done by telephone, very rarely do people come and see me all the time. And with the Covid environment that's reducing their contacts as well".* **N8**

Some nurses felt that this new experience with and general acceptance of virtual consultations should be brought forward to future care, expressing a broad view that it was better for both the patient and service capacity.

*"Moving forward, like everything post Covid. I'm looking at for example very well fit men who were on abiraterone and enzalutamide, maybe*

*we should only see them in the oral clinic every 2 or 3 months and let the GP do their interval bloods. So, I think not just for our clinic, hopefully it would be something in all outpatients, but I think it will be something that could be a very positive outcome from Covid that we actually bring the patients into hospital way too often."* **N6**

#### *5.4.2.2 Challenging issues for an expanding service*

Nurses described how the monitoring of patients prescribed OATs presents some unique challenges and how monitoring is often incorrectly considered by many people to be much simpler when compared to the monitoring of patients receiving IV anti-cancer treatments. Nurses were aware that both the medicines themselves as well as their manner of delivery presented challenges for patients and those responsible for their care, particularly with regards to patient understanding and compliance, given that nurses would not be directly observing administration of the medicine as they would with a parenteral agent. Nurses described how this service may rapidly expand in the future given the constant increase in the number of new OATs, as well as projections of the number of cancer patients in the future.

##### *5.4.2.2.1 Challenges of monitoring*

All of the interviewed nurses made clear that OATs are not as straightforward as is often thought. They believed that there is a perception amongst patients and sometimes healthcare professionals outside the specialty of oncology that because the medication is taking orally, it does not present the same complexities regarding toxicities and complications as intravenous therapies.

*"I see there's a perception that sometimes the oral treatments are bit easier but actually the opposite is true because …… What people think that it because it's an oral treatment at it's easier but these cohort of patients are often a lot more complex because they're metastatic patients".* **N1**

*"She's coming on oral treatment, so the perception would be 'oh, this is very straightforward', but it's not. It's someone who's coming out who's quite sick. So, it's not just a matter of taking blood and giving them another tablet and going home, you are managing them clinically as well and their symptom profile that can be a lot more complex than the likes of the IV adjuvant treatments".* **N3**

Nurses noted that as part of their remit they must ensure that patients understand and are compliant with their medications given that OAT is not supervised with the same attention as with IV therapies administered in hospital day units.

*"They're at home taking the tablets themselves, so you have to make sure that they are fit and able to do that, that they are competent. So, a lot of education is needed in around that to ensure that they are compliant with the medications at home and that they are aware to contact us if they have any issues or any problems".* **N5**

*"With an oral drug, there's a huge challenge, because you are then trying to educate the patient effectively to safely …. I suppose empower them to administer their own medication in the community. So that is a huge challenge and it's a huge responsibility. We have to be very clear*

*in our initial education about time to take the tablet, take them altogether, between meals, after meals, same time each day, 12 hours apart. There is a lot of education".* **N7**

Nurses were keen to highlight the benefits to the patients of taking their medicine at home, particularly the psychological benefits.

*"I feel they are a little bit more in control of their own treatment and I think that helps them. I think the fact that they are at home, you know what I mean that they are able to take their medication…I think it must be and some of them would say that, it's kind of nice for them to be at home and be able to monitored like that, instead of coming in and seeing, I suppose they get kind of traumatised… coming in and seeing people very sick in a day ward situation or very young people coming in having chemo. That can really impact on older patients when they see younger people there and sicker people".* **N3**

*5.4.2.2.2 Communication with community*

Given that patients are taking their oral anti-cancer medication away from hospital supervision, nurses discussed their interactions with community healthcare professionals, particularly GPs and community pharmacists. The majority of nurses were consistent in their praise of GPs and community pharmacists.

*"Generally, the communication is fantastic. And pharmacies are very good at getting onto us if they have any concerns, reading the dose of medication which is great, especially with different prescribers*

*prescribing them and reduce the incident of errors. To have that back up that they will check if they are in doubt if any of the doses of chemotherapy is very good".* **N5**

One nurse commented that she felt that community pharmacists often did not have the specialised knowledge that it may take to effectively monitor the patient, whether that be for interactions or side effects.

"*I just feel that community pharmacists sometimes are lacking in that way, in the knowledge of the medicine. They might have seen it once in the last year or sometimes might have never seen it. And there's a lot to them, very specific things to be watching out for. So I'd be worried sometimes that if we're not seeing because they don't come into us for the medicines that things might go unnoticed".* **N9**

Some nurses did note that contacting a patient's GP can be difficult and time consuming, particularly during the Covid-19 pandemic because of increased service demands from other patient groups.

*"GPs' ……. communication has been poor as well. It's been very, very difficult to get GPS in the last year, to get through to surgeries, or just be holding and holding and I don't have the time for that".* **N2**

*5.4.2.2.3 More medicines and more demand*

Nurses described how the constant influx of new medications and new patients is demanding more of them and of the oncology service. They described how this constantly increasing demand can negatively affect the patients.

*"I feel it's huge, bursting at the seams at the moment. There is so many new treatments, new therapies change of treatments, there's new ones coming on the line the whole time, that it's more the volume now of people coming through the system. Before you would have a really nice amount of time to spend with the patient. But now it's very much they need to get started, they need to call me, you don't feel that you are spending as long with them and education and getting to see them as often."* **N11**

Some of the nurses worked in clinics by themselves and described their concerns about how the service might not be able to operate safely if they became temporarily unavailable.

*"So I suppose as the service keeps going and the more patients on oral treatments, I would…. I would need somebody else with me because you know you're trying to manage a huge cohort of patients on your own. Again, I'm only doing it two days a week so ideally there would be somebody else. It's not ideal to be running the service, to be one person doing the service. Obviously if you were sick or you know whatever, I don't know how it could work, you might have to draft someone else in who wouldn't know the patients or the medicines as well."* **N1**

Nurses were keen to expand the service in anticipation of the increased number of medicines and patients they could be seeing in the coming years.

*"We'd like to add another, expand it and get extra, get another day to run, because the oral therapies, there is going to be a lot more coming*

*down the line. And maybe get someone else trained up to work in the oral clinic with us".* **N11**

#### *5.4.2.3 Dedicated oral anti-cancer therapy clinics*

Although not all nurses operated in dedicated oral anti-cancer therapy clinics, there was unanimous agreement that this type of service was needed both currently and as the service grows. One nurse who worked in a hospital without a dedicated clinic noted that there may be confusion when handling oral patients for one session before switching over to manage intravenous treatments.

> *"Ideally if you could have a dedicated base it would be better, it would be better for the patients, probably better for us, better for me anyway. Because obviously if I'm mixed in between with the oral chemotherapy and the patients on IV treatments, and I'm often called from one to the other. Obviously if there was a dedicated oral clinic I could just focus on that. And it's extremely busy".* **N10**

Nurses noted that dedicated clinics allow for improved patient care.

> *"I do think that having specialised nurses in the area would be better. Very beneficial and it would be continuity care and they'd get to know the patients very well and they'd get to know the oral treatments very well. I definitely think having oral clinics would be a huge benefit to the service".* **N5**

A specialised oral clinic allows for improved efficiency in the oncology day-ward and improved patient access.

"*From a practical point of view, it freed up capacity on the day ward. Patients have sort of easy access to one or the other via bleep things like that*"**. N6**

*5.4.2.3.1 Clinic requirements*

The nurses who had been involved in the initiation of an oral anti-cancer therapy clinic discussed how best to set it up and run it. Nurses who set up an OAT clinic said they could operate similarly to existing day-ward services, with similar protocols and practices.

*"The actual protocol which [we] put together, the protocol of the assessment, the examination, the overseeing of the patient, there's very little difference in that and what goes on in our normal day ward. So, the practice that we run the oral chemotherapy day ward, is very similar to what happens in the normal day ward, it's just that we are specifically concentrating on oral chemotherapy".* **N6**

The setting up of these clinics was generally agreed as drawing heavily from National Cancer Control Programme protocols.

*"I mean I have to say the NCCP protocols are excellent. Most of what we do in the clinic is following them, from the very start. I open them in the morning when I go in and I don't come out of them until I go home. And to be honest with you, they are pretty fool-proof if you can follow them in regards the lab assessments and your parameters you are not really going to go far wrong".* **N2**

One nurse discussed how there should be a clear outline from the outset about the number of patients being monitored in the clinic. They believed the goal of the clinic should be about quality, not quantity.

> *"Like I say, I spoke to one or two colleagues who are saying "Oh my God, it just was mental and we had so many patients". I don't understand, if I'm running a service it has to be a service that's controllable, it was never ever about taking all the patients that were on oral treatments. I mean that's insane. I'm sure in another 5 years that could be 70% of all ambulatory chemotherapy patients. So, I suppose where I would have been I think disciplined or strict with myself and certainly this would come from my experience, as I say I'm setting up my own role would be that it's set up in a very controlled way".* **N6**

Nurses who operate clinics discussed the need for a structured method of organising patient visits. They believed that given the complexities presented by these patients, it would be best to organise the clinics by tumour site to minimise confusion.

> *"I think my advice would be to cohort the patients, so that you are dealing with the same medication in one day if that's possible or in a morning and then an afternoon. Because I just think your mind changes direction a little bit… I think for me scheduling an oral chemotherapy clinic if you were to do it Monday to Friday, I would be cohorting the patients, really by tumour site".* **N3**

Nurses felt that having a clinical pharmacist input as part of the clinic would be invaluable. Those who operated without the help of a pharmacist admitted it is

often a struggle given the wide range of medicines that a patient may be prescribed during their treatment.

> *"Our pharmacists do a really good drug reconciliation, so they highlight any drugs that interact and sometimes the project changing over different treatments or certain drugs, they might have to stop and go on other kind of drugs. Because they might interact, we are really lucky because this is all highlighted before the start".* **N11**

> *"You as a nurse and the consultant and the registrar are trying to determine if there is any drug interaction. Whereas if we had a clinical pharmacist to do that in a much safer way for us. As I say, that's the biggest challenge we have at the minute."* **N4**

*5.4.2.3.2 Nurse attributes*

For the successful and safe operation of a nurse led oral anti-cancer therapy clinic, certain attributes of the clinic lead nurse were discussed as being necessary. Primary among these was experience. There was agreement that it would not be suitable for a newly qualified oncology nurse to run an oral anti-cancer therapy clinic.

> *"What you do need to be is an experienced oncology nurse. So, I don't think you could just do the oncology H-dip[loma] or your masters education and go straight into running a nurse led service. Because I don't think you'd have the clinic experience… we can problem solve practically on the spot or we can order radiology and we can investigate it and then revert back to our consultant. And I think you need a lot of clinical experience to do that".* **N7**

Beyond the need for organisational skills as previously discussed and extensive knowledge of the medicines prescribed in the course of operating an oral anti-cancer therapy, certain other skills were deemed especially important. These included a clear understanding of how and where to access the necessary drug information and excellent assessment skills, of the patient's physical, emotional and social status.

> *"It's mainly like education really of all the different treatments, there is a lot of them that are new, that we wouldn't have used before... And it's keeping yourself up to speed the whole time. Knowing how to access the NCCP protocols and other good sites of education. That's really invaluable".* **N11**

> *"But the big thing, you need really excellent assessment skills and you need to really holistically assess the patient.... And you need to do a very, very good assessment at the beginning, I think that's the key. And also you need to assess them, not just medically but socially as well, you need to have a very good grasp on the social circumstances of each patient."* **N7**

#### *5.4.2.4 The future of the service*

Given the ever-increasing demand being placed on the service by the steady train of new medicines and an increasing number of patients using OATs, there was discussion on what and how the service needs to adapt in the immediate future.

*5.4.2.4.1 A move to the community*

In line with recent literature, some nurses felt that there could be a drive to move certain additional aspects of the cancer treatment service into the community. These considerations were accelerated by the Covid-19 pandemic, where there was a sudden need for more community involvement given that patients were often unable to attend the hospital due to safety concerns. One nurse felt that a centralised community clinic would be the best solution, with easier access for patients.

> *"I think in an ideal world you would have an ANP and a couple of pharmacists working together in clinics, assessing people via virtually or face to face. Again I think it should be a patient led approach. And I think it could be displaced from the hospital to a community setting. And centralised even within a community setting, so that we are not going sort of sporadically different places".* **N2**

> *"But I actually think this is still taking up hospital capacity that could be used for more acute care. If we look at the Sláintecare programme they are saying that basically so much stuff could be done virtually, could be done closer to the patient's home".* **N2**

This general point was mostly agreed with, but some nurses were sceptical about the viability of such a change in practice.

> *"In an ideal world yeah, I think it would be great. But it's hard to see it happening to be honest, I think there'd have to be a huge change, even politically and things like that to move it out. I think there's a reason for the hospital clinic, where it's usually centralised".* **N8**

*5.4.2.4.2 Nurse meetings*

Some nurses interviewed were part of a nurse network where nurses responsible for monitoring OATs could meet and discuss what works in their care setting. These nurses were highly enthusiastic about these meetings, particularly about the manner in which they provide learning material and potential improvements to their own work.

> *"And then we have an oncology nurse group as well and that provides a yearly [update]. We meet up, for a day and a half and that's fantastic for education and focuses a lot on immunotherapies and new treatments".* **N3**

Other nurses were not involved in such a professional network and discussed how being part of such a network could be highly beneficial to them. One nurse discussed the possibility of a national oncology nurse network that could be established in the future, accessible to all practicing oncology nurses. They felt that meeting and hearing from nurses who had established their own effective and efficient work practices would greatly improve the national standard of care.

> *"If there was some sort of a network for nurses involved in oral clinic, just as a resource for information sharing and for support and if you have got challenges within your service that you can call on somebody that works in another hospital and say what you do in your centre or what works for you. And just for information sharing and advice, that would be definitely helpful I think. It never hurts to hear what works well for others".* **N4**

*5.4.2.4.3 Improved IT systems and databases*

Some nurses, particularly those working in more remote parts of the country, felt that the move to virtual consultations had highlighted some of the IT problems that are present in the healthcare system. Internet access was often unreliable, meaning nurses sometimes had to rely on their own initiative to host virtual meetings.

> *"Even when I want to face time or do Zoom or anything in my office with the likes of this, I set up a hot spot to my phone and run my laptop off that, because our internet is just not strong enough in the hospital to run this type of stuff".* **N2**

Nurses felt that more could be done with regard to regional and national databases.

> *I drew up lists last week of people that are on oral anti-cancer treatment, that should be available at the touch of a button. You shouldn't be relying on a nurse somewhere to go through your Microsoft Excel database, that she has the initiative to keep.* **N2**

One nurse discussed the possibility of having a national reporting database for OATs, where adverse reactions, prescribing errors or dispensing errors could be reported for both improved knowledge as well as increased accountability.

> *I just think there's a lack of reporting now. If I see there's been a mistake somewhere along the line, I don't know where to report that. So, if there's no learning, what's to stop the same mistake again next month. If there was a central database where nurses, pharmacists, GPs,*

*consultants they could all report if they see an error, or even if they see an unusual reaction to a drug that they think might be useful for others to know.* **N8**

## 5.5 Discussion

This is the first study to report a time, cost and qualitative assessment of the monitoring of OATs by oncology nurses. This fast-growing service is placing an increasing demand on the wider health service as well as the staff involved in its delivery. This study allowed nurses to express their beliefs on how the service is operating, and what may be done in the future to allow for a continuing safe and effective service with the increased demands. Nurses felt that the service is under serious strain and that full-time dedicated oral clinics, along with more community involvement and improved IT and system databases are needed to allow the service to grow.

The median time per monitoring consultation was 33 minutes, giving a median cost of €22.10 when using the Clinical Nurse Specialist adjusted salary and €26.51 when using the Advanced Nurse Practitioner adjusted salary respectively. This time per visit is broadly in line with the results reported by (216) who measured the time per patient visit to an outpatient oncology clinic and reported an average visit time of 24.7 minutes. The physicians in the study of Guy & Richardson performed mostly similar duties to the nurses in this study, such as symptom checks and physical examinations. Russell *et al* (2008) reported a much longer average visit time of 74 minutes when they measured patient attendance time at all types of outpatient department visits. The present study is the first to calculate the costs of nurse monitoring of oral

anti-cancer treatments. Given that many intravenous chemotherapies can often require a lengthy administration time, sometimes up to hours, this may point to oral chemotherapy being a cheaper alternative to intravenous agents. This potential cost saving has been previously reported (217). An important point is that the majority of the interventions that were timed were carried out in a 30-minute appointment slot. Given the median consultation time was 33 minutes, this suggests that the service is stretched to near its current limit. Any amount of time beyond 30 minutes means a delay for other patients and a longer day for nurses, especially when some nurses are the sole person responsible for the monitoring of treatment. Nurses stated that their time is very limited at the moment, and that they often may not have time for administrative activities. This assessment is supported by the time recordings.

The Covid-19 pandemic has severely disrupted both direct patient care and healthcare service itself in the last year. Nurses were aware that some of the cancer patients in their care were experiencing increased anxiety as a result of the pandemic. Cancer patients in general are more likely to experience anxiety (20), so any worsening of this condition would have required increased surveillance and management. Karacin *et al.* (2020) found a significant increase in chemotherapy postponement due to patient anxiety since the beginning of Covid restrictions. This is especially challenging for patients receiving oral chemotherapy agents, given that patients may stop taking their medications unnoticed at home. Nurses in the present study were particularly keen that members of the community healthcare service, especially

community pharmacists, would be involved in the monitoring of home medication compliance and help with the use of dosettes. This approach to medication supply is known to increase patient compliance (218) and has been successful in increasing compliance in other long-term, debilitating conditions such as HIV, dementia and inflammatory bowel disease (219-221).

The nurses interviewed shared a unanimous belief that a dedicated oral anti-cancer treatment (OAT) clinic is the best way to deliver care and monitoring to patients on OATs. They believed that a more specialised care approach, with less mixing of therapy types, could provide better care for the patient and less confusion for staff. Wong *et al.* (2016) evaluated the need for the effectiveness of an oral chemotherapy management clinic. They demonstrated a reduction in potential medication errors, increased compliance and detailed a cost saving of $125,761.93 per year for each 1.0 full time employee when compared to the same setting prior to the set-up of a dedicated clinic. These findings highlight both the clinical benefits and cost saving impact of a dedicated OAT clinic.

Patient compliance with their OAT is one of the main challenges in the monitoring of this type of medicine. Moore (2007) discussed the need for both patient and family education at the beginning of treatment as a way of highlighting the importance of strict compliance with the medication. This emphasis on strict medication compliance was replicated by the nurses in this study. Nurses discussed how an in-depth, holistic first assessment was vital to ensure proper care for the patient. Indeed, nurses indicated this type of assessment skill as the most important a nurse responsible for this type of

treatment monitoring should possess. As previously discussed, the negative effects of the Covid-19 pandemic on direct face-to-face patient contact may have made non-compliance an even larger issue for many cancer patients.

Some nurses believed that parts of the service, in particular blood sampling, could move to the community, whether that be GPs or dedicated clinics similar to those in the hospital. The aim would be both to free up capacity in the hospital and to make access to specialized care easier for patients. In Chapter 3 a shift of the location of cancer care services to the community reduced patient travel time by an average of 34.67 minutes. This is relevant, given that any increase of travel time is particularly arduous for cancer patients (17). Another suggestion by the nurses was the continuing of virtual consultations even after the Covid-19 pandemic has passed. Although some nurses expressed a belief that virtual consultations could never be as informative as face-to-face consultations, there may be scope to reduce the constant hospital visits, especially for patients who are deemed lower risk. However, for virtual consultations to be a viable option in the future, there is a clear need to upgrade internet and IT facilities in some hospitals, particularly rural ones. Nurses also discussed the limitations of their hospital IT capabilities, which could come under increased strain if more consultations are done online.

### 5.5.1 Limitations

As part of the process mapping exercise, it is recommended that the authors "*walk the journey*" to gain a better understanding of the individual processes (122). This was not possible given the restrictions on hospital visits imposed by the Covid-19 pandemic (222).

There may have been a risk of biased answers from the nurses, given that they may have wished to put forward their work and environment in an optimum light. However, the authors are confident that this was not an issue, as most nurses were critical of some aspect of the care.

There were only 11 interviews conducted, which may be considered a relatively low number. However, the final sample size was dictated by the pre-defined stopping criterion of 7 interviews. One more interview raised new topics, followed by three interviews where no new topics were discussed. This follows the recommended sample size calculation for qualitative semi-structured interviews (187). There is also a very limited number of suitable potential interviewees. Most hospitals would only have one or two nurses who are primarily responsible for the delivery of OAT monitoring. The authors are confident that the interviewees selected are a true representation of the oncology service types, with a mix of public and private, urban and rural, and large and small hospitals represented.

Ideally patients receiving oral chemotherapy would have been interviewed to gain an understanding of their experience, but the restrictions put in place by Covid-19 and data safety concerns regarding patients' own virtual connections meant that only nurses were interviewed. However, the needs and requirements of patients were a consistent discussion point in all interviews.

No usage data of oral anti-cancer therapies were available to the researchers. Data of this kind may lend credence to some of the discussion of this study regarding the continuing expansion of the service.

## 5.6 Conclusion

This study highlighted the challenges faced by nurses responsible for the monitoring of OATs. Individual monitoring consultations were shown to be time-consuming, often presenting challenges that are urgent and that increase the time demand on the nurse performing their duties. The overall healthcare system, nurses and patients have all experienced difficulties in the last year as a result of the Covid-19 pandemic. Nurses showed an ability to adapt to these challenging circumstances, and with proper support can take lessons learned from the last year forward to improve the service in the future. Dedicated oral anti-cancer therapy clinics are seen as vital for the delivery of a safe and effective care package. An increase in staff numbers to deal with the actual and projected increase in patient numbers and complexity should be considered.

# Chapter 6. An economic evaluation of the OPERAM (Optimising thERapy to prevent avoidable hospital Admissions in Multi-morbid older people) randomized controlled trial in an Irish hospital

## 6.1 Abstract

**Introduction:** Adverse drug reactions (ADRs) are a serious problem in the care of older persons. Inappropriate prescribing can lead to an increased likelihood of ADR occurrence, and an increased risk of hospitalization and/or death. Older persons are more likely to be treated with polypharmacy and thus more likely to experience a drug reaction. The STOPP/START criteria were developed to reduce drug interactions. The OPERAM trial utilised a clinical decision support system to apply the STOPP/START criteria to patients across four different countries. This chapter is the economic evaluation of this system in the Cork site of the trial.

**Methods:** Participants were followed over a 12 month-follow up period after the application (intervention arm) or not (usual care, control arm) of the intervention. Unit costs were gathered from Irish sources. Quality of life was calculated using the EQ-5D questionnaire. The cost-effectiveness of the intervention was determined by both simple difference between the control and intervention arm and the generation of a Seemingly Unrelated Regression (SUREG) model.

**Results:** 346 participants were analysed. The intervention showed no significant improvement in quality of life. By simple difference, the average difference in total costs was €757 in favour of the intervention group, this was

not a significant finding (p=0.790). In the SUREG model the intervention showed a cost saving of €1477, not a significant difference. (p=0.341).

**Conclusion:** The intervention cannot be deemed cost-effective. Further work is necessary to explain why the intervention did not improve the clinical outcome of participants after previous success.

## 6.2 Introduction

An adverse drug reaction (ADR) can be defined as '*an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product; adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen, or withdrawal of the product'* (223). ADRs represent a serious and growing problem in healthcare in general, particularly for the growing populations of older people worldwide. A recent systematic review found that an ADR can cost as much as €9,015 in an inpatient setting (224). Up to 3.5% of all hospitalizations may be the result of ADRs, and up to 10.1% of hospitalised patients may experience a clinically significant ADR during their stay (225).

Older persons are at an increased risk of experiencing ADRs compared to younger patient groups (226). Older patients are more likely to be multimorbid, with an estimated prevalence of more than 70% in patients aged more than 65 years in primary care (227). With this increase in concurrent chronic conditions, older patients are more likely to be treated with an increased number of long-term medications (228). Often the result is the patient being treated with multiple medications i.e. polypharmacy in proportion to their

multimorbidity, polypharmacy usually being defined as the prescription of five or more long-term medications (229). Polypharmacy in older persons increases the risk of ADRs by 58% (five drugs) and 82% (7 or more medications) (230).

Inappropriate prescribing (IP) is "*the use of medicines that introduce a significant risk of an adverse drug-related event where there is evidence for an equally or more effective but lower-risk alternative therapy available for treating the same condition*" (231). This includes drug over-prescription (prescription without an evidence-based indication), drug under-prescription (no prescription despite evidence-based indication) and excessive exposure to potentially adverse drug-drug interactions. IP has been associated with several adverse outcomes for older persons, particularly multimorbid older persons, including drug related hospital admissions (DRAs) (232), decreased quality of life and increased mortality (233).

There have been notable tools developed to help reduce the likelihood of IP. One such tool is the Screening Tool of Older Person's Prescriptions and the Screening Tool to Alert doctors to the Right Treatment (STOPP/START) criteria, currently at version 2 (48). This list of 80 STOPP criteria and 34 START criteria has been demonstrated to reduce unnecessary polypharmacy, the use of drugs at incorrect doses, potential drug–drug and drug–disease interactions and the underutilisation of clinically indicated medications (234).

Despite these findings, it remained uncertain whether systematic criteria-based pharmacotherapy optimisation can improve clinical outcomes. As a result, the **OP**timising th**ER**apy to prevent **A**voidable hospital admissions in

the **M**ultimorbid elderly (OPERAM) clinical trial was designed and undertaken. This was a multi-site, European double-blinded randomised controlled trial (RCT) that recruited more than 2000 in-hospital patients aged over 70 years who were multimorbid and being treated with polypharmacy in four study sites; Bern in Switzerland (lead site), Cork in Ireland, Utrecht in The Netherlands and Brussels in Belgium.

OPERAM used a customised software-based tool incorporating STOPP/START criteria. These computerised interventions, also known as clinical decision support systems (CDSS), are associated with reduced patient complications, costs and mortality when used in a hospital setting. They have been shown to significantly decrease Potentially Inappropriate Prescribing (PIP) in hospitalised older adpersons, though large-scale multinational RCTs, such as the OPERAM trial, were needed to confirm this (237).

The primary outcome of the trial was first adjudicated DRA within 12 months of randomisation. Given that an eventual aim of the trial was to demonstrate whether the intervention could become part of usual care, and that there are always financial constraints within health systems, it was necessary to conduct a cost-effectiveness assessment of the new automated intervention. A recent systematic review of CDSS was inconclusive when examining their cost-effectiveness (238). Three of the studies examined found that CDSSs were cost-effective in hospital settings, but three other studies concluded that CDSSs were not cost-effective. This same review found the evidence demonstrating the positive effects of CDSSs on economic outcomes to be sparse. While there was a trend towards cost-saving by implementing CDSSs

in a range of settings, these were moderate savings and inconclusive when viewed as a whole. STOPP/START criteria as an intervention have previously been shown to be both of clinical benefit as well as potentially cost-reductive, due to a reduction in medication usage due to STOPP criteria (234, 239), or a reduction in incident ADRs and the associated health costs (240). This chapter presents the cost-effectiveness assessment of the patients recruited in the Cork OPERAM trial site, in order to evaluate the economic results of the use of a CDSS using STOPP/START criteria in a large RCT.

## 6.3 Methods

### 6.3.1 Recruitment and trial design

This study followed the previously published OPERAM protocol (241). Patients aged 70 years and older with multimorbidity and polypharmacy were eligible for inclusion. Multimorbidity was defined as three or more chronic medical conditions, and polypharmacy was defined as the use of at least five daily drugs for more than 30 days. Exclusion criteria were (i) a planned transfer to palliative care within 24 hours of admission, and (ii) the participant having undergone a structured drug review outside of their usual care, such as by a hospital pharmacist, other than the trial intervention.

Physicians were randomly assigned on a 1:1 basis to either the control or intervention arm, Participants were cluster randomized by their prescribing physician to either the control arm of usual care or the intervention arm, where their medication was assessed with the Structured History taking of Medication (SHiM) questionnaire (242). This was entered into the Systematic Tool to Reduce Inappropriate Prescribing Assistant application (STRIPA), a decision-

support software that applies the STOPP/START criteria STRIPA, together with the patient's known diagnoses (235) The output of STRIPA was used to generate specific prescribing recommendations to present to the prescribing physician. Participants were followed-up at intervals of 2 months, 6 months and 12 months after randomization.

Baseline data gathered included: (i) patient characteristics (including number of falls, alcohol intake etc.), (ii) medical history (documented ADRs, vaccination status), (iii) all medications, (iv) healthcare utilization (e.g. number of primary care visits, number of public nurse visit hours), (v) quality of life (using the European Quality of Life 5 Dimensions [EQ-5D] questionnaire UK dataset) (67), (vi) activities of daily living (using the Barthel Index Basic Activities of Daily Living) (243), and (vii) participants' drug compliance assessed with the ©MMAS-8 questionnaire (244). As part of follow-up, all patient hospitalizations and/or death was recorded, along with updated information for the baseline data.

### 6.3.2 Unit costs

Unit costs were drawn from external sources and are detailed in each section below.

#### *6.3.2.1 STRIPA intervention*

The cost of the STRIPA intervention was calculated by multiplying the time taken to carry out the intervention by the midpoint of the salary of the healthcare professionals (either a physician or pharmacist or both) carrying it out using the HSE consolidated salary scale (245). Because of problems with the initial recording of the timing data within the OPERAM trial, a separate

database using non-OPERAM patients with the same characteristics was used.

#### *6.3.2.2 Healthcare costs*

Hospitalization costs were estimated using disease-related group-based reimbursement. The Irish Health Service Executive Ready Reckoner Case-mix Report (246) was used to assign a cost to each International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) diagnosis code recorded in the OPERAM database. Because the case-mix report uses Diagnosis Related Group (DRG) codes as opposed to the ICD-10 codes recorded in the OPERAM database, a manual conversion was done for all ICD-10 codes to their respective DRG codes. To calculate hospitalization costs for OPERAM participants, the case-mix cost was divided by the average length of stay of that DRG indicated in the case-mix report, and this value was multiplied by the length of stay of the OPERAM participant. In the case where an ICD-10 code had multiple possible DRG codes, the average cost was used.

Costs of outpatient visits by specialty and other outpatient services were drawn directly from studies supplied by the hospital finance department.

Costs of visits to general practitioners were based on the standard fee in Ireland for a general practitioner visit (€55).

Costs of home nursing care was calculated using the midpoint of public health nursing salaries from the consolidated HSE salary scales (245). Nursing home stay and rehabilitation stays were drawn from Health Service Executive data (59).

Informal care costs were calculated using the human capital method (166) and the national average wage (247). In cases where the age of the carer was over 70 years, no cost was assumed given that the person is older than the Irish public service compulsory retirement age (248).

Drug costs were estimated using a pre-purchased Irish wholesaler price list. ATC codes were used to identify and cost each drug used. In the case where multiple strengths or formulations were available for an ATC code, the cost was calculated by finding the average cost per relevant unit (i.e. price per mg, price per ml, price per unit), and multiplying this value by the amount of these relevant units in the database entry. Using the interval of the drug delivery (e.g. once daily, once weekly etc.) and the initiation and discontinuation dates of the drug, the total cost for each drug for the entire trial period was then calculated. The sum of all individual drug costs was added to obtain the total drug cost for the participant. The price of the generic equivalent was used as the cost for the ATC code, unless the database specified the use of a specific brand. The database was manually examined by the author to identify if any implausible or impossible entries were present. This issue is detailed more in the missing data section of this chapter.

### 6.3.3 Quality adjusted life years

Quality adjusted life years (QALYs) were calculated using the UK dataset for the European Quality of Life 5 Dimensions [EQ-5D] questionnaire (67). The Irish dataset had not been produced when the OPERAM trial began, so the UK dataset was chosen as the most representative alternative. QALYs were estimated for the 12 month trial observation period, using standard area under

the curve (AUC) methods following the trapezium rule (249). When calculating time passed between each follow-up period, it was assumed that all recorded follow-ups occurred at exactly 2 months, 6 months and 12 months post-recruitment. This was because using the real time points would have increased the number of missing data, as some follow-up dates were missing.

### 6.3.4 Missing data

Multiple imputation was used to replace missing data values in the study. Before multiple imputation was performed, pre-defined rules for variables were applied. For some categories of costs (including hospitalizations, rehabilitation facilities, medical visits, nurses' visits at home), the cost of each of the three time periods of follow-up was calculated by multiplying the cost per visit and the number of visits (or length of stay) in the relevant period. The total cost was then calculated by summing these partial costs. In cases where the partial costs for one or two of the three time periods were missing, these values were treated as zeroes. The percentage of such missing values were always in the range of 10-15% of total observations; occurrence was always equally distributed across arms. Only when all the three components were treated as missing, the whole cost per patient was a missing value and thus multiply imputed. This decision was made to avoid imputation of a huge number of variables with the associated risk of losing precision.

For nursing home stays, it was assumed that if two out of three answers regarding length of stay were zero days and one missing, they were all considered to be zero days.

A similar approach was used for drug costs as for the other cost categories. A concern with drug costs was the presence of implausible or obviously incorrect entries, for example when the unit of measurement was clearly incorrect (e.g. a patient recorded as using 400g atorvastatin once daily). In these instances, a missing value was assigned. In the case of missing drug dose, start date or end date information, or unit of measure, the drug cost was treated as missing. Drug data entries with at least one missing piece of information amounted to 23% of the total, equally distributed across arms. The cost of each drug was summed up for each patient to obtain a total drug cost per patient. Similarly, as in the case of the medical costs, missing drug costs were treated as zeros when summed up at patient-level. The drug cost per patient was missing for patients who had missing values for all drugs taken. This occurred in 3% of the patients.

For the EQ-5D-based utilities, any missing value was multiply imputed, in order to obtain as much information as possible.

Following these steps, 25.14% of patients had missing data. Multiple imputation was used on variables for each cost category and for the utility at baseline, 6 months before baseline, and each follow-up (FUP) time point. The patients' personal characteristics with no (or very few) missing values were used as the basis to statistically impute the variables with missing values.

### 6.3.5 Cost-effectiveness analysis

Two methods were used for the cost-effectiveness analysis. To confirm the findings of the simple difference method, it was decided to collaborate with OPERAM colleagues in Bern, Switzerland in order to calculate costs and

QALYs using a multivariable regression method suitable for cost-effectiveness analysis.

#### *6.3.5.1 Simple difference*

The total costs in both trial arms were calculated. This included all medical costs of the participant over the 12-month period in the control arm, and all medical costs plus the cost of applying the intervention in the intervention arm. Using the mean total cost for each group and their respective mean QALY gain/loss, an Incremental Cost-Effectiveness Ratio (ICER) was calculated. The drawback of this method is that it does not consider any potential effect of confounders.

#### *6.3.5.2 SUREG model*

This multivariable regression would consider the correlation between individual costs and outcomes. Initially a Generalised Structural Equation Modelling (GSEM), which would be beneficial for the often skewed nature of cost data, was attempted. However, this model did not converge. Instead, a Seemingly Unrelated Regression (SUREG) model was used. From this model, the total cost coefficient and QALY coefficient in each arm were calculated. These values were used to calculate an ICER as with the simple difference method. Non-parametric bootstrapping with 1000 replications was conducted on the difference in mean costs and mean ADR events to generate ICER replicates. The ICER replicates were used to generate a cost effectiveness acceptability curve (CEAC).(250) This links the probability of a treatment being cost effective to a range of potential threshold values (k) that the health system may be willing to pay for an additional unit of effect.(251)

### 6.3.6 Reporting

All data were analysed graphically and formally (Kolmogorov-Smirnov and Shapiro-Wilks) for normal distribution. Skewed data were described using the median and interquartile range (IQR), and normally distributed data were described using means and standard deviations. Comparisons between skewed data were made using Mann-Whitney U test and normally distributed data were compared with student's t-test. All significance reporting was at the 95% confidence level. All cost data are from the year 2018 and reported in Euros (€).

### 6.3.7 Software

Statistical analysis and imputations were carried out in Stata® Version 16. R Version 4 and the JOMO package were used for multiple imputations.

### 6.3.8 Guidelines

This paper was reported in accordance with the International Society for Phramacoeconomics and Outcomes Research (ISPOR) Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines for reporting health economic evaluations (164).

## 6.4 Results

In total, 346 OPERAM trial participants were recruited in the Cork site. 138 were allocated to an intervention cluster and 208 were added to a control cluster. Of the 346 participants, 3 were lost to follow up and 13 withdrew from the trial. Descriptive statistics of the participants are shown in **Table 6.1** below.

**Table 6.1 Baseline characteristics of participants**

| Variable | Control | | | Intervention | | |
|---|---|---|---|---|---|---|
| | Obs (N) | Mean | Std. Dev. | Obs (N) | Mean | Std. Dev. |
| Female (%) | 208 | 48.7 | | 138 | 57.1 | |
| Age (years) | 208 | 80.4 | 6.28 | 138 | 80.5 | 6.09 |
| Number of drugs | 208 | 11 (median) | 8-13 (IQR) | 138 | 11 (median) | 8-13 (IQR) |
| Number of co-morbities | 208 | 9 (median) | 7-11 (IQR) | 138 | 9 (median) | (7-11) IQR |
| Housebound (%) | 208 | 20.9 | | 138 | 21.4 | |
| Quantity of alchohol units consumed per week | 208 | 3.13 | 7.18 | 138 | 3.21 | 8.36 |
| Smoking (%) | 208 | 8.8 | | 138 | 9.2 | |
| Body mass Index (kg/m2) | 144 | 27.1 | 5.4 | 96 | 27.2 | 6.3 |
| Education status: | | | | | | |
| Less than high school (%) | 123 | 61.2 | | 87 | 60.0 | |
| High school (%) | 51 | 24.3 | | 34 | 25.2 | |
| University (%) | 30 | 14.7 | | 21 | 14.8 | |
| Number of hospitalizations in the previous year | 207 | 1.01 | 1.261 | 137 | 0.92 | 1.279 |
| Number of falls in the previous 12 months | 208 | 1.58 | 7.1 | 138 | 1.62 | 6.6 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Lost weight (≥ 5% of stable weight) in the previous year (% yes) | 207 | 0.3 | 0.5 | 137 | 0.3 | 0.6 |

Patients' median age was 80 years old and on average had one hospitalization during the twelve months prior to entry to the trial. At trial recruitment, patients were taking an average of just under 11 drugs and had over 10 co-morbidities, both well over the inclusion criteria of 5 drugs and 3 chronic comorbid conditions respectively. The average quantity of alcohol consumed was 3.3 units per week and current smoking was observed in 7.9%. The average Body Mass Index (BMI) was 27.1, indicating the average patient was overweight. Given the cross-European nature of the trial, unfamiliar nomenclature for Irish education status was reported. Less than high school can be interpreted as less than the Junior Certificate (or equivalent), and completing high school as completing the Leaving Certificate (or equivalent).

The characteristics of participants, including the number of comorbidities (median of 9 in the intervention group, median of 9 in the control group), number of medications (median of 10 in the intervention group, median 10 in the control group) were identical in both groups.

### 6.4.1 Unit costs

The breakdown of medical costs for the participants is shown in Table 6.2 below. The cost data was skewed, as expected. In order to give some explanation of the distribution of the data, the mean of some observations is included where the median was 0.

**Table 6.2 Unit costs by category**

| Cost category | Median € (IQR) | | Mann Whitney U-Test |
|---|---|---|---|
| | Control | Intervention | |
| **Observations** | 208 | 138 | |
| ***Total Cost*** | 11923 (3688-28346) | 10391 (3394-31246) | Z=0.630 (p=0.529) |
| ***Follow-up hospitalizations*** | 2042 (0-11904) | 926 (0-12253) | Z=0.989 (p=0.322) |
| ***Medical visits*** | 873 (439-1307) | 736 (33-1265) | Z=1.239 (p=0.216) |
| ***Rehabilitation*** | 0 (0-0) (816 mean) | 0 (0-0) (633 mean) | Z=0.427 (p=0.666) |
| ***Drugs*** | 1972 (1183-3289) | 2061 (885-3227) | Z=1.087 (p=0.277) |
| ***Nursing homes*** | 0 (0-0) (4545 mean) | 0 (0-0) (3940 mean) | Z=1.239 (p=0.256) |
| ***Home nurse visits*** | 0 (0-1294) | 0 (0-681) | Z=0.651 (p=0.515) |
| ***Informal care*** | 0 (0-8372) (6896 mean) | 0 (0-7636) (6272 mean) | Z=1.166 (p=0.243) |
| ***Cost of medicine reconciliation*** | 23 (10-34) | 89 (38-119) | Z=18.474 (p<0.001) |

The only significant difference in unit cost across groups was the cost of medicine reconciliation, which included using the STRIPA software assessment tool.

Figure 6.1 shows the mean cost differences by category between the trial arms (intervention - control), as well as the significance of each difference. A positive cost difference (on the right hand-side) means that costs were higher in the Control arm, while a negative cost difference (on the left hand-side), indicates that costs were higher in the intervention arm.

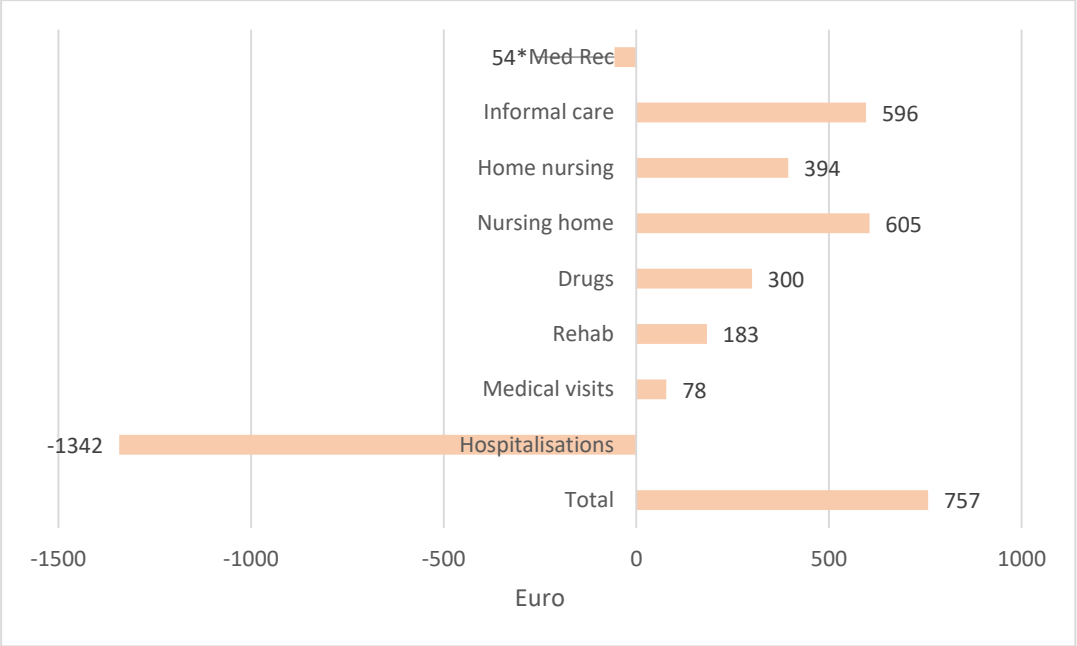



**Figure 6-1 Cost difference between intervention and control participants by category**

* Indicates a significant result

Intervention patients were on average costlier in terms of hospitalizations (€1,342) and the STRIPA intervention (€5), and less costly in all categories, with the greatest difference being in informal care costs (€596). The average difference in total costs was €757 in favour of the intervention group, this was not a significant finding (p=0.790, 95%CI €-4839 - €6354).

### 6.4.2 QALYs

The QALYs accrued over the one-year period of the trial in each group are detailed in Table 6.3. The QoL utilities accrued are equal to the number of QALYs given that the time period of observation was one year.

**Table 6.3 QALYs accrued**

| **QoL utilities** | Obs | Mean | Std. Dev. | Min | Max |
|---|---|---|---|---|---|
| Control arm | 171 | 0.5641 | 0.31 | 0.00 | 1 |
| Intervention arm | 110 | 0.5546 | 0.35 | 0.00 | 1 |

The control participants accrued on average 0.0095 more QALYs than the intervention group. The difference between these two figures was shown to be non-significant (p=0.816, 95% CI -0.0711 – 0.0905).

### 6.4.3 Cost-effectiveness

#### *6.4.3.1 Simple difference*

Calculating the ICER, the intervention arm provides an average cost-saving of €757 and causes a 0.0095 reduction of QALYs when compared to the control group. This results in a theoretical ICER of €79,684, but in the reverse manner of how this metric is usually recorded, which represents an increase of cost and a gain in QALYs. Another way of describing the findings would be that the intervention could provide a €79,684 saving at the expense of one QALY lost.

#### *6.4.3.2 SUREG*

The main results, the incremental costs and incremental QALYs representing differences between the intervention and control arms, are represented by the coefficients in Table 6.4. A positive effect on costs indicates that the variable is associated with a higher average cost per patient, while a negative cost means that the variable is associated with a lower average cost per patient. Similarly, a positive value of the coefficient in the QALY regression calculation indicates that the variable is associated with an *increase* in QALYs, while a negative value indicates a *reduction* in QALYs.

**Table 6.4 Results of SUREG model**

| | Coefficient | P-value | 95% CI |
|---|---|---|---|
| **Total Cost** | | | |
| Arm | -1477.03 | 0.321 | -6339.01 – 2740.65 |
| Age | 351.11 | 0.102 | -70.26 – 771.85 |
| Gender (female) | 992.28 | 0.690 | -3893.22 – 5877.76 |
| Quality of life (baseline) | -2269.42 | 0.710 | -14290.16 – 9750.85 |
| Quality of life (12 months previous) | -12764.11 | 0.010 | -22442.87 – 3085.71 |
| Number of drugs | 441.74 | 0.175 | -196.93 – 1078.55 |
| Number of comorbidities | 592.75 | 0.065 | -37. 243 – 973.43 |
| Housebound | 3040.65 | 0.373 | -3659 – 9736.10 |
| Smoking status | 376.33 | 0.939 | -9348.858 - 10101.38 |
| High school (Leaving Certificate) | 1321.01 | 0.665 | -4664.11 – 7307.77 |
| University | -3590.09 | 0.313 | -10573.97 – 3391.87 |
| Dementia | 4613.48 | 0.393 | -5973.02 – 15199.78 |
| Nursing home | 33640.56 | <0.001* | 15418.78 – 51861.97 |

| | | | |
|---|---|---|---|
| Hospitalizations in previous year | 2345.67 | 0.023* | 326.68 – 4364.23 |
| Medical ward (vs surgical) | 13644.15 | 0.182 | -6413.22 – 33702.55 |
| Duration of index hospitalization | 132.32 | 0.066 | -8.64 – 274.15 |
| **QALY** | | | |
| Arm | -0.0121 | 0.706 | -0.0750 - 0.0508 |
| Age | -0.0071 | 0.004* | -0.0120 - 0.0020 |
| Gender (female) | -0.0487 | 0.120 | -0.1103 - 0.0128 |
| Quality of life (baseline) | 0.1476 | 0.046* | .0024 - 0.2926 |
| Quality of life (12 months previous) | 0.3473 | <0.001* | 0.2260 - 0.4686 |
| Number of drugs | -0.0095 | 0.018* | -0.0173 - -0.0016 |
| Number of comorbidities | 0.0008 | 0.834 | -0.0069 - 0.0086 |
| Housebound | -0.0457 | 0.294 | -0.1318 - 0.0405 |
| Smoking status | .0259 | 0.680 | -0.0981 - 0.1499 |
| High school | -0.0000 | 1.000 | -0.0703 - 0.0703394 |
| University | 0.0302 | 0.469 | -0.0515 - 0.1120 |

| | | | |
|---|---|---|---|
| Dementia | -0.0269 | 0.682 | -0.1557 - 0.101979 |
| Nursing home | -0.0676 | 0.584 | -0.3153- 0.1800 |
| Hospitalizations in previous year | -0.0245 | 0.043* | -0.0482 - -0.0008 |
| Medical ward (vs surgical) | -0.2650 | 0.032* | -0.5069 - -0.0230 |
| Duration of index hospitalization | -0.0035 | <0.001* | -0.0052 - -0.0017 |

The arm variable, which describes the effect of the intervention is negative in both cases. This means that the intervention causes an average cost saving of €1477, and an average reduction of -0.0121 in QALYs, although neither of these findings are statistically significant (p=0.341 and p=0.706 respectively). These results give a theoretical ICER of €122,066. As with the simple difference results, this would theoretically provide a savings of €122,066 per QALY sacrificed.

A graphical representation of the bootstrapping, which illustrates the probability of the intervention being cost effective is detailed in Figure 6.2. The majority of data points are in the south-west quadrant of the cost-effectiveness plane, indicating that the intervention group is likely to be considered cost-effective.

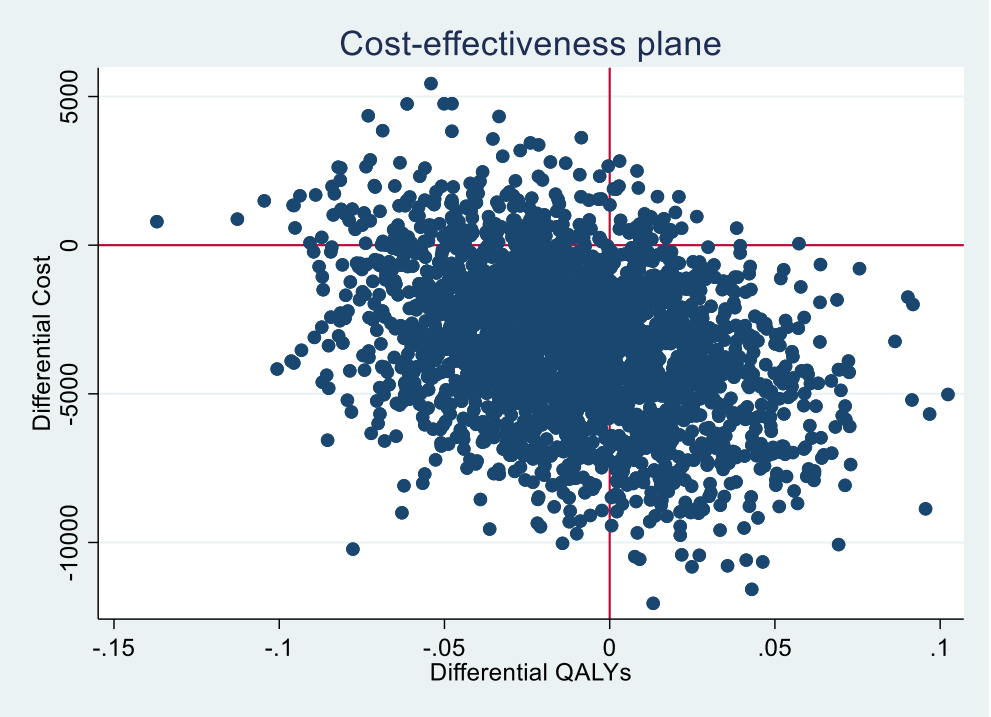



**Figure 6-2 Graphical representation of cost-effectiveness of intervention**

Using these ICER estimates, a CEAC was created to show the likelihood of cost-effectiveness at various willingness-to-pay thresholds. This is shown in Figure 6.3. Due to the nature of the results, there is no marked difference in cost-effectiveness probability at different willingness-to-pay thresholds, mainly due to the apparent negative health benefit of the intervention.

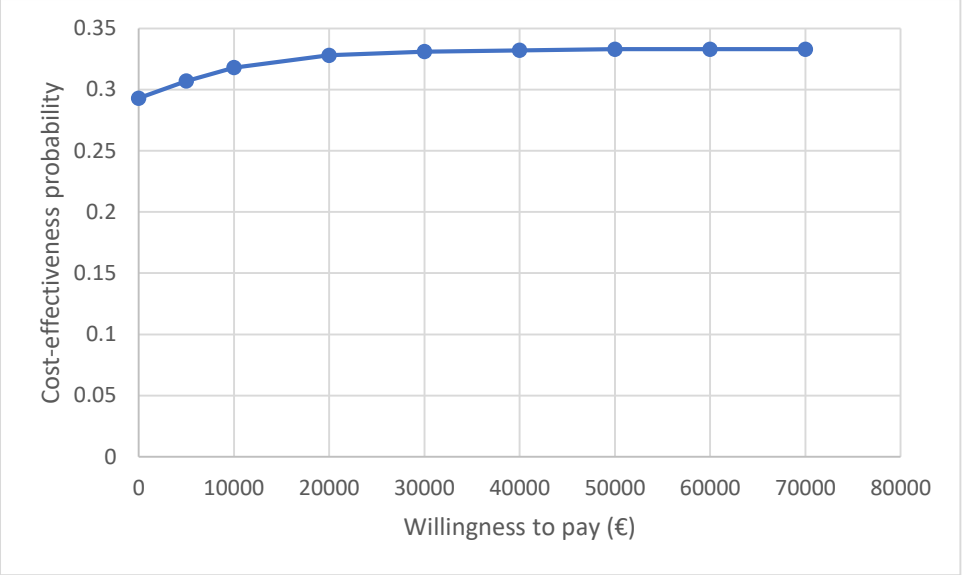



**Figure 6-3 CEAC of intervention**

## 6.5 Discussion

The OPERAM cluster-randomized trial set out to demonstrate whether the use of STOPP/START criteria in a computerised clinical decision support system could attenuate drug-related hospital admissions. Within the scope of this trial, the present study examined whether this tool could be cost-effective, taking into account all of a patient's medical expenses. The findings of this study were that the STRIPA tool provided a cost saving an average cost saving of €757 per admission in intervention patients when compared to patients receiving usual care, but at the expense of 0.0095 QALYs, however both cost savings and QALYS changes were non-significant findings. While the former could be expected given that all medical expenses were being accounted for, the latter was an unexpected finding given the previous beneficial results when applying the STOPP/START criteria(234).

The OPERAM trial paper details why the intervention may not have succeeded clinically. Notably, about half (52%) of participants in the intervention arm had

≥1 STRIPA-generated STOPP/START recommendation implemented. A previous review examined the reasons for deficient uptake of medication recommendations(252). These reasons mostly relate to prescriber attitudes and behaviour and included lack of awareness (poor insight, discrepant beliefs and practice), inertia (prescriber beliefs and attitudes such as fear of negative consequences or difficulties with stopping medication), and self-efficacy (such as prescriber belief and confidence regarding gaps in knowledge, skills, evidence and clinical picture (252). A qualitative examination of the factors affecting the implementation rate of the computer generated recommendations in the the **S**oftware **EN**gine for the **A**ssessment & optimisation of drug and non-drug **T**herapy in **O**lder pe**R**sons (SENATOR) trial could explain why the implementation rates could be so low (253). Prescribers were hesitant to make changes to longstanding medications, especially ones outside their own specialty area of practice. They often felt that their duty lay with responding to the acute medical incident they were treating. Additionally, there was a perceived delay in the time prescribers were reviewing the patient and the point at which the recommendations were provided, as well as the generation of recommendations of low clinical relevance.

One key difference between OPERAM trial and the SENATOR trial (254) was the use of an intervention team that screened the recommendations and brought them directly for discussion with the attending physician. This was thought to improve the implementation rate of the recommendations.

Regardless of this, the fact that there was no significant increase in QALYs when compared to usual care is a highly relevant, if disappointing, finding in

OPERAM, even taking into account this low implementation rate. There was a non-significant decrease of 0.0095 QALYs in the intervention group compared to the control. As well as being non-significant, this difference is very small. A study attempting to identify the minimally important difference in the UK EQ-5D algorithm concluded that a 0.084 QALY difference was the mean minimally important difference (255). As an example reference, the difference in QALYs between a completely healthy individual and one who has slightly anxiety or depression but is otherwise fully healthy is 0.121. STOPP/START criteria have been shown to reduce ADRs in smaller trials,(234) so it is difficult to imagine why their implementation in this study could negatively impact on a patient's quality of life.

A welcome finding was the overall cost-reduction impact of the intervention. The use of STOPP/START criteria has previously shown to be cost reductive in terms of drug costs. O'Connor et al. demonstrated a significantly lower median medication cost per patient in the intervention group (€73.16) than in the control group (€90.62) at discharge.(239) Although the findings of this study showed a similar reduction on mean medication costs, the findings here were not significant. Other than the expected difference in cost of applying medicine reconciliation due to the STRIPA tool, none of the cost differences observed was significant. A noteworthy finding is the difference in cost of follow-up hospitalizations, where costs in the usual care group was cheaper than in the intervention group, with a mean difference of €1342 (p=0.202). Similar to the effect on QALYs, it is difficult to understand how applying STOPP/START criteria would result in a patient experiencing costlier future hospitalizations. Previous RCTs using STOPP/START recommendations

have shown a reduction in PIP, but no real effect on future hospitalizations. Gallagher et al. demonstrated significantly reduced PIP in a trial that randomized 400 older persons to control (usual pharmaceutical care) or intervention (single time-point application of STOPP/START criteria) arms, but not hospitalizations after 6 months of follow-up.(234) An RCT from Campins et al. involving 503 older patients demonstrated reduced PIP, but not hospitalizations after one year of follow-up (256). At worst, it could be expected that the intervention arm would be cost-neutral with respect to future hospitalizations. To reiterate, this was not a significant finding; it is noteworthy, nonetheless.

The two methods of cost-effectiveness estimation produced similar results in terms of both costs and QALYs. The simple difference, the mean difference between total costs and QALYs in the two groups produced a theoretical ICER of €79,684. The results of the SUREG model gives a theoretical ICER of €122,066. Both of the ICERs provided by the two models are unconventional, in that they imagine a scenario where a healthcare provider could save money, but at the cost of a patient's quality of life. Both methods provided similar results in both total costs and QALYs accrued.

Gallagher et al. used STOPP/START as part of a pharmacist medication review. They found a reduction in mean healthcare cost of €807 [p = 0.548, 95 % CI -3443 - 1829), as well as a decrease in the mean number of ADR events per patient of -0.064 (p = 0.081, 95 % CI -0.135 to 0.008). Because of the intervention being dominant in both variables, they were able to estimate the likelihood of cost-effectiveness at various willingness-to-pay thresholds, with

probabilities of cost-effectiveness at €0, €250, €500, €750, €1000 and €5000 willingness-to-pay thresholds of 0.707, 0.713, 0.716, 0.718, 0.722 and 0.784 respectively. In the present study, the fact that the intervention shows no significant clinical impact in QALYs gained means that it very unlikely to be accepted as a cost-effective tool in the context of healthcare, regardless of willingness to pay thresholds. Because of the uncertainty of the findings, there is a chance that the intervention is cost-effective. At Ireland's willingness-to-pay threshold of €45,000, the estimates of this study show a 0.333 probability of being cost-effective, based on the current OPERAM trial data. However, this is primarily driven by uncertain and non-significant cost-reductions, so this finding should be taken with caution.

Despite the negative findings with regard to the cost-effectiveness of the STRIPA software intervention, the present study provides valuable information about the healthcare costs of multimorbid older persons in Ireland experiencing polypharmacy. As expected, the cost data were highly skewed. While the median patient in most categories was inexpensive, a few very high-cost patients skewed the data. Noticeable examples are the cost of follow-up hospitalizations, where the median was €1,714 but with a mean of €9,550, nursing home costs with a median of €0 and a mean of €4,320, and informal care costs with a median of €0 and a mean of €6612. These high-cost patients were to be expected. The healthcare utilisation of these older persons may be an interesting finding for those examining the breakdown in the cost of caring for these patients.

The SUREG model provides some insight into the effect of patient characteristics on both their medical costs and quality of life over the course of a year. When examining cost, the significant findings were:

i. The effect of quality of life 12 months prior to recruitment ($p=0.010$)
ii. The number of hospitalizations in the year prior to trial recruitment ($p=0.023$)
iii. Whether the patient was in a nursing home prior to recruitment ($p<0.001$)

Findings (i) and (ii) are hardly surprising, since older persons who are more ill will cost more to treat medically. The effect of the patient being in a nursing home upon recruitment was not only the most significant finding, but also the category with the highest cost coefficient, meaning it had the largest effect on overall cost. This is largely driven by the resultant cost of being in a nursing home for the next year in many instances. Some categories that might have been expected to have a more significant effect include whether the patient had dementia or their smoking status, both of which would intuitively result in greater healthcare costs. Although both conditions were associated with an increase in total cost, neither was statistically significant.

The most significant effects on the patient's quality of life were the patient's age ($p=0.004$), quality of life 12 months prior to recruitment ($p<0.001$) and the length of their index hospitalization ($p<0.001$). These are all intuitive findings. An interesting finding was that patients assigned to a medical ward experienced a worsening of quality of life when compared to patient on surgical wards, with a coefficient of 0.2650 ($p=0.032$). This is a high coefficient value

relatively speaking and indicates a large drop in quality of life, being second only to the quality of life 12 months prior to recruitment.

## 6.6 **Limitations**

Ideally, a larger sample size could have been gathered which would allow more certainty when declaring results. Most of the findings of this study are tempered by non-significant results. 346 participants is a robust sample usually, but due to the fine margins of the results more precision would be valuable.

There was a significant amount of missing data, which could lead to inaccuracies. Every possible step was taken to minimise this effect through multiple imputations as detailed in the Missing data section.

The initial time-recording exercise for medicine reconciliation which used OPERAM patients was not successful. This was due to issues with contacting prescribers who were often away from the hospital after completing an overnight shift and were unavailable to contact. An external database had to be used instead. This could lead to some distortion of results. However, given that the cost of time recording was the smallest of the cost components considered, this issue most likely did not introduce any considerable bias or dramatic changes to the cost-effectiveness results.

## 6.7 **Conclusions**

The STRIPA intervention used in the present study was found to be a non-cost-effective tool in the treatment of multimorbid older persons with polypharmacy. Although the intervention appears to reduce total medical care

cost when compared with usual care, there was a negative impact on the patient's quality of life. Although a theoretical ICER could be calculated, this is not usable in practice. The effect of the intervention on total cost and quality of life is not significant in either instance.

#### *6.7.1.1 Implications for practice*

Although the intervention appears to provide an average cost saving per patient, it also showed a possible negative impact on their quality of life. This study demonstrates that this is not a cost-effective tool because of this negative clinical impact. Given that the OPERAM trial did not succeed in its primary outcome of reducing the time to first drug-related hospital admission, the intervention was unlikely to be used in practice regardless.

Regardless of the negative findings, this RCT provides a good methodology for future studies to follow. The OPERAM trial successfully used cluster randomisation and multiple imputations for a large RCT. The methodology with which unit costs were calculated may provide a blueprint for future studies.

# Chapter 7. Discussion

## 7.1 Chapter description

The overarching aim of this thesis was to assess novel services targeting two vulnerable and increasingly costly patient groups i.e. cancer patients and older persons in Ireland. The purpose of this chapter is to synthesise the findings and relevance of each individual chapter in this thesis. The discussion on this thesis will focus on the following:

i. The key findings of each chapter,
ii. The implications of these findings for future health policy,
iii. The strengths and limitations of the research and evidence presented in this thesis and
iv. Recommendations for future research in this area.

## 7.2 Findings by chapter

Chapter 1 of this thesis was a narrative review, aiming to provide context for the research in this thesis, as indicated the global medical costs are rising at an unsustainable rate for future health budgets (1). The rising costs of healthcare globally and in Ireland mean that there is a necessity to find novel methods of delivering safer and more cost-effective healthcare in all countries. Two patient groups i.e. cancer patients and older persons, were identified as particularly costly healthcare subgroups. These patient groups are both experiencing a rapid rise in numbers, with the number of cancer patients in Ireland expected to double over the next 25 years (31) and the number of

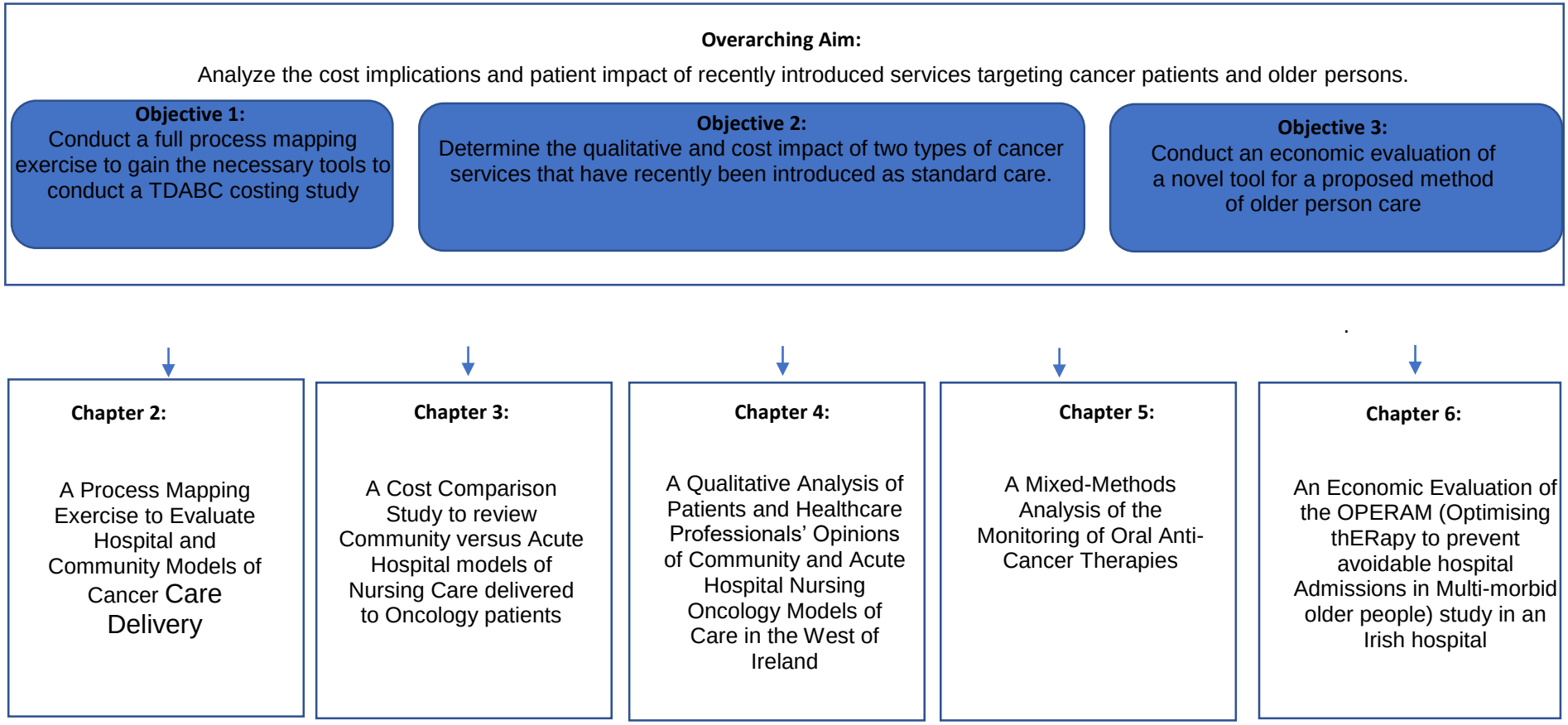
adults aged over 80 projected to rise by approximately 90% by 2030 (257). These population groups also carry increased healthcare resource utilisation and associated cost of care (42, 258). Based on this, the overall thesis aim was established (Section 1.7), i.e. to analyze both the cost implications, via economic evaluations, and patient impact, by means of qualitative research, of recently introduced services targeting both cancer and older person populations. It is hoped that the findings of this thesis will aid policy makers in healthcare decision-making relating to these population groups by identifying the cost-effectiveness and quality of these novel services. Research objectives for the thesis were identified. These were:

- To conduct a full process mapping exercise to gain the necessary tools to conduct a TDABC costing study.
- To determine the qualitative and cost impact of two types of cancer services that have recently been introduced as standard care.
- To conduct an economic evaluation of a novel tool for a proposed method of older person care.

The thesis outline was presented in the Figure 1.3 (and is reprinted below to aid readers).

Introduction (Chapter 1):

The rising costs of healthcare are placing an ever-increasing strain on the world's health systems. Cancer patients and older persons are two of the most vulnerable and costly patient cohorts. This thesis aimed to assess both the costs and the patient impact of novel health services that target these patient groups. Chapter 1 provides a narrative review of the current status and trends of these population groups globally and in Ireland.




**Discussion (Chapter 7):**

Provide a synthesis of the findings of each chapter, discuss the strengths and limitations of the research and how the findings of this thesis should be brought forward to health policy and future research.



**Figure 1.2 Thesis outline**

From here, the focus moved to the evaluation of novel services targeting these population groups that could be costed and qualitatively assessed for their impact on both the patient and those healthcare staff responsible for their delivery. The first such opportunity arose in the form of the Community Oncology Nursing Programme in the West of Ireland, which aims to deliver cancer support services in the primary care setting, including the patient's own home. The assessments of this programme are detailed and evaluated in Chapter 2-4. Process mapping formed the first step in this evaluation exercise of the models of cancer care across both the hospital and primary care settings. Chapter 2 details this process and was required for both an understanding of the fine details and processes of the service, and development of the necessary tools for a TDABC model of cost evaluation (123). Meetings with the key stakeholders in both settings were held to identify each process in the patient pathway, followed by the recommended "*walk-the-journey*" (122) approach, to gain a further appreciation of the process flow. This method of cost calculation is most useful where the main driver of costs is time-related costs, and is more accurate than traditional activity based costing methods (129). As well as being used to assess cancer services in previous studies, TDABC has been used in other disciplines of healthcare, including paediatrics, neurology and emergency medicine (125-128, 141). These studies used the TDABC methodology to both assess time-driven costs, and as a tool for service evaluation. The TDABC model has been highlighted as useful both as a method of service evaluation, as well as to inform policy decisions (129). This made it a suitable method of assessing the costs of the newly implemented Community Oncology Nursing Programme.

Chapter 2 provided the necessary building blocks for the cost-comparison study to follow in Chapter 3. Outside of this, the chapter elucidated some of the strengths of process mapping as an exercise for service evaluation. The strengths identified in Chapter 3 were:

- provision of an opportunity for key stakeholders involved in the respective processes to critically assess the performance of their own service.
- identification of inefficiencies in the service if any were present.

Inefficiencies within healthcare systems and processes may be tackled by applying lessons from the industrial engineering toolkit. Process mapping has been successful in reducing costs and improving process flow in healthcare settings (120, 137). The review by Antonacci *et al* interviewed the participants of eight quality improvement projects within the NHS, exploring participants' experience of using process mapping in their projects and perceptions of benefits and challenges related to its use. Eight key benefits (gathering a shared understanding of the reality; identifying improvement opportunities; engaging stakeholders in the project; defining project's objectives; monitoring project progress; learning; increased empathy; simplicity of the method) and five factors key to performing a successful process mapping exercise (simple and appropriate visual representation, information gathered from multiple stakeholders, facilitator's experience and soft skills, basic training, iterative use of process mapping throughout the project) were identified. The findings in Chapter 2 similarly highlighted some of these benefits, particularly gathering a shared understanding of the reality, engaging stakeholders and identifying improvement opportunities. One additional benefit found in Chapter 2 was the

ease in which similar processes could be compared in a top-level manner. This was crucial in aiding to design data collection forms that both collected comparable information, but also were specific to the setting that they would be collecting data from.

Chapter 3 compared the cost of delivering cancer support services in the community versus the traditional hospital-based services. We used a TDABC methodology similar to other studies where such an approach was used (125-128, 142). This chapter compared costs incurred in a hospital day unit of a large teaching hospital in the West of Ireland to costs incurred in either primary care centres or in the patient's own home in the same geographical location. An unpublished pilot study of the cancer care delivery programme in the community had shown no worsening of clinical status, with no adverse clinical events reported and a qualitatively assessed improvement in patient quality of life (QoL). Due to this, a purely cost-comparison approach was used to compare the two cancer care settings. The hospital setting was found to be €17.13 (95% CI €13.72 - €20.54, $p<0.001$) per patient cheaper than the community setting when viewed solely from the health payer's perspective, but no significant difference in costs was found between the two settings when viewed from the societal perspective. Sensitivity analyses indicated that it was more likely that the community setting was the less expensive option from this perspective. Similarly, other studies have reported that providing care in the community can be more expensive from the health payer's perspective but the more inclusive societal perspective often shows community care to be the cheaper option (145, 159). Rischin *et al* compared the costs of delivering chemotherapy care in Australia in the community versus the hospital. Their

study calculated costs solely from the hospital (health payer) perspective, using similar methodology to that used in Chapter 3 by assessing the time-driven costs of the nurses providing the care, along with the relevant overheads. They found that delivering care in the community was on average of $83 AUD (equivalent to €85 in 2019) more expensive than in the hospital setting (145).

There is a drive for the societal perspective to have greater influence on both economic analyses and decision making policy (260). A 2018 International Society for Pharmacoeconomics and Outcomes research (ISPOR) task force recommended reporting both health payer and societal perspectives for the sake of clarity and to aid policy makers in making a fully informed decision on the intervention being assessed (77). Gordan *et al.* identified total healthcare costs, both from the hospital and patient perspective, and found that patients treated in a community setting had significantly less expensive healthcare costs per month than patients treated in a hospital setting. While the methodology of Gordan *et al*'s study did not entail a direct observation of time costs, the results pointed towards the possible cost savings of providing care in the community when viewed from the societal perspective.

Chapter 3 achieved the objective of carrying out a full economic assessment of a novel cancer service in Ireland. The patient impact of a move to the community had not previously been fully assessed. Hence, using qualitative methodology i.e. semi structured interviews with thematic analysis (Chapter 4) it was possible to assess the lived experiences of the patients and nurses involved in this programme, as well as those in the hospital setting. The semi-

structured interviews allowed for a more in-depth exploration of the advantages and disadvantages of providing cancer care in the community. The findings of this chapter were in line with previously published work, principally the improved level of patient care in the community and the development of a stronger nurse-patient relationship as the two core themes that emerged (181, 190, 261). Patients were identified as being more comfortable receiving their cancer care in their own home, and were thereby able to avoid some of the psychological stress that often arises from hospital visits (261).

Chapter 4 also detailed findings more specific to this study regarding the importance of the patient's home location for receiving oral anticancer therapies, and roadblocks to the enhancement of the cancer service. Previous studies have shown that cancer patients face an increased burden of travel compared to non-cancer patients (17), and this study was conducted in a relatively sparsely populated region where travel times could be expected to be especially long, due to less developed transport infrastructure and limited public transport compared to more populated parts of Ireland. There is a global impetus for cancer services to be moved into the community, both to improve patient outcomes as identified in Chapter 4 (section 4.4.1) and in order to reduce the demands of the hospital setting (28, 178). The findings of this chapter are supportive of this shift, as all participants in the study were unanimous in their view that the community-based service was positive for the both patients and cancer care service itself as a whole.

Therefore, Chapters 2, 3 and 4 provide an overall wide perspective of the novel Community Oncology Nursing Programme for cancer care in the West of Ireland. The combined findings of these chapters point to a cost-viable service that is safe and valued by patients in providing an enhanced level of care and comfort. On the basis of these preliminary findings, it appears that this programme may be suitable for a national roll-out. The National Cancer Strategy was discussed in Section 1.3.2. Four of the areas of focus for this strategy are: (i) patient centred care, (ii) addressing inequalities, (iii) improved service delivery, and (iv) innovation and modernisation (37). The findings of this thesis support the idea that the Community Oncology Nursing Programme is successful in meeting these goals. The implications of this research as it pertains to Sláintecare, Ireland's national health reform plan, are outlined in Section 7.3.

Chapter 5 assessed another aspect of cancer care, i.e. the monitoring of oral anti-cancer therapies (OATs) by nurses in hospitals throughout the Republic of Ireland. Many hospitals are beginning to introduce dedicated OAT clinics, whereby nurses can be fully dedicated to the care of strictly patients managed with OATs. This chapter used a mixed-methods approach to evaluate the monitoring of OATs, associated staff and patient costs, and the lived experience of the nurses responsible for the monitoring of such therapies. For the purposes of this thesis, a mixed-methods approach was deemed appropriate for a single chapter due to some of exterior limitations. The restrictions imposed as a result of the Covid-19 pandemic made a full process mapping exercise impossible. For the economic evaluation, no comparator was available in the literature to reflect the ideal scenario. There was a limited

number of nurses available nationally for interview, and the timelines of research ethics committee approval meant that all nurses who were eligible for participation were contacted. With all these factors taken into account, the work described in Chapter 5 was based on a mixed-methods evaluation.

As reported in Section 5.4.1, the median time of individual monitoring sessions was found to be 33 minutes, with an associated staff cost of €26.51 using advanced nurse practitioner rates and €22.10 using clinical nurse specialist rates. From the societal perspective, there was an additional cost of €14.06 as a result of the patient's lost work productivity time. The themes of the impact of the Covid-19 pandemic, the continuing expansion of the oncology service, the importance of dedicated clinics and the future of the service emerged from the interviews. One of the key talking points was the challenges of patient monitoring, particularly surrounding patient understanding and adherence. Other qualitative assessments of oral chemotherapies and their providers reported similar results, where the provider felt that ensuring full patient understanding was paramount to care (262, 263). Wei *et al.* did report a divergence in what the patients felt was most important to their consultations, positive and encouraging information, compared to provider's focusing on product safety, adherence and toxicity recognition. The nurses interviewed in Chapter 5 (Section 5.4.4 and 5.4.5) were highly aware of their patients' social and emotional needs. In fact, they felt that with the improved access that a dedicated OAT clinic offers, they could develop an improved and more insightful nurse-patient relationship than if they were working in a general oncology day-unit. The thesis conclusion of a full assessment of the service is that the nurses provide an effective and efficient service, but that the quality of

the service is being challenged and possibly eroded by the steady release of new treatments and an increasing number of patients needing the specialist service. Chapters 3, 4 and 5 achieved one of the thesis objectives, i.e. to determine the qualitative and cost impact of two types of cancer services that have recently been introduced as standard care.

A recently published framework for cancer health economics research by Halpern *et al* (264) shows the importance of the variety of research topics examined in this thesis. The framework is shown in Figure 7.1 below.

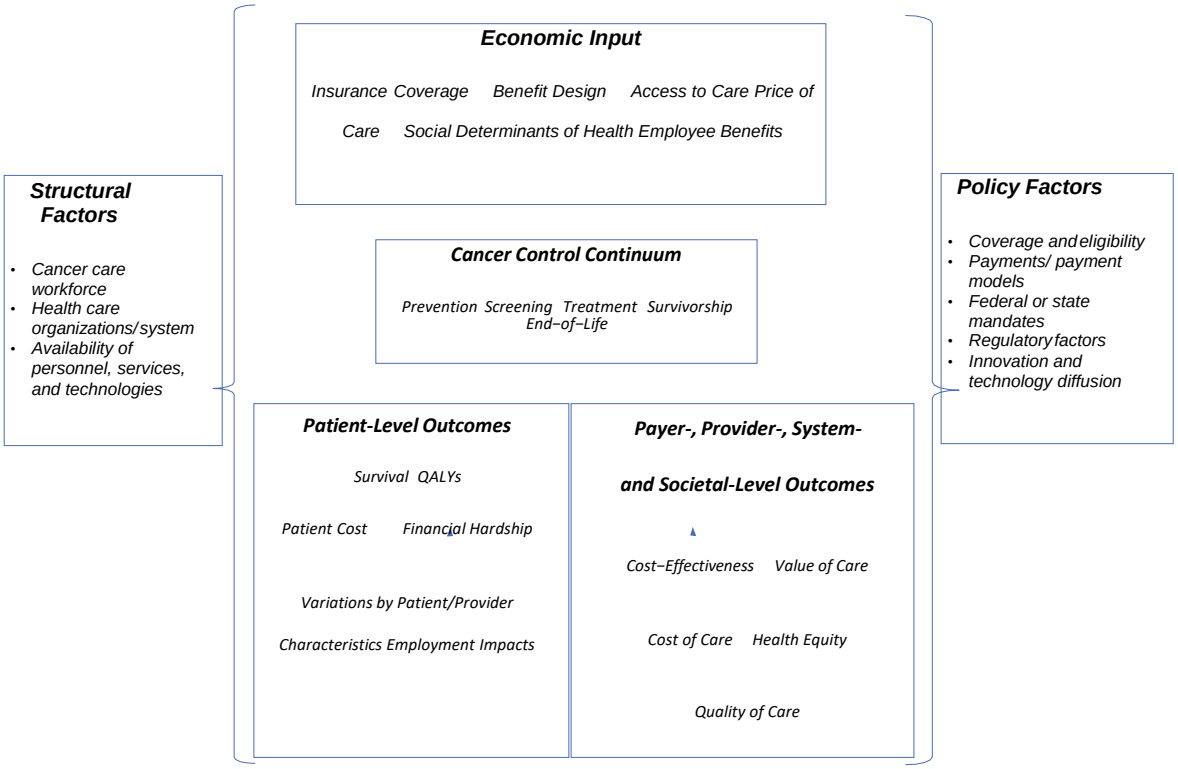



**Figure 7-1 Framework for cancer health economics research (Halpern *et al)***

Chapters 3, 4 and 5 address the components of this framework. The studies described in this thesis evaluate the financial costs, policy effects, patient outcomes, health payer outcomes and structural factors relating to the lived experience of the oncology service nursing workforce. The key message from this framework is that cancer health economics research extends beyond the simple measurement of costs or expenditures. It also involves the impacts of policies, programs, and multiple factors on the supply, demand, and delivery of cancer-related services, as well as the impact of economic factors on health equity, quality of care, and patient outcomes related to cancer. The findings of Chapters 4 and 5 give context to these components of cancer care, and show that a simple cost evaluation of a service is not sufficient for cancer health economics research.

One of the reasons for the projected growth in cancer patient numbers is the projected aging of the population. This link between cancer care and care of older persons highlights the need for the two patient groups to be examined and in tandem. Chapter 6 described an economic evaluation of the Cork study site of the OPERAM trial, where the semi-automated application of the STOPP/START version 2 criteria using the STRIP-A software tool was applied to adults aged over 70 years who were being treated with polypharmacy (five or more medications) and managing three or more chronic comorbidities (265). This was a full cost-effectiveness analysis, with the measurement of both total healthcare costs for patients and QoL measurement over a 12-month follow-up period. A SUREG model and simple difference calculations between OPERAM trial arms were reported. Given previous reporting of the positive clinical outcomes of the application of the STOPP/START criteria (234), it was

anticipated that patients in the intervention arm would experience a significant improvement in QoL compared to the patients in the control arm. However, this chapter found no significant difference in QoL between arms in either model, as indicated by EQ5D data. Both models reported patients in the control arm accruing more QALYs, a 0.0095 (p=0.816) simple difference and 0.121 (p=0.706) difference in SUREG model calculation, both of these findings were statistically non-significant. Cost differences were also not significantly different. There was a non-significant difference of €757 (p=0.790) using simple difference and a cost saving of €1477 (p=0.341) using the SUREG model, both in favour of the intervention. From this, the intervention was deemed not cost-effective.

Section 1.4.1 introduced the method of cost-effectiveness calculation using the Incremental Cost-Effectiveness Ratio (ICER). The most common calculation of an ICER involves a new intervention that is costlier but provides superior health outcomes in terms of QALYs gained. Although providing a "positive" ICER in both models, the intervention analyzed in Chapter 6 is not a conventional ICER result, as it is a "double negative" ICER, where the costs are reduced but there is a net QALY loss when using the intervention. It may not be feasible for a health policy decision maker to choose to introduce an intervention that is in theory more damaging to the patient's health, regardless of theoretical cost savings. Results from the overall OPERAM trial dataset reported no decrease in time to first drug-related hospital admission through the use of the intervention (266).

Another clinical trial within the same domain of minimizing inappropriate polypharmacy in the multimorbid older adult population i.e. 'The SENATOR trial' reported a similar negative finding (254). These results call into question the effectiveness of the application of the STOPP/START version 2 criteria through the use of an automated clinical decision support system. There may be issues regarding the uptake of the recommendations provided by the system by attending physician prescribers/deprescribers, the reasons for this were qualitatively assessed in a follow-up qualitative study relating to the SENATOR trial (253). Some of the reasons included the recommendations being considered to be of low clinical relevance, a perceived time delay between the prescribers reviewing the patient and the point at which the recommendations were provided, and a hesitancy to change long-term medications outside individual physicians' own specialty. Following the release of the main OPERAM trial results, it is anticipated that there will be further studies and investigation into the reasons for the overall negative effect of the trial intervention. Outside of the cost-effectiveness of the intervention, this chapter provides important healthcare utilization and associated healthcare cost data relating to older persons in Ireland, as well as a useful methodology for future studies to follow.

Both the findings and methodology used in this thesis help to highlight the breath of health economics research. Chapters 3 and 5 used a TDABC model of costing, while Chapter 6 followed total healthcare costs over a year long period, drawing from previously published literature for unit costs. This thesis showed the utility of both the simpler cost comparison studies, as well as a complete cost-utility analysis, using health gain/loss in terms of QALYs. What

can be taken from the findings of Chapters 3 to 6 is the message that health economics research is not solely a measurement of healthcare costs. There is a need for greater understanding of the context surrounding the measured intervention, and how the actors, facilities and patient's needs interact and affect the intervention. Chapter 3 presented a cost comparison for providing cancer care in two different settings. To gain further appreciation for the patient impact, as well as the ways the service could be improved, Chapter 4 provided a qualitative assessment to help bolster the findings of Chapter 3. Chapter 5 performed a similar context using mixed methodology. The surprising findings of no significant difference in QALY gain highlights the importance of complete measurement of an intervention provided by health economics. Both models used in Chapter 5 showed a non-significant reduction in QALYs in the intervention arm. A pure cost evaluation would not have been sufficient in assessing the intervention's cost-effectiveness. Future research from the OPERAM trial should provide the context surrounding the intervention, and why it was not as effective as had been anticipated.

## 7.3 Implications on health policy

The studies described in this thesis provide useful information for health policy decisions makers. The findings from this thesis will be available to decision makers, and the data reported in Chapters 3, 4 and 5 will be available in open-access journals. The findings of Chapter 6 will be released as part of the overall economic assessment of the OPERAM trial across the four study sites. Work completed during this thesis was also presented at ISPOR Europe 2018 and Virtual ISPOR 2021 conferences.

The studies reported in Chapters 2, 3 and 4 were conducted in association with the National Cancer Control Programme (NCCP), the Office for Nursing and Midwifery Service directorate and the Health Service Executive (HSE). The findings reported in this thesis were circulated to these bodies as part of an overall report on the Community Oncology Nursing Programme. Extensive consultation took place with these agencies prior to, during and following the conduct of this research. These findings may have influence in future decision-making relating to increasing the capacity of this programme and expanding it to other parts of Ireland. The positive findings reported in both Chapters 3 and 4 are favourable indicators for an increased rollout of such primary care services nationally. Chapter 4 also reported the opinions of both patients and nurses on how the service could be improved. Chapter 2 provided a quality assessment of the cancer service processes in community and hospital day-unit cancer care delivery. Inefficiencies were identified in the hospital process flow, and although they could not be tackled contemporaneously due to time and cost constraints, they were shared with the hospitals concerned and could help inform future service developments in cancer care delivery.

Chapters 3 and 4 present findings that the CONP may be cost-viable from the societal perspective and offers patient benefits. The nurses interviewed in Chapter 5 expressed their view that the monitoring of OATs could be moved into the community in order to free up hospital capacity and offer improved, more easily accessible care to patients. These findings are in line with the recommendation of the Sláintecare healthcare reform plan. The aim of Sláintecare is to move services away from the hospital setting towards primary care and is supported by the experience with the Community Oncology

Nursing Programme. The expressed wishes of some nurses responsible for OAT monitoring are to improve patient access and to increase capacity in an increasingly pressurized service. Ireland's primary care services are relatively deficient when compared to other affluent countries, which is the reason for Sláintecare's development. The report highlighted that "*Ireland is extremely unusual in a European context in terms of the difficulties in accessing care for many people, the full price and high cost paid by many people, and the absence of legal entitlements to care*". Beyond the services offered by the Community Oncology Nursing Programme, community nurses expressed a desire for the expansion of services provided, including blood sampling and delivering chemotherapy, as is already done in other countries (146, 148). These findings should help inform the future development of community cancer services across the country. The extraordinary circumstances of the Covid-19 pandemic have shown that not only is a move away from the acute hospital setting viable, with enhanced virtual communication services, but necessary. The repeatedly stated patient preference is for care that is easier to access through delivery in the community as well as the hospital. A central tenet of Sláintecare is easier healthcare access for patients which facilitates early cancer detection and overall better management of most cancers. With an expansion into the community being the clear policy-driven way forward, there will be a need for greater investment in improved IT systems in the healthcare system. Over the course of this thesis, there was a near unanimously expressed view from healthcare professionals that both the hardware and software that are currently used by healthcare professionals, especially in hospitals, are outdated and problematic. Of particular note was

the difference in IT application when consulting with an experienced industrial engineer in Chapter 2, who noted how deficient the IT systems in the hospital were. In healthcare, there will always be a degree of catching up when investing in IT, as newer versions are released on to the market. Given the issues encountered by staff over the course of this thesis, as well as the recent problems experienced by the NHS and HSE resulting from their systems' cyber security deficiencies, the argument for strengthening existing healthcare IT systems within the HSE should be compelling.

Although the findings of Chapter 3 show that the care offered as part of the Community Oncology Nursing Programme can be cost-viable when viewed from the societal perspective, it was shown to be significantly costlier when viewed solely from the health payer's perspective. Given the rising healthcare costs detailed in Chapter 1, there may be a question as to whether sufficient funding can be provided. The Sláintecare report highlights that the desired shift of location from hospital to community settings cannot be achieved without investment. The findings of Chapter 4 discussed the unanimous agreement that the programme was of benefit to patients, including physical, psychological, social and financial benefits. There will always be a weighing of financial costs and patient benefits in healthcare. Future research that may be done to further clarify these results is discussed in section 7.5.

Chapter 5 highlights the need for further investment in dedicated oral chemotherapy clinics. However, the limited available health budget may be a barrier to investment, especially with the projected economic consequences of the Covid-19 pandemic (267). However, the inevitable increase in demand

for publicly provided healthcare services over the coming years mandates that a safe and effective method of care delivery must be in place. Nurses' expressed concerns about confusion when dealing with different therapy types and a lack of patient access were discussed. These issues are likely to worsen as oncology service demand increases. Given the aims of Sláintecare discussed previously, it is possible that new oral anti-cancer therapy clinics may be set up in the community. A multidisciplinary team of prescribing physicians, specialist nurses and pharmacists could provide a more easily accessible and more comfortable care package for patients using oral anti-cancer chemotherapy drugs. One interviewee expressed the view that such a clinic could move from one primary care centre to another, allowing for a more complete patient coverage within a catchment area. From the process mapping exercise undertaken as part of Chapter 5, the only specialised piece of equipment needed for patient monitoring is an ECG machine.

The findings of Chapters 4 and 5, when compared with some of the pharmaceutical care deficiencies identified in the OPERAM trial show the importance of human relationships and interactions in healthcare. Nurses described seeing the same patient for each visit, and how that strengthened their nurse-patient relationship. This made the nurse more aware of the patient's circumstances, allowing them to identify specific problems more quickly if any arose. Patients were able to access their usual treating nurse more easily, aiding in better reporting of problems. One of the reasons for the lack of uptake of the recommendations provided by the automated clinical decision support software (CDSS) tool in the SENATOR trial was a lack of direct face-to-face interaction between primary researchers and the patients'

attending physician prescribers (253). It can be surmised that a similar problem may have arisen in the OPERAM trial given the similarity of the intervention. CDSS-based interventions have been shown to be effective in managing Potentially Inappropriate Prescribing (PIP) (238), and in the future may be implemented in standard pharmaceutical care of older people. However, one should never disregard the element of human interaction with these software systems. If prescribers were able to interact with these software systems in the same manner as with a researcher making a prescribing recommendation, there might have been an end result more similar to previous studies reporting the clinical impact of STOPP/START criteria (234).

Chapter 6 reported a "positive ICER" of € 122,066/QALY (Section 6.4.3). While this is above the Irish standard ICER threshold of €45,000 for cost-effectiveness (212), it is an unconventional ICER result, in that the likelihood of cost-effectiveness is minimally affected by an increase in the willingness-to-pay threshold due to the slight cost savings in the intervention arm. It is impossible for any health policy decision-maker to implement an intervention that shows a worsening of clinical status, as was reported in Chapter 6. Hence, it is not anticipated that the STRIP-A software tool used in the OPERAM trial will be deployed as part of the standard care in its current iteration. Sub-studies of the OPERAM trial will help identify reasons for the trial's overall negative result. The previous positive findings using the STOPP/START criteria suggest that there is potential for STRIP-A to be used as part of an automated CDSS(234). What will be needed is a way to deliver and implement the recommendations as quickly and as completely as possible. A possibility may be a more interactive method of delivering recommendations, rather than

simply putting the recommendations in printed report. Prescribers have indicated that there is a high likelihood of simply missing the recommendations when they are sent by email or included as a report in the patient's medical records (253). A systematic review of the factors that influence the success of a CDSS may aid in future development of medication optimizing interventions (268). This systematic review noted that of particular concern to prescribers was the belief that CDSS can undermine the doctor-patient relationship, and can be intrusive in clinical practice. A CDSS that could provide recommendations in a manner that allows more engagement by the prescriber, where the rationale for each decision could be explained, could allow the physicians to use CDSS tools as an information resource rather than viewing them as an intrusive force dictating their prescribing practice. The context of this potential intrusion of the patient-centred care can be contrasted with the enhanced nurse-patient relationship identified in Chapter 4. The healthcare worker-patient relationship is vital in assuring the highest standard of care possible, and is something that should be cultivated and focused on. Increasing the patient involvement as part of these CDSS-based interventions may allow for an improvement in the physician satisfaction with the recommendations and thus an associated increase in their uptake.

While dissemination of research through academic journals is an important aspect of a research thesis, communication through these channels may not be reaching the intended audience if the aim is to help inform policy at a national level. In the course of this thesis, the author has attempted to disseminate the findings as broadly as possible, through conferences locally, nationally and internationally, through communication and dissemination of the

results with participants and participating sites. For instance, the author has collaborated with national policy strategists, primary care departmental heads and eight diverse hospitals distributed across the country in the course of working on this thesis.

## 7.4 Strengths and limitations

The studies in this thesis used a range of methodologies. Both quantitative and qualitative research was used to gain a fuller understanding of the patient and staff impact of the services being evaluated. The economic evaluations in this study were diverse, including a simple cost-effective evaluation in Chapter 5, a cost-comparison study in Chapter 3 and a cost-utility study in Chapter 6. The methods for cost evaluation differed across the various studies/chapters, with Chapter 6 collecting unit costs for healthcare services of varying types in Ireland. A study published by another Irish based research team (43), which was published after the completion of Chapter 6 provides unit costs for healthcare professionals whose salary is not publicly available as is the case for HSE staff. The lack of this type of data at the time meant that an extensive literature search of the most recent available data was required to obtain unit costs.

The chapters within this body of work used a variety of rich data sources to inform the overall analyses and subsequent conclusions drawn from this thesis. The findings from Chapter 4 are based on a diverse sample that was representative of patients and nurses. A sampling framework was developed to ensure that patients and nurses of all types were recruited and represented within the study. This mediates concerns regarding selection bias in recruitment.

Studies based on the contents of Chapters 3 and 4 have been published in a peer-reviewed journal (215, 269), and another manuscript based on the contents of Chapter 5 is currently under review (see Appendix F – Chapter 3

publication, and Appendix I – Chapter 4 publication). A narrative review of process mapping in healthcare was published by the author during the course of this thesis, with content from Chapters 1 and 2 forming part of the review (270) (see Appendix D – Process Mapping, Journal of Pharmacology and Pharmaceutical Research). The findings of Chapter 6 will form part of the full economic evaluation of the OPERAM clinical trial. At the outset of the OPERAM trial, participating sites agreed to pool data from individual sites for publication purposes, but that each site could and would analyze their own data. The authors of the full economic evaluation helped verify and review the contents of Chapter 6, and the analysis from the Cork study site will be peer-reviewed as part of the overall OPERAM health economics publication.

This thesis followed International best practice research guidelines for reporting healthcare economic data and qualitative research. The economic evaluations of Chapters 3 and 6 followed the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines (164), while the qualitative studies in Chapters 4 and 5 used the consolidated criteria for reporting qualitative research (COREQ) statement (189) (Appendices M, N, O, P attached).

Individual thesis chapters elaborate on the specific limitations of each study. When comparing across chapters, all chapters other than Chapter 6 used data generated by the author for the sole purpose of the conduct of the studies in those chapters. The time recording data collected in both Chapters 3 and 5 was self-reported by the nurses involved. The risk of bias and/or misreporting was mitigated in Chapter 3 by direct observation of a sample of observations.

This was not possible at the time of the conduct of Chapter 5 due to the research restrictions brought about by the Covid-19 pandemic restrictions (222). These restrictions also meant that the author could not follow the "*walk the journey*" methodology that is recommended for process mapping exercises in healthcare (122), although this "*walk the journey*" method was applied in earlier chapters.

Chapter 6 used data generated from a large randomized control trial (RCT). It can be expected that manually collected datasets in such a large trial will have missing or incomplete data. There were issues with regard to the database from which the economic data were drawn for the study, especially missing or incorrect/implausible data in the drug file. This issue and how it was dealt with was discussed in detail in Chapter 6.

The research within this thesis focuses on experience around separate interventions in one country (Ireland) at one time point, rather than comparing and contrasting experience across several countries or over an extended time period, across different health policies or across sectors within a country, or between implementing units and people/patient groups. While the international context of the conditions and service types evaluated in this thesis are provided in Chapter 1 and referred to in the individual chapters, it is possible that the findings from this thesis may not be generalizable to other international health settings, particularly regarding the qualitative research in Chapters 4 and 5, where the topics discussed were often unique to the Irish setting at a particular time point. Nevertheless, this thesis provides findings of interest for an international readership. The Community Oncology Nursing Programme

evaluated in Chapters 2 to 4 can be replicated in other countries where cancer care in the community has not yet been implemented. The findings of Chapter 4 with regards to some of the drawbacks of the programme and how it may be improved could aid in the development of a similar programme elsewhere. The findings in Chapter 6 are broadly similar to the results reported in other OPERAM study sites. The methodology used in Chapter 6 for conducting an economic evaluation of a large RCT can inform other similar studies, as will the healthcare utilization costs of older persons reported in Chapter 6.

Political context for the services evaluated in Chapters 2 to 5 was considered through the context of the Sláintecare healthcare policy and its aim for a shift of focus to primary care services. Undoubtedly, the political context described for each health-related policy decision is more complex than illustrated. An example includes the nurses responsible for monitoring OATs hoping for some aspects of that service to be moved from hospital to community, but expressing doubt about whether the relevant actors in the community setting would be willing to accommodate such a move. The influence of power and actor relations has been reported in the literature (271). Stakeholder analysis is one method used to help understand the context surrounding relevant actors, their intentions, interrelations, agendas, interests, and the influence or resources they have or could use for decision-making processes (272). However, given that most health-related policies explored throughout this thesis were positioned at local and regional level, it is believed that a stakeholder analysis would contribute no additional benefit to the description of the policies in question with regards for increased national or international context.

## 7.5 Future research

The findings of this thesis provide an opportunity for further exploration of the services evaluated and of other services provided for both cancer patients and older persons. The findings of Chapters 3 and 4 regarding the success and value of the Community Oncology Nursing Programme point to the value of a further expansion of the programme to other areas within the Republic of Ireland. The findings of these chapters were intended to be as broad as possible, but the geographical context of where the studies were based means that further evaluations may be necessary in other regions. Just as international studies may not be applicable to the Irish situation, the context of providing cancer care in the West of Ireland may not be fully applicable to the rest of the country, particularly more densely populated areas.

A quantitative approach to assessing the patient impact of the service may be useful. It was the intent of the author to use the Consultation Satisfaction Questionnaire (273) to assess the quality of consultation across the hospital and community settings. This questionnaire has been used in an Irish nursing context previously (274). This study could not be completed due to nursing work time constraints and commitments in both settings, but it may provide valuable information in the future. Additionally, a cancer-specific QoL indicator, such as the Functional Assessment of Cancer Therapy (FACT-G) questionnaire or the European Organization for Research and Treatment of Cancer (EORTC) quality of life questionnaire (275, 276), could be used to examine the long term impact on patient QoL of providing cancer care in the community. Any developments in the nature of the monitoring of OATs, such

as a widespread commitment to full time clinics or a transfer of this service to the community, could be similarly examined using these tools.

The findings of Chapter 6 provide many opportunities for further research. While it is anticipated that there will be a large amount of publications based on the OPERAM trial data in the coming months, there is a need to explore the reasons for the lack of clinical impact of the intervention. Qualitative discussion with the physicians recruited as part of the trial and the patients' GPs may provide important insights to the trial's STRIPA tool and its utilities and potential limitations, similar to how a review reporting the factors that affected uptake of recommendations in the SENATOR trial which identified flaws in the SENATOR software report implementation (253). Given the similar lack of clinical impact reported in the SENATOR trial (254), it appears unlikely that another large scale randomized control trial will be conducted applying the STOPP/START criteria using the current clinical decision software system. It would still be useful to examine these software tools, especially if the researchers could bring about a higher uptake of the recommendations by the attending physician prescribers compared to that reported in the two large RCTs. If the previously reported positive clinical impact of the application of the STOPP/START criteria could be achieved (234), the economic evaluation reported in this thesis would point towards the intervention being highly cost-effective. The recommendations provided by systematic review describing what makes for an effective CDSS should be used to develop a more effective method of providing recommendations(268). This review recommended that physicians should be involved from the beginning in the design, development and rollout of the CDSS. Recommendations should be patient-specific, with

an explanation of the rationale while providing a holistic view of the patient's drug therapy. What was prevalent in both this review and the review of Dalton *et al. (253)* was the timing of the provision of recommendations. Given that some physicians felt the recommendations were provided too early and some too late, recommendations should instead be provided in line with the prescribers own personal preference and daily working practices. The healthcare resource utilisation of older persons provided in this chapter may be useful in aiding other research studies aiming to examine the costs or time resources spent in older person care in Ireland.

## 7.6 Conclusion

The global and national trends in healthcare spending highlight the need for innovation in the way healthcare is delivered to achieve better value for money. The primary aim of this thesis, to evaluate newly introduced services targeting vulnerable and costly patient groups, i.e. cancer patients and older multimorbid persons, was achieved through both quantitative and qualitative methodology.

The findings of this thesis offer insight into the effectiveness of the examined services and the potential for alternative methods of care delivery to be incorporated into national policy. The continued development and improvement of the Irish healthcare system, particularly with the Sláintecare policy reform plan, is vital to ensuring a safe care standard for patients and a cost-effective one for the available health budget. The findings of this thesis provide both specific information for policy makers on these interventions as well as providing a roadmap for future research of novel evaluations targeting the vulnerable population groups assessed here.

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# Appendices

## Appendix A – All publications

| Citation | Peer –reviewed journal | Authorship Status |
|---|---|---|
| **Full citations** | | |
| O'Mahony, Cian, et al. "A qualitative evaluation of community and acute hospital nursing oncology services in Ireland." *European Journal of Oncology Nursing* 51 (2021): 101912. | *European Journal of Oncology Nursing* | 1st |
| O'Mahony, Cian, et al. "A cost comparison study to review community versus acute hospital models of nursing care delivered to oncology patients." *European Journal of Oncology Nursing* 49 (2020): 101842. | *European Journal of Oncology Nursing* | 1st |
| O'Mahony, C. et al. "Process mapping" *Journal of Pharmacology and Pharmaceutical Research* 4.1 (2021) | *Journal of Pharmacology and Pharmaceutical Research* | 1st |
| "O'Brien, Gary L., et al. "Cost minimization analysis of intravenous or subcutaneous trastuzumab treatment in patients with HER2-positive breast cancer in Ireland." *Clinical breast cancer* 19.3 (2019): e440-e451. | *Clinical Breast Cancer* | 2nd |
| **Conference abstracts** | | |
| A cost comparison study to review community versus acute hospital models of nursing care delivered to oncology patients | *Value & Health* | 1st |
| A cost saving measure from the utilisation of biosimilar Infliximab in the Irish secondary care setting | *Value & Health* | 2nd (presenting author) |
| **Under Review** | | |

| | | |
|---|---|---|
| A Mixed-Methods Analysis of the Monitoring of Oral Anti-Cancer Therapies. | | 1st |
| Cost-effectiveness of a software-assisted, structured medication review approach for multimorbid older people: within-trial analysis of the OPERAM study | | 2nd |
| Optimizing Therapy to Prevent Avoidable Hospital Admissions in Multimorbid Older Patients: the OPERAM Cluster Randomized Clinical Trial | | **31st** |

## Appendix B – Postgraduate taught modules completed

| Module code | Module name | ECTS |
|---|---|---|
| PG6001 | STEPS - Scientific Training for Enhanced Postgraduate Studies | 5 |
| ST6013 | Statistics and Data Analysis for Postgraduate Research Students | 10 |

## Appendix C – Training courses and conferences attended

| Training course name | Location |
|---|---|
| Foundations of Economic Evaluation in Health Care | University of York |
| HRB-TMRN Workshop: An Introduction to Economic Evaluation alongside Randomised Controlled Trials | UCC |
| Introduction to SPSS | UCC |
| ICH Good Clinical Practice (GCP) Training | UCC |
| NVivo Software Training | UCC |
| General Data Protection certificate | UCC |
| ISPOR Europe short courses | International Convention Centre, Barcelona |

| Conference | Location |
|---|---|
| National Centre of Pharmacoeconomics – Update on health economics research in Ireland | Dublin |
| ISPOR Europe 2018 | Barcelona |
| New Horizons Research Conference | UCC |

| | |
|---|---|
| UCC School of Pharmacy Research Seminar | UCC |
| Virtual ISPOR 2021 | Online |

## Appendix D – Process Mapping, Journal of Pharmacology and Pharmaceutical Research

Research Open
Journal of Pharmacology and Pharmaceutical Research
Volume 4 Issue 1

Short Commentary

# Process Mapping

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Process mapping can be described as an "*entire approach that leads to a holistic understanding of the process under review*" [1] Although it has its roots outside lean thinking, process mapping has become part and parcel of the lean "*toolkit*", and is used with lean practice given its strengths in data collection and process re-design by identifying value add and non-value add processes [2-4]. It involves documenting activities of a process in a detailed graphical format. Process mapping has long been an important technique in service assessment and improvement [5]. It has the advantage of communicating roles and responsibilities to team members, providing a useful "*what-if*" tool and improving all round efficiency [1]. In recent years, it has become a key component of popular techniques such as Six Sigma and lean thinking [6,7]. Figure 1 is an example of a process map from a project examining discharge of high risk patients [8].

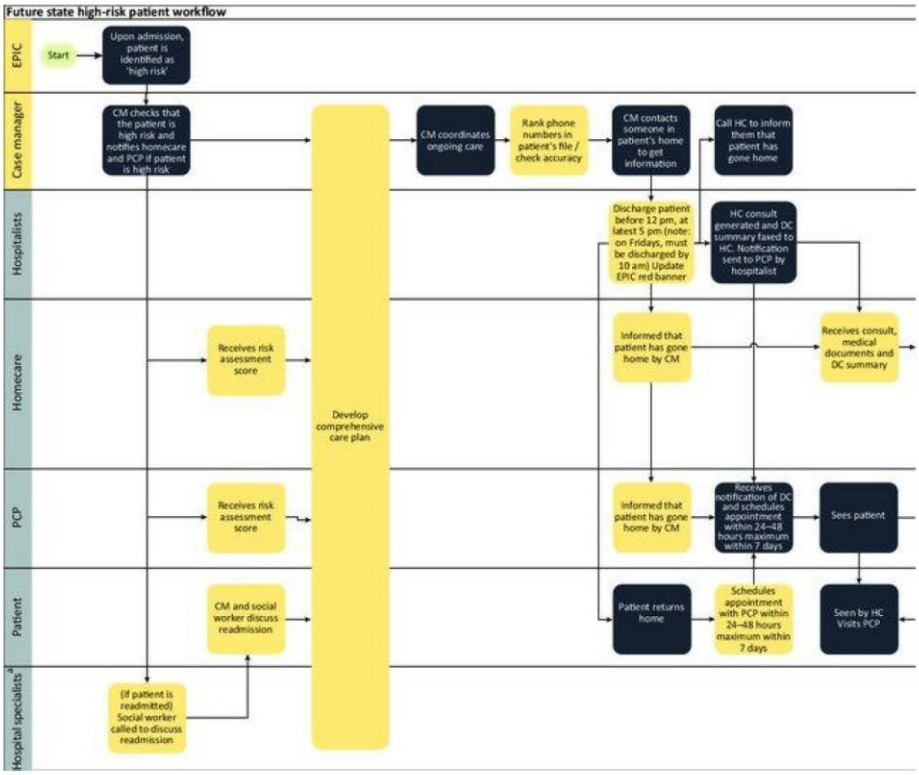


Figure 1: Swim lane diagram outlining steps within the discharge process.

## Process Mapping in Healthcare

Process mapping has recently been used to examine and improve healthcare processes. It may also allow health policy decision makers to view the management of a medical condition in the form of sequential events, and by doing so gaining an insight into both the patient and staff experience [9]. Process Mapping has demonstrated clinical benefit in improving efficiency and reducing unnecessary or ineffective care [10].

A recent review of the literature by Antonacci et al. examined the findings of eight quality improvement projects from different healthcare settings within the NHS [11]. Inductive analysis on interviews of partcipants experience of using process mapping was carried out. There were eight key benefits related to process mapping reported by the participants;

(i) Gathering a shared understanding of the reality.

(ii) Identifying improvement opportunities.

(iii) Engaging stakeholders in the project.

(iv) Defining the project's objectives.

(v) Monitoring project progress.

(vi) Learning.

(vii) Increased empathy.

(viii) The simplicity of the exercise.

Five factors related to a successful process mapping exercise were identified;

(i) Simple and appropriate visual representation.

(ii) Information gathered from multiple stakeholders.

(iii) Facilitator's experience and soft skills.

(iv) Basic training.

(v) Iterative use of process mapping throughout the project.

There are limitations to process mapping. It can be a costly and lengthy exercise. Manual process mapping takes resources in the form of money and time. There is a team directly responsible for producing the map, as well as the employees who are brought away from their work to be contribute their knowledge to the project [12], Process mapping often relies on the memory of the person describing the process, and any gap in that recollection can lead to a gap or error in the process map [12]. One way of remedying this is the "walk the journey" method of data collection, where the entire process is observed by the mapping team. This technique has been recommended for use in process mapping exercises in healthcare, with the added advantage of experiencing the patient journey and improving patient empathy [13].

## Time Driven Activity Based Costing

Another use of Process Mapping is that of a costing approach, where the sequential events derived from process mapping can be used in time-driven activity-based costing (TDABC). TDABC uses two parameters [14];

Table 1: Seven steps of TDABC in healthcare.

| Step | Process |
|---|---|
| Step 1 | Select the medical condition. |
| Step 2 | Define the care delivery value chain. |
| Step 3 | Develop process maps of each activity in patient care delivery. |
| Step 4 | Obtain time estimates for each process. |
| Step 5 | Estimate the cost of supplying patient care resources. |
| Step 6 | Estimate the capacity of each resource, and calculate the capacity cost rate. |
| Step 7 | Calculate the total cost of patient care. |

Footnote: Steps 2 and 3 of this model are delivered by the use of Process Mapping. In order for a precise costing model to be achieved, each event in the process must be detailed and a cost allocated.

(i) The unit cost supplying capacity and

(ii) The time required to perform the activity.

In 2011, Kaplan and Porter set out a seven step approach to TDABC in healthcare settings [15], presented in Table 1 below. TDABC model has been shown to be successful in process assessment and costing activities across a variety of disciplines, including emergency medicine, paediatrics, neurology and oncology [16-19]. In the systematic review of TDABC studies in the literature, Keel *et al.* found TDABC to be used in both operational improvement and also to inform reimbursement policy [20]. TDABC was found to be a simple procedure, yet more accurate than traditional activity-based costing. They noted that other than defining the medical condition and care delivery value chain, all other steps set out by Kaplan and Porter are mandatory for a proper TDABC analysis. The emerging theme was that TDABC is a growing discipline and should be slowly incorporated into existing systems to provide the best cost assessments possible [20].

## Conclusion

Process mapping has long been a valuable tool in industrial engineering. It is beginning to find its way into healthcare settings and this should be welcomed, both for service improvement and of more general service evaluation, with a notable example being time-driven activity based costing. This methodology provides an easy-to-follow and accurate cost evaluation of healthcare services where staff time is the main driver of cost.

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*J Pharmacol Pharm Res*, Volume 4(1): 3–3, 2021

## Appendix E - Chapter 3 Ethics approval letter

Saolta
Grúpa Ollscoile Cúram Sláinte
University Health Care Group

Ospidéal na h-Ollscoile, Páirc Mheirlinne
*Merlin Park University Hospital*
GALWAY UNIVERSITY HOSPITALS

Clinical Research Ethics Committee
Room 59
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HR Building
Merlin Park Hospital
Galway.

27th November, 2018.

Professor Stephen Byrne
Professor of Clinical Pharmacy Practice and Head of School
School of Pharmacy
University College Cork
Cavanagh Building
College Road
Cork.

***Ref: C.A. 2084 -*** ***A Cost Comparison Study to review Community versus Acute Hospital Models of Nursing Care delivered to Oncology Patients***

Dear Professor Byrne,

I have considered and reviewed the above submission, and I wish to confirm Chairman's approval to proceed. The following documentation was reviewed:

- Crec Application Form
- Study Protocol
- Participant Information & Consent Forms
- Signed and Dated copy of PI CV
- Signature Sheets

Yours sincerely,

Professor B. Gerard Loftus
Chairman Clinical Research Ethics Committee.

Your attention is drawn to new EU regulations concerning Data Protection, and provisions in Irish legislation for application of these regulations in Medical Research. Guidance is available from HRB on the following link:http://www.hrb.ie/funding/gdpr-guidance-for-researchers/health-research-regulations-2018-faq/ , and youtube presentation https://www.youtube.com/watch?v=jcfSRpvxY5A

The CREC cannot interpret GDPR or approve consent waivers.

# Appendix F – Chapter 3 publication

European Journal of Oncology Nursing 49 (2020) 101842

Contents lists available at ScienceDirect

European Journal of Oncology Nursing

journal homepage: www.elsevier.com/locate/ejon

# A cost comparison study to review community versus acute hospital models of nursing care delivered to oncology patients

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ARTICLE INFO

*Keywords:*
Cancer
Cost analysis
Micro-costing
Community cancer care
Primary care

ABSTRACT

*Purpose:* Ireland's Sláintecare health plan is placing an increased focus on primary care. A community oncology nursing programme was developed to train community nurses to deliver care in the community. While the initial pilot was proven to be clinically safe, no cost evaluation was carried out. This study aims to compare the costs of providing cancer support services in a day-ward versus in the community.

*Methods:* 183 interventions (40 in day-ward and 143 in community) were timed and costed using healthcare professional salaries and the Human Capital method.

*Results:* From the healthcare provider perspective, the day-ward was a significantly cheaper option by an average of €17.13 (95% CI €13.72 - €20.54, $p < 0.001$). From the societal perspective, the community option was cheaper by an average of €2.77 (95% CI -€3.02 – €8.55), although this was a non-significant finding. Sensitivity analyses indicate that the community service may be significantly cheaper from the societal perspective.

*Conclusions:* Given the demand for cost-viable options for primary care services, this programme may represent a national option for cancer care in Ireland when viewed from the societal perspective.

## 1. Introduction

Cancer is one of the leading causes of morbidity and mortality across the world. An estimated 18.1 million new cancer diagnoses and 9.6 million cancer deaths were reported by the Global Cancer Observatory in 2018 estimates(Bray et al., 2018). Cancer incidence is estimated to double by 2035(Bray et al., 2018) and with that both the costs and demands of oncology services will similarly increase. As a result, healthcare providers such as the Health Service Executive (HSE) are seeking ways to either (i) directly reduce costs of cancer care or (ii) moving the provision of health care interventions from the secondary care setting to the primary and community care sectors (Rischin et al., 2000; Lowenthal et al., 1996; Sprandio, 2012), in order to reduce the pressures of an increasing cancer patient population and to reduce the cost associated with the provision of care, as well as to ease the difficulties placed on patients facing long journeys for their cancer care.(Hall and Lloyd, 2008).

Nurse-led interventions have become increasingly common as a way of enhancing the efficiency of care and improving resource-utilisation in the healthcare system. As an increasingly specialised profession, there are many opportunities for nurses to expand their roles within all sectors of healthcare provision. The literature reports that nurse practitioners are clinically effective (Newhouse et al., 2011) and cost-effective (Martin-Misener et al., 2015) in healthcare provision and role expansion. Increased training for nurses has allowed for new enhanced services to be provided for the patients' benefit, with the healthcare provider and society also benefiting. Specialist cancer nursing interventions have shown enhanced patient outcomes, experiences and improvement in cancer management, in terms of both clinical and cost outputs(Lewis et al., 2009; Aiken et al., 2014; Corner et al., 2013).

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Patients value communication, nursing experience and personal education while receiving care, which oncology nurses have been shown to demonstrate(Griffiths et al., 2012).

The study was conducted in a catchment area of 22,572 km$^2$. This leads to long journeys and poses problems for patients looking to access services located centrally in hospitals. Oncology patients deal with many challenges in receiving their care, such as disruption of work, social life, psychiatric disorders (Derogatis et al., 1983), depression, (Spiegel and Giese-Davis, 2003) anxiety (Stark and House, 2000) and a general decline in quality of life(Heidrich et al., 2006). There is also a demonstrated strain on the family caregiver of those who receive oncology care (Stenberg et al., 2010). It should be incumbent to provide such people with every possible opportunity to improve both the quality and accessibility of their care. One such method is introducing oncology care to the community setting. Initiatives in USA (Lowenthal et al., 1996), Australia (Rischin et al., 2000) and in the United Kingdom (Hall and Lloyd, 2008) have shown success, in terms of patient preference, quality of care and cost, in moving oncology care services from secondary to a primary care setting. A recent study in USA has shown a decreased patient expense for those receiving oncology care in primary care rather than in secondary care setting(Gordan et al., 2018).

In 2010, a community oncology nursing programme was developed in response to service pressures within acute Medical Oncology Departments in Ireland. The programme enables community nurses to provide shared nursing care to acute oncology patients at home and in primary care centres. The nurses first completed a specifically tailored Level 9 University-accredited education course. A pilot program of this initiative has been evaluated and was found to have had a positive impact on (i) patients, through a qualitatively demonstrated improvement on quality of life and (ii) community and acute hospital-based oncology services, showing enhanced integration of patient care, both assessed qualitatively(O'Toole et al., 2013). The programme was introduced to HSE Community Healthcare Organisation (CHO) Area 2 (Health Service Executive, 2014) and there has been an ever-increasing demand on the community oncology service since. Table 1 below indicates the number of community oncology interventions in Galway in the last 3 years. The large increases in services provided between January and June 2019 can be attributed to an increase in the level of trained nurses, allowing for further roll out of safe primary care services. Costings were not undertaken in the initial evaluation as there was only a small volume of patients involved in the piloting of this programme. Hence, it was deemed necessary to complete a cost-comparison analysis of this new programme, before further roll-out was implemented nationally.

Ireland is in the process of implementing a 10-year plan for health reform called Sláintecare. The aim is to establish a universal, single-tier health service as well as re-structuring the health system "towards integrated primary and community care that is consistent with the highest quality of patient safety in as short a time-frame as possible"(Burke et al., 2018). There is an aim to move health services into primary care where possible. The community oncology programme examined here aims to provide both a safe and viable method of delivering cancer services in the community instead of providing the same care within an oncology day-ward of an acute hospital. This was the first study of its kind to the best of the author's knowledge.

**Table 1**
Number of community oncology services in Galway.

| Time Period | 5-FU disconnection pump | Other oncology services | Total |
|---|---|---|---|
| **January 2017 – June 2017** | 349 | 693 | **1042** |
| **July 2017 -December 2017** | 369 | 657 | **1026** |
| **January 2018 – June 2018** | 330 | 715 | **1045** |
| **July 2018 – December 2018** | 388 | 762 | **1150** |
| **January 2019 – June 2019** | 435 | 1353 | **1788** |

## 2. Methods

This study utilised a micro-costing approach to calculate costs in the hospital and community settings, both from the healthcare provider's perspective and the societal perspective in Ireland during the latter months of 2019. Micro-costing is a type of costing method involving the direct enumeration and costing out of every input consumed during an intervention(Weinstein et al., 1996). It has become the gold-standard of costing methods due to its precise nature. Studies comparing the cost estimates made by micro-costing studies versus gross costing studies, whereby average costs are identified per treatment group (Drummond et al., 2015), have shown that micro-costing methods produce superior results, especially in the context of this study that takes place in a hospital and where the main driver of cost is labour-related costs(Clement et al., 2009; Tan et al., 2009; Wordsworth et al., 2005; Swindle et al., 1999).

### 2.1. Study sites

#### 2.1.1. Hospital

The oncology day ward that was costed as part of this study is a University teaching hospital in the west of Ireland, with 521 beds providing a range of specialities. Patients are assessed and manages and treatment and interventions include chemotherapy, adjuvant therapies, 5-Flurouracil (5-FU) pump disconnections, catheter insertion supportive care and dressings.

#### 2.1.2. Community

The community service was costed in two counties in the west of Ireland (Galway and Mayo). For each county, a community nurse who has completed the community oncology education programme is responsible for a given area and population. Patients in this area are given care in either Primary Care centres located in the given area, or in the patient's own home depending on certain circumstances.

### 2.2. Intervention

Several oncology interventions have been deemed suitable to be delivered in the community. Governance over the patient population and the interventions which can be delivered in primary care rests with the consultant and his/her cancer team in secondary care. The nurses carried out interventions such as 5-FU pump disconnections, PortaCath flushes, the care of Peripherally Inserted Central Catheter (PICC) lines and Hickmann lines, head-to-toe patient assessment and other auxiliary oncology services such as medication administration, medication management and blood sampling. These services were carried out under HSE best practice and values, in accordance with the community oncology nursing programme resource book (available on request).

### 2.3. Process mapping

In order to carry out an accurate micro-costing, process maps were created for all sites involved in the study during 2019. This involved consultation with process leaders in the sites, these being the nurse managers, followed by direct observation of the patient and nursing pathways by the lead author (COM). The finalised process maps can be seen in Figs. 1, 2 and 3 below. The process maps were designed at a top-level manner, aiding in outline each step in the respective processes. This was needed to identify resource utilisation across all sites, at the start of the micro costing study.

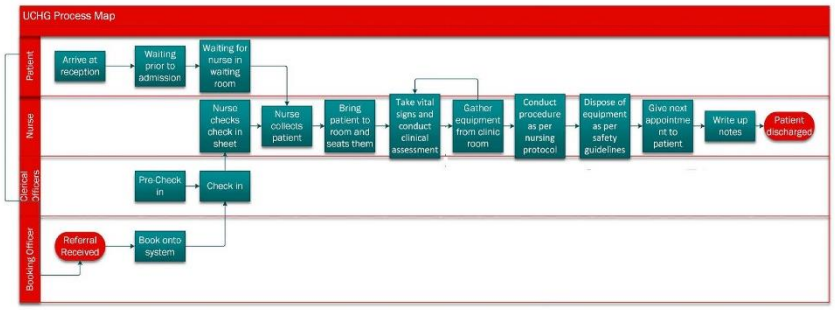


**Fig. 1.** Oncology day ward process map.

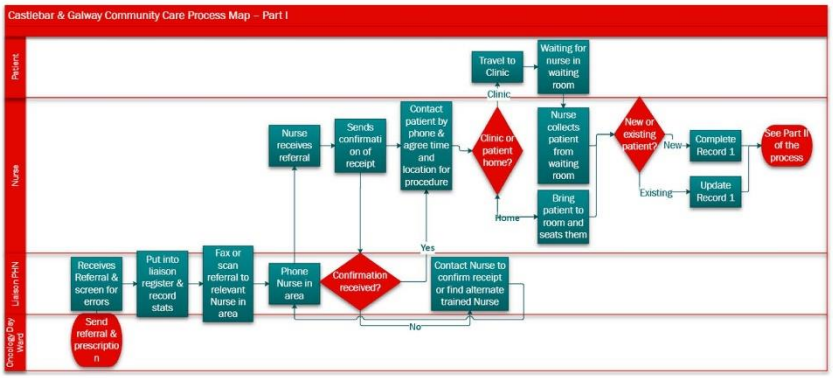


**Fig. 2.** Community care process map.

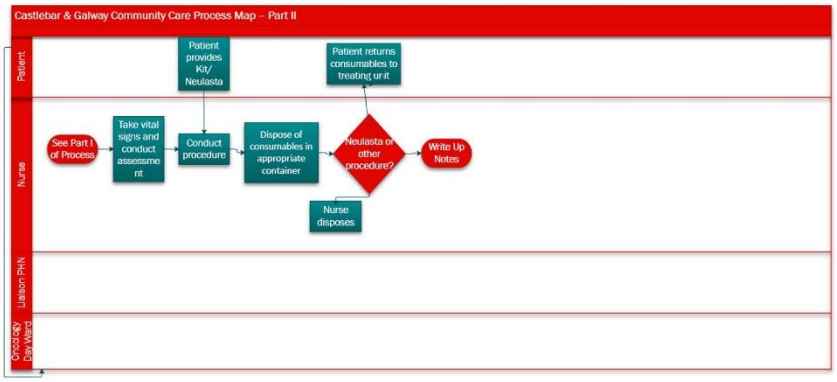


**Fig. 3.** Community care process map continued.

### 2.4. Cost-comparison analysis

A micro-costing approach was undertaken to accurately calculate costs. Both the healthcare provider and societal perspective were calculated, based upon available costs and measurements taken in 2019. Direct and indirect costs were calculated. Direct costs included healthcare professional time, expenses and consumable cost. Indirect costs included patient productivity time lost, travel costs and overheads. The currency used in all cases was Euro (€).

To calculate time-related costs, active time spent by nurses on carrying out tasks related to the patient's oncology care were recorded using a direct observation approach with a stopwatch. Patient-related time costs were calculated from total time spent waiting as well as travel time, using patient self-reported times. For nurses travelling to patients' homes, nurse travel time was recorded using an observation sheet and stopwatch (Appendix 1). The HSE healthcare professional pay scale (as per 2019) was used to cost the times observed. The midpoint of the relative professions pay scales (Health Service Executive, 2018) was used and adjusted for according to guidelines for economic evaluations in Ireland, (Health Information and Quality Authority, 2019) including pension payments, insurance and overheads. The hourly consultation rate was calculated by dividing the midpoint salary by the number of weeks worked per year and the number of hours worked per week. The number of weeks worked per year is 48 and the hours per week are 39. Public health nurse rates were applied to the community observations, and staff nurse rates were applied to the in-hospital day ward observations. Patient time-related costs were calculated using the Human Capital Method.(Van Den Hout, 2010) The average national hourly income as of 2019 Q2 (€23.81) was used.(Central Statistics Office, 2019) This method has been used previously to detail production loss in cancer (Norum et al., 2007; Stanisic et al., 2010). No discounting was needed given that the data collection period was carried out over 3 months. Similar methods of time-related cost calculation have been used by the study team previously(O'Brien et al., 2018, 2019).

The procedures that were costed were the head to toe patient assessment, 5-FU pump disconnection, PICC line dressing, PortaCath Flush, Hickman lines and some miscellaneous procedures. Nursing experts were consulted on the consumables used in each of these processes. The costs of consumables were determined by invoices issued from the finance department of the hospital involved in the programme in 2019. The resource utilisation and unit costs of consumable were used to calculate the total consumable cost for each process. This is outlined in Table 2. The cost of consumables used in the community are the same as those used in the hospital.

Total cost of a procedure was calculated from the public healthcare payer's perspective (HSE), by summing the total consumable cost and healthcare professional costs (procedure time, travel time, travel expenses), and the societal perspective cost, which was calculated by summing the cost of patient time and expenses to the health payer's cost.

There was no clinical data recorded in this study. This is because the pilot study for the Community Oncology Nursing Programme demonstrated no clinical difference in providing care in the two settings (19). During the evaluation period there were no adverse events reported among the patients who were treated at home by the PHNs. There were no emergency phone calls made by the PHNs to the mobile phone number that had been specifically available for consultations and enquires as well as emergencies. While there was no quantitative assessment of a change in patient quality of life, a qualitative assessment found an emphasis on the improvement of quality of life for patients treated in the community. The training provided by this programme is crucial to the viability of this project. The majority of the community nurses carrying out the interventions in the community would have no formal education specialising in oncology care prior to completing this programme. Without this programme, any cost study would need to detail clinical values for a cost-effectiveness study to be completed. Given that there was found to be no difference in clinical outcomes, comparing the costs incurred in both settings is enough to determine the viability of this intervention.

The costs in both settings were analysed graphically and formally using Kolmogorov-Smirnov and Shapiro-Wilks. Parametric data were compared using an independent sample two-tailed *t*-test, with $\alpha$ level 0.05 to test for significance. Levene's test for variance equivalence was used, and equal variance was not assumed if a significant result was found. For the cost-comparison analysis, the cost of consumables was excluded to remove it as a confounder i.e. The consumables used for each procedure do not vary between hospital and community settings. A cost-comparison analysis for procedures carried out in both settings was completed, as there were some procedures only observed in the community setting. The cost of community interventions in the two counties was compared using an independent samples *t*-test.

### 2.5. Sensitivity analysis

Although most day ward procedures are carried out by staff nurses, a portion of procedures are carried out by clinical nurse specialists. The costs incurred using a clinical nurse specialist hourly rate at levels of 5%, 10% and 15% involvement was calculated.(Health Service Executive, 2018).

Given that many cancer patients are too unwell to travel alone, a sensitivity analysis was undertaken to examine the impact of another person accompanying the patient on the social cost (without consumables) of the intervention. The cost of this person was calculated using the same Human Capital Method as the patient cost. To examine the variable effects of a patient being accompanied, 20%, 40%, 60%, 80% and 100% of the sample in all settings were analysed as if another person had accompanied them. For interventions carried out in the patient's home, no increase in cost was incurred, as there would be no need for an accompanying carer. The difference in cost between secondary and

**Table 2**
Consumables used per single procedure.

| Items | Pump disconnection | Port Flush | PICC dressing | Hickmann Dressing | | |
|---|---|---|---|---|---|---|
| | | | | Single lumen | Double lumen | Triple lumen |
| **Heparinised Saline 10 units per ml** | 1 | 1 | 2 | 1 | 2 | 3 |
| **Sterile posiflush syringe** | 1 | 2 | 4 | 3 | 4 | 6 |
| **Syringe luer lock** | 1 | 2 | 4 | 3 | 4 | 6 |
| **Sani Cloth** | 2 | 3 | 6 | 4 | 6 | 8 |
| **Sterile Dressing Pack** | | 1 | 1 | | | |
| **NeutraClear Needle Free Connector** | | 1 | 2 | | | |
| **Filter Needle** | 1 | 1 | 2 | 1 | 2 | 3 |
| **Gloves Surg Gammex** | | 1 | 2 | 2 | 2 | 2 |
| **Dressing Opsite IV 3000** | | | 2 | 2 | 2 | 2 |
| **Gripper Needles** | | 1 | | | | |
| **Gauze square** | 2 | | | | | |
| **Opsite post op 6.5v5cm** | 1 | 1 | | | | |
| **Chemotherapy gloves** | 2 | | | | | |

primary care interventions in this group was analysed using independent samples *t*-test.

### 2.6. Ethical considerations

Ethical approval was granted from the clinical research ethics committees of both the local hospital network and primary care network in the region (Saolta University Health Care Group C.A 2084).

### 2.7. Guidelines

This paper was reported in accordance with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines for reporting health economic evaluations(Husereau et al., 2013).

### 2.8. Software

Analysis was carried out using IBM SPSS Statistics Version 24 and Microsoft Excel 2016. Process maps were created using Microsoft Van Den Hout, 2010.

## 3. Results

Table 3 below details the cost of consumables as provided by the finance department used in each procedure identified in the process mapping exercise e.g. the costliest procedure was a Hickmann 2 dressing at €8.37.

### 3.1. 3.1 Healthcare professionals' cost

The annual salary midpoint for staff nurses is €38,546, resulting in an adjusted salary of €53,868 and an hourly consultation rate of €28.76. The annual salary midpoint for public health nurses is €54,888, resulting in an adjusted salary of €76,110 and an hourly consultation rate of €40.66.

### 3.2. Cost comparison analysis

A total of 183 procedures were analysed over the study period (between April and August 2019), 40 from the hospital setting and 143 from the community. Ideally an equal number of interventions would have been assessed across both settings but this was not feasible due to the lesser number of interventions that occur in the hospital. The number of each type of intervention is shown in Table 4.

As shown, some interventions were recorded only in the community setting. As such, an analysis of procedures recorded in both settings was deemed necessary.

Descriptive statistics of observations in each setting are shown in Table 5. Given all recordings were normally distributed, the mean and standard deviation are shown. Given that for the purpose of this analysis waiting time and travel time can be grouped together, these are combined in the variable additional time.

The cost of procedures from the healthcare payer's perspective was analysed. Equal variance was not assumed. The hospital setting was shown to be an average of €17.07 (95% CI €14.02 - €20.12, $p < 0.001$) less costly per procedure. When selecting only procedures done in each setting, equal variance again was not assumed and the hospital setting was an average of €17.13 (95% CI €13.72 - €20.54, $p < 0.001$) less costly per procedure.

For the societal perspective, equal variance was assumed. The community setting was cheaper by an average of €2.77 (95% CI -€3.02 – €8.55) per procedure, although this was a non-significant result ($p = 0.347$). When selecting only procedures done in each setting, a similar result was found, with the community setting being cheaper by an average of €3.47 (95% CI -€2.84 - €9.75), again a non-significant difference ($p = 0.278$).

**Table 3**
Consumables cost. The consumables used for each procedure do not vary between hospital and community settings. As such, it was excluded from the cost comparison analysis.

| Procedure | Cost (€) |
|---|---|
| 5FU pump disconnection | 3.32 |
| PICC line dressing | 8.31 |
| PortaCath flush | 7.11 |
| Hickmann 1 dressing | 5.77 |
| Hickmann 2 dressing | 8.37 |
| Hickmann 3 dressing | 11.98 |

**Table 4**
Number of each intervention analysed.

| | Hospital | Community | Total |
|---|---|---|---|
| **5-FU disconnection** | 18 | 65 | 83 |
| **PICC line dressing** | 2 | 9 | 11 |
| **PortaCath Flush** | 18 | 7 | 25 |
| **Hickmann 1** | 0 | 0 | 0 |
| **Hickmann 2** | 0 | 8 | 8 |
| **Hickmann 3** | 0 | 9 | 9 |
| **Multiple procedures** | 2 | 13 | 15 |
| **Neulasta/Neupogen injections** | 0 | 26 | 26 |
| **Other** | 0 | 5 | 5 |
| **Missing** | 0 | 1 | 1 |
| **Total observations** | 40 | 143 | 183 |

**Table 5**
Descriptive statistics of observations.

| | Hospital | | Community | |
|---|---|---|---|---|
| **Procedure time (minutes)** | 15.93 (9.95) | | 26.79 (14.99) | |
| **Additional nurse time (minutes)**[a] | 0 (0) | | 10.39 (13.22) | |
| **Additional patient time (minutes)**[a] | 45.03 (33.31) | | 10.35 (12.38) | |
| **Nurse travel costs (€)** | 0 | | 1.17 (2.02) | |
| **Patient travel costs (€)** | 7.70 (7.24) | | 0.833 (1.67) | |
| **Total cost (health payer) (€)** | Not including consumables 7.83 (5.46) | Including consumables 13.51 (5.32) | Not including consumables 24.90 (15.11) | Including consumables 30.02 (14.99) |
| **Total cost (societal) (€)** | Not including consumables 32.46 (19.47) | Including consumables 38.14 (19.29) | Not including consumables 29.69 (15.38) | Including consumables 34.81 (15.22) |

[a] Travel time + waiting time.

### 3.3. Home care versus primary care

The cost of providing the interventions in the primary care centre was significantly lower when compared to interventions in the patient's own home, from both the healthcare payer's and societal perspective. Equal variance was assumed in both comparisons. The primary care centre was an average of €15.36 (95% CI €10.83 - €19.89, $p < 0.001$) from the healthcare payer's perspective and an average of €7.59 (95% CI €2.44 - €12.73, $p = 0.004$) from the societal perspective.

Comparing the cost of only interventions carried out in the primary care centre versus those in the hospital, the hospital was found to be cheaper by an average of €5.69 (95% CI -€1.09 - €12.47) from the

healthcare payer's perspective, but this was not a significant difference ($p = 0.098$). From the societal perspective, the primary care centre was cheaper by an average of €11.15 (95% CI €8.49 - €13.89) ($p < 0.001$).

Table 6 below details the location of interventions carried out in the two counties. Comparing the cost of interventions in the two counties, interventions carried out in Mayo was shown to be an average of €6.96 (95% CI €1.88 - €12.02) cheaper from the health payer's perspective and €5.34 (95% CI €0.34 – €10.36) cheaper from the societal perspective ($p = 0.008$ and $p = 0.034$ respectively).

### 3.4. Sensitivity analysis

The salary midpoint of a clinical nurse specialist was €54,462, resulting in an adjusted annual salary of €76,706 and an hourly consultation rate of €40.975, resulted in a 41% increase in staff costs in the hospital setting. The societal cost of clinical nurse specialists carrying out 5%, 10% and 15% of procedures resulted in the community care being cheaper by €2.92 (95% CI -€2.82 – €8.76, $p = 0.331$), €3.10 (95% CI -€2.61 – €8.96, $p = 0.317$) and €3.22 (95% CI -2.42 – €9.08, $p = 0.302$) respectively. None of these findings were significant.

The cost of accompanying supporters of patients examined at rates of 20%, 40%, 60%, 80% and 100% of interventions is detailed in Table 7. Equal variance was not assumed for comparisons.

At all rates above 40%, there was a significant difference in mean cost, ranging from €8.66 (95% CI €0.96 - €16.36, $p = 0.03$) at 40%, to €15.90 (95% CI €7.61 - €21.20, $p < 0.01$) at 100%.

## 4. Discussion

This study showed that there is a significant cost increase in providing this service in the community from the health payer's perspective, with a mean difference of €17.07 ($p < 0.001$). This was expected given the increased staff costs in travelling in the community. Nurse travel time was the primary driver in this cost increase, with average nurse travel time in all community interventions being 13.22 ($\pm$10.39) minutes, equating to €9.09 (+/−€7.14) in salary cost. The travel costs incurred also played a role in the increase. The average procedure time was significantly longer in the community ($p < 0.001$), even when examining only similar procedures. This may be due to the additional public health role of the nurses delivering the oncology care, as described in the community oncology handbook (available on request).

This study captured the societal perspective by calculating the loss of productivity via the human capital method as well as the health care payer perspective. Sanders et al. recommended for the sake of consistency and comparability, analysts should report "reference cases" from 2 perspectives— the health care sector perspective and the societal perspective(Sanders et al., 2016). This was also corroborated by an ISPOR Special Task Force report (Garrison et al., 2018). When using the societal perspective, this study found that there was no significant difference in the cost of delivering the oncology services between the two settings. A non-significant cost reduction of €2.77 ($p = 0.278$) when delivering interventions in the community was discovered. The primary reason for this change compared to the health payer's perspective is the reduction in patient travel time. The patient travel time is reduced by an average of 35 min (95% CI 27.97 min–41.38 min). This finding may be as important as the cost-saving from the health payer's perspective, given that a central aim of Sláintecare is an accessible and affordable healthcare system for all, with an increased focus on patient-centred care(Burke et al., 2018).

**Table 6**
Location of community interventions.

| | Primary Care Centre | Patient's home | Missing | Total |
|---|---|---|---|---|
| **Galway** | 22 | 39 | 1 | 62 |
| **Mayo** | 34 | 38 | 0 | 82 |
| **Total** | 56 | 87 | 1 | 144 |

**Table 7**
Cost of patient accompaniment.

| % of patients being accompanied | Mean social cost € (SD) | | Difference in cost (€) |
|---|---|---|---|
| | Hospital | Community | |
| 0 | 32.46 (15.38) | 29.69 (15.38) | 2.77 ($p = 0.432$) |
| 20 | 35.69 (21.22) | 31.32 (15.67) | 4.37 ($p = 0.115$) |
| 40 | 43.63 (31.98) | 34.97 (16.01) | 8.66 ($p = 0.025$) |
| 60 | 49.50 (32.55) | 35.04 (16.76) | 14.46 ($p = 0.016$) |
| 80 | 52.31 (32.87) | 36.99 (17.39) | 15.33 ($p = 0.008$) |
| 100 | 55.36 (33.20) | 39.45 (19.85) | 15.90 ($p = 0.006$) |

The analysis of the different primary care settings showed the expected result that the primary care centre was a cheaper option for the health payer, being an average of €15.36 (, $p < 0.001$) than the patient's home. The primary care centre was found to be an average of €5.69 (95% CI -€1.09 - €12.47) more expensive than the hospital from the health payer's perspective but not significantly ($p = 0.098$). This may be because the community nurses were recorded in some instances to be travelling back to the centre after dealing with a house call. From the societal perspective, the primary care centre was significantly cheaper than the hospital, by an average of €11.15 (95% CI €8.49 - €13.89, $p < 0.001$). It is important to note that as part of any oncology primary care package home visits will be a necessity. Given their condition, certain patients require a home visit. This finding does show that from a societal perspective, interventions given in a primary care centre close to a patient's home represent a significant cost reduction, before even considering the improvement in access to services from the patient's viewpoint.

While all analyses indicated that providing the intervention in the community resulted in a significant cost increase for the health payer, the sensitivity analyses demonstrated that there is a possibility that providing this cancer care in the community represents a cheaper alternative from the society perspective. Frail oncology patients are often accompanied for travel and support reasons. This study found that in a scenario where a randomly selected 40% of the patients in both settings were accompanied by another person, a significant cost reduction of €8.66 (95% CI €0.96 - €16.36, $p = 0.03$) was observed. This trend continued the more patients that were accompanied. Unfortunately, the study did not record if someone had travelled with the patient or not.

When viewing from the societal perspective, these are welcome findings for the development of oncology care in Ireland. Providing oncology support services in the community is in line with the aims of Sláintecare, and this study shows that this represents a viable economic option. By moving these services away from oncology day unit within busy acute hospitals, there would be benefits for all. The freed-up space in the oncology would allow for more of the treatments that can only be provided in the day unit, such as chemotherapy. In addition to the economic benefits, there may be a quality of life benefit for the oncology patient by providing these interventions in the community, due to a reduced risk of infection associated with travel to hospital(Plowman, 2000). Patients have stated their preference for receiving oncology care in their own home(Rischin et al., 2000). The reasons include avoidance of travel and parking problems, reduction in hospital-associated anxiety, feeling of comfort in their own home and not burdening their carers and family.

Given that these oncology support interventions can be provided in a cost-effective manner, there may be scope for expanding the duties of community nurses to include other oncology services. The UK has long

allowed for chemotherapy to be administered as part of primary care (Lennan et al., 2010). Even if only the less complex interventions were handled in the community, this would further reduce the demands on the day wards within our acute hospitals. There is also appetite amongst both patients and nurses for blood samples to be collected in the community to streamline the chemotherapy administration process.

All interventions analysed were from two counties in the West of Ireland. One of the counties is particularly sparsely populated. This may skew the travel times of both patients and nurses, as many other counties in Ireland may have primary care centres and hospitals available at a shorter distance. The average distance to healthcare facilities can be up to seven times larger in rural areas than urban areas.(Central, 2016 Table 8 below shows the population density of the counties in the study compared to other Irish counties.

This study used time recordings across community and hospital settings to compare the cost of delivering oncology support services. A micro-costing methodology was used. Other studies in this area have shown some differing results, albeit with different methodologies and focuses. Rischin et al. used direct and indirect costs based on services received and found that the average chemotherapy treatment was $83 more expensive to deliver in the community than in hospital(Rischin et al., 2000). Gordan et al. discovered a significant decrease in cost per patient per month when delivering care in community oncology clinics compared to hospital clinics, primarily driven by the increased cost of chemotherapy and provider visits in hospital-based clinics(Gordan et al., 2018). No previous study of this kind has used the precise, micro-costing method of cost collection used in this study.

### 4.1. Limitations

The only costs estimated in this study were the costs incurred in the carrying out of the oncology interventions. The cost of training in the Community Oncology Nursing Programme is not included in this analysis. If this cost were included, it would favour the hospital setting. However, given that this is a lifelong qualification, it may be biased to include the cost of training when analysing the sample of interventions recorded. If it was included, the average cost per intervention carried out by a trained community nurses over the duration of her career would be negligible.

Ideally, a larger number of interventions would have been analysed for more robust results. These would ideally have come from the hospital setting to get more equitable sample sizes to compare, and thus provide more precise comparisons. However, where possible these support services were carried out in the community to free up needed space in the day unit, an imbalance in the proportion carried out in the community compared to the hospital was expected.

The sensitivity analyses were needed due to a lack of information regarding the type of staff who carried out the intervention and if the patient was accompanied by another person. The sensitivity analysis attempting to assess the impact of patients being accompanied to the hospital by carers only assessed accompaniment to the hospital. While the journey to the community centre may be less arduous, it is possible that the patient could be accompanied by a carer in that circumstance.

## 5. Conclusion

This study has shown that providing oncology support services in the community in Ireland can be a viable economic option when viewed from the societal perspective. The community oncology nursing programme has demonstrated safety in its provision of these interventions in the community, this shows that the services that these trained community nurses provide may be a cost-effective service. Given previous studies have shown the preference for community interventions and with Ireland's increasing focus on building a health system emphasising primary care, this community oncology programme may provide an option in reducing the oncology demands in hospital.

**Table 8**
Population densities in Republic of Ireland.

| County | Population | Population density (per km$^2$) | Rank (of 26) |
|---|---|---|---|
| **Mayo**[a] | 130,507 | 23.3 | 25 |
| **Galway**[a] | 258,808 | 40.2 | 14 |
| **Dublin** | 1,347,357 | 1459.2 | 1 |
| **Louth** | 128,884 | 155.4 | 2 |
| **Kildare** | 222,504 | 131.0 | 3 |
| **Cork** | 542,868 | 72.3 | 5 |

[a] Study counties.

## CRediT authorship contribution statement

**Cian O'Mahony:** Conceptualization, Methodology, Formal analysis, Writing - original draft, Project administration. **Kevin D. Murphy:** Validation, Writing - review & editing, Supervision. **Gary L. O'Brien:** Methodology, Writing - review & editing. **Joe Aherne:** Writing - review & editing, Supervision, Project administration. **Terry Hanan:** Conceptualization, Supervision. **Louise Mullen:** Conceptualization. **Maccon Keane:** Writing - review & editing. **Paul Donnellan:** Writing - review & editing. **Claire Davey:** Writing - review & editing. **Helen Browne:** Writing - review & editing. **Kathleen Malee:** Writing - review & editing. **Stephen Byrne:** Conceptualization, Methodology, Validation, Writing - review & editing, Supervision.

## Declaration of competing interest

The authors have no conflicts of interest to declare.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejon.2020.101842.

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# Appendix G – Chapter 4 Ethics approval

Saolta
Grúpa Ollscoile Cúram Sláinte
University Health Care Group

Ospidéal na h-Ollscoile, Páirc Mheirlinne
*Merlin Park University Hospital*
GALWAY UNIVERSITY HOSPITALS

Clinical Research Ethics Committee
Room 59
1st Floor
HR Building
Merlin Park Hospital
Galway.

28th May, 2019.

Professor Stephen Byrne
Department of Clinical Pharmacy Practice and
Head of School
University College Cork
Cavanagh Building
College Road
Cork.

***Ref: C.A. 2183 -*** ***A Qualitative analysis of patients and healthcare professional's opinions of community and acute hospital nursing oncology models of care in the West of Ireland***

Dear Professor Byrne,

I have considered and reviewed the above submission, and I wish to confirm that I am happy to grant Chairman's approval to proceed.

*'This submission has been reviewed from an ethical perspective only. It is the responsibility of the PI/sponsor/data controller and relevant Data Protection Officer to ensure and monitor compliance with any relevant legislation in the country where the study is due to take place or any local policy in the site where the study is due to take place.'*

Yours sincerely,

B. Gerard Loftus FRCPI,MD
Emeritus Professor of Paediatrics, NUI,Galway
Adjunct Professor of Paediatrics, IMU, Kuala Lumpur
Chair, Galway Clinical Research Ethics Committee.

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Cork.

Professor Maccon Keane, Consultant Oncologist, Department of Oncology,
University College Hospital, Galway.

## Appendix H – Chapter 4 topic guides

This is the topic guide for nurses in the community setting

**Demographics** Please state your profession, grade, clinical area and number of years of experience.

How long have you been delivering oncology care in the community?

1. (**IF APPLICABLE)** Could you describe your experience of the oncology service in this area before the introduction of this programme?
   - No community service? Lack of support for patients/nurses?
2. How would you describe the training you undertook as part of this programme?
   - Any difficulties? Any learning experiences? Increased abilities/competence?
3. Are there any benefits to the nurses involved in the community oncology nursing programme?
   - Better career pathway? Increased professional competence? Personal involvement? Efficiency? Reduced time wasted? Cost?
4. How do you find the referral process from the liaison centre?
   - Admin challenge? Increased confidence from screening/integrated liaison?
5. Are there any benefits to the clients involved in the community oncology nursing programme?
   - Reduced travel? Comfort? Privacy? Quality of life?
6. Are there any challenges for the nurses delivering the community oncology nursing programme?
   - Lack of CRGN/other support? Time pressures? Travel? Lack of additional staff to cross-cover? Increased clinical case-load?
7. Are there any challenges for the clients receiving care as part of the community oncology programme?
8. Do you have any suggestions as to how this service could be improved?

- Improve efficiency? Increased staffing/support? Improve Quality of care/life for clients?

9. Do you think any aspects of this programme could be implemented in other nursing areas?
10. All in all, what are your overall thoughts on the community oncology programme?
11. Is there anything else I haven't asked you about the community oncology programme that you would like to mention?
12. Is there anything we've discussed that you would like to further expand upon?

That brings us to the end of the interview. Thank you for participating.

Note: This is the topic guide for patients

**Demographics :** How long have you been receiving oncology care?

What services do you receive as part of the community programme?

1. (**IF APPLICABLE)** Could you describe your experience of the oncology service in this area before the introduction of this programme?
   - Difficulties in travel? Lack of community support options?
2. What are your thoughts on receiving the service in the community as opposed to in hospital?
3. Are there any benefits of receiving the service in the community as opposed to in hospital?
   - Travel time? Convenience? Comfort? Quality of life?
4. Are there any challenges of receiving the service in the community as opposed to in hospital?
5. Do you have any suggestions as to how this service could be improved or expanded?
   - More resources? Chemotherapy? More support for nurses?
6. Do you think a programme like this would be beneficial in other aspects of your medical care?
   - Other illness support? Increased nursing consultations?
7. Is there anything else I haven't asked you about the community oncology programme that you would like to mention?
8. Is there any point that was raised that you would like to discuss further or expand upon?

That brings us to the end of the interview. Thank you for participating.

Note: This is the topic guide for nurses in the hospital setting

**Demographics:** Please state your profession, grade, clinical area and number of years of experience.

1. How would you describe your experience of working in the oncology day ward?
2. What are the benefits you feel as part of working in the oncology day ward?
   - Part of team? Experience of those around you? Extra support?
3. What are some of the common challenges you encounter as part of your work?
   - Extra administration steps? Time pressure?
4. Are you aware of the community oncology care programme?
   - Yes=continue to 7. No=continue to 6
   5. A community oncology nursing programme was developed in response to service pressures in acute medical oncology departments. The programme enables community nurses to provide nursing care to oncology patients at home/in community setting. The nurses complete a Level Nine University accredited education course. These nurses are then allowed to perform certain interventions for oncology patients in their own home which would previously have been delivered in the acute hospital setting. After referral from the day ward, regional nurses are assigned to patients and agree to meet them either in the patient's home or a nearby public health centre. Patients are provided with their own waste bins and equipment for the procedures in the community.
6. Can you see any benefits of this programme?
   - Time saved for patient? Increased nurse competence/ability? Privacy of patient? Patient quality of life? Patient comfort?
7. Can you see any challenges of implementing this programme?
   - Anything about the hospital setting that improves standard of care? Increased burden on nurse? Increased admin?

8. Is there anything else I haven’t asked you about your work or the community oncology programme that you would like to mention?
9. Is there anything we’ve discussed you would like to expand upon?

That brings us to the end of the interview. Thank you for participating.

# Appendix I – Chapter 4 publication

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# A qualitative evaluation of community and acute hospital nursing oncology services in Ireland

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ABSTRACT

*Purpose:* Cancer patients are a particularly vulnerable population group, facing an increase in physical, mental, logistical and financial difficulties. This, as well as Ireland's increased focus on primary care with the Sláintecare health plan, led to the development of the Community Oncology Nursing Programme, where community nurses are trained to provide cancer care in the community. This paper sought to explore the lived experiences of the patients and nurses involved in this programme in order to examine its impact as well as determine facilitators and roadblocks for future development.

*Methods:* A qualitative examination of the service was carried out by interviewing cancer patients receiving care as part of the programme as well as the nurses delivering care, both in the community and hospital day-ward. Thematic analysis was used.

*Results:* Themes of improved patient experience, nurse-patient relationship, the importance of location and roadblocks to further implementation of the programme emerged. There was a universal belief that the programme offered benefits to the patient and improved their care in some manner.

*Conclusions:* The Community Oncology Nursing Programme has been well received by both nurses and patients. The service provided by community nurses as part of this programme offers benefits to patients and an improved cancer service.

## 1. Introduction

Cancer is one of the leading causes of morbidity and mortality across the world with an estimated 18.1 million new cancer diagnoses and 9.6 million cancer deaths reported in 2018 (Bray et al., 2018). Cancer, along with its treatments, has been shown to be debilitating, worsening the patient's physical and mental well-being (Stein et al., 2008; Stark and House, 2000; Mitchell et al., 2011). Cancer patients face long term difficulties in a range of physical and mental conditions. Cancer has a long term impact on quality of life (QoL), anxiety, depression and fertility as well as social difficulties such as a feeling of shame or stigma attached to the condition (Chapple et al., 2004; Wagner et al., 2010; Zebrack et al., 2004; Ferrell et al., 1995; Reich, 2008). Cancer patients have been shown to have fears of uncertainty and recurrence, triggering a worsening of their mental health (Gil et al., 2004). Patients face additional financial burdens, with Irish cancer patients facing an average income drop of €1527 per month, as well as additional medical and home bill expenses (Irish Cancer Society, 2019). Travel time and distance has been shown to influence a patient's decision to decline treatment, particularly in rural areas which are an hour or more away from a treatment facility (Zucca et al., 2011).

Primary care is becoming a key component in cancer care delivery. A recent report in the Lancet highlighted the expanding role of primary care in cancer control and management. Primary care has a diverse set of roles in cancer care, ranging from screening and early detection to end of life care (Rubin et al., 2015). Primary care was found to have a

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continuous role in care for cancer patients. This report showed that the strengths of primary care, especially the development of a continuous relationships with the patient, is particularly evident in cancer care.

There is universal agreement that home-based chemotherapy is the preferred option for patients receiving cancer treatment (Rischin et al., 2000), and patients with advanced cancer have been shown to prefer home care for end of life treatment (Higginson and Sen-Gupta, 2000). Home care treatments have been shown to improve clinical outcomes for patients, including gastro-intestinal side effects, pain, fatigue, insomnia and anxiety (Molassiotis et al., 2009; Hall and Lloyd, 2008). Patients have shown to value the care provided by nurses in the community which provides them with psycho-social benefits (Griffiths et al., 2013), an "*unsurpassable*" level of care (Vooght and Richardson, 1996) and increased communication during their treatment (Griffiths et al., 2012). Nurses have been shown to have improved care abilities when dealing with patients in the patient's own home, due to better observation of surroundings and a more personal relationship with the patient and their primary carers/families (Leirbakk et al., 2017).

A community oncology nursing programme was developed in Ireland in 2010 in response to service pressures in acute medical oncology departments. Ireland is in the process of implementing a 10-year plan for health reform called Sláintecare. The aim is to establish a universal, single-tier health service as well as re-structuring the health system "*towards integrated primary and community care that is consistent with the highest quality of patient safety in as short a time-frame as possible*" (Burke et al., 2018). Sláintecare aims to move health services into primary care where possible, with a focus on patient-centred care. The programme enables community nurses to provide shared nursing care to acute cancer patients at home/in a community setting (i.e. via a primary healthcare centre). The nurses first complete a specifically tailored Level Nine (postgraduate) University accredited education course (in collaboration with National University of Ireland Galway - NUIG) (Nursing and Midwifey Board of Ireland, 2020). The programme consisted of didactic lectures, case scenarios, reflective learning and workshops. The nurses completed a clinical placement of 20 h and a final assessment consisting of a multiple-choice questionnaire and a detailed case study presentation. Upon successful completion of this programme, nurses are then deemed competent to perform certain clinical interventions safely for cancer patients in their own home which would previously have been delivered in the acute hospital setting, such as 5-Fluorouracil (5-FU) pump disconnections, PortaCath flushes, the care of Peripherally Inserted Central Catheter (PICC) lines and Hickmann lines, head-to-toe full nursing assessment focusing on cancer and the consequences of its treatments, and other auxiliary cancer support services such as medication administration and medication management. A pilot program of this initiative (undertaken in the northwest of Ireland) has been evaluated and was found to have had a positive impact on patients, on community-based and acute hospital-based cancer services showing enhanced integration of care (Hanan et al., 2014). However, community nursing services in Galway, Mayo and elsewhere are challenged in responding to the increased demand of caring for these patients without the support of additional resources.

A concurrent cost-comparison study, comparing the hospital versus community setting was undertaken simultaneously to this study (O'MAHONY et al., 2020). However, this pure costing study will not show some of the personal and professional benefits or drawbacks of this new programme. Hence, a qualitative approach is proposed to elucidate the thoughts/opinions of those involved in the programme, as well as its impact on patients. This study aimed to capture the benefits and challenges of this programme, as well as to examine the facilitators and roadblocks for future rollout of the programme, potentially at a national level.

## 2. Methods

### 2.1. Ethical considerations

Ethical approval was granted from the clinical research ethics committees of both the local hospital network and primary care network in the region.

### 2.2. Participants

Those involved in providing care and patients receiving care via the new community oncology nursing programme were invited to participate in this study. This included cancer patients in both the day ward and community setting. The oncology day ward is part of a University teaching hospital in the west of Ireland, with 521 beds providing a range of specialities. Patients are assessed and manages and treatment and interventions include chemotherapy, adjuvant therapies, 5-Flurouracil (5-FU) pump disconnections, catheter insertion supportive care and dressings. The community service is provided in two counties in the west of Ireland (Galway and Mayo). Mayo is particularly sparsely populated, with a population density of 23.3 individuals per $km^2$, especially compared to Dublin which has a population density of 1459.2 individuals per $km^2$ (Central Statitics Office, 2016). For each county, a community nurse who has completed the community oncology education programme is responsible for a given area and population. Patients in this area are given care in either Primary Care centres located in the given area, or in the patient's own home depending on certain circumstances. Nurses in both settings were also invited to participant, including nurses in the oncology day ward, clinical nurse managers, liaison public health nurses, primary care regional general nurses who have been trained as part of the programme and regional manager nurses.

### 2.3. Sampling strategy

Purposive sampling (Patton, 2002) using a pre-defined matrix for maximum variation sampling of patients, and nurses in the hospital setting and public health nurses in the community. A sampling framework was used to ensure that there was as wide a variation as possible in interview participants. The sample framework is detailed in Table 1 below. Final sample size for interviews was determined using the Francis et al. method of sample size calculation for qualitative interviews (Francis et al., 2010). This method involves setting out a minimum sample size for initial analysis, the initial analysis sample, and a stopping criterion, specifying how many interviews will be conducted with no

**Table 1**
Sampling matrix for participants.

| Nurse | | Patient | |
|---|---|---|---|
| Hospital | Community | Hospital | Community |
| >10 years experience | >10 years experience | >60 years old | |
| <10 years experience | <10 years experience | 40–60 years old | |
| Accredited cancer qualification | Completed CONP (or other accredited cancer qualification) | <40 years old | |
| No accredited cancer qualification | Not completed CONP (or other accredited cancer qualification) | Urban Galway residence | Urban Galway residence |
| Experience in community | Galway urban based | Rural Galway residence | Rural Galway residence |
| | Galway rural based | Experience with CONP | Urban Mayo residence |
| | Mayo urban based | No experience with CONP | Rural Mayo residence |
| | Mayo rural based | Male | |
| | | Female | |

new ideas emerging. The initial analysis sample was decided to be 7 Interviews across nurse and patient interviews, and the stopping criterion was 3 new interviews with no new themes arising. Data collection was complete when thematic saturation was deemed to have occurred.

### 2.4. Recruitment

Participants were identified with the help of the Clinical Nurse Manager in the oncology day ward and the Director of Public Health Nursing in both counties. When identified, participants were provided with Participant Information Leaflets and consent form by a nurse. Participants were invited to read the information leaflet and given time to decide whether they wished to take part. Where possible, this information leaflet was provided days or weeks in advance. If patients were willing to participate then their contact details were given to the primary researcher (COM) to arrange the interview. Prior to the beginning of the interview, participants were given the opportunity to ask any questions before signing the consent form. Participants were made aware of the reason behind the interviews, and the motivation of the primary researcher of using this research as part of a PhD thesis.

### 2.5. Data collection

Study participants were asked questions according to a topic guide (Appendix 1 in supplementary file). Three distinct topic guides were used, one for each type of participant. The topic guides focused on the participants' thoughts on any benefits or drawbacks of the programme, how it could be improved and envisioning a scenario where the service was no longer available. More specific questions for each participant group were also included, such as thoughts on the training aspect of the service for those nurses who had undertaken the programme. Given that the topic guides shared broadly similar questions and discussion points, all participants were analysed as one group. Topic guides were developed using the research groups own experience as well as direct input with experts with experience in the process of cancer care. The topic guides were initially piloted with one member of each participant group, and were amended following feedback. These pilot interviews were not included in the final study analysis.

Interviews were carried out face-to face by the primary researcher (COM), who was trained in qualitative research methods from a university postgraduate training module. Audio recordings of these interviews were transcribed verbatim. Field notes were also taken to inform of non-auditory responses.

Interviews took place where best suited the participants. For the hospital nurses and patients interviewed in hospital, interviews took place in a room adjacent to the oncology day ward. Interviews in the community took place in a suitable meeting room in the Primary Care centre. One interview took place in the patient's own home due to travel issues. All interviews were conducted in private. All participants who were approached took part in the study. No transcripts were requested by the participants. The shortest interview was 8 min long, the longest was 26 min long. The median duration was 13 min.

### 2.6. Analysis

The interviews were audio recorded and transcribed by COM. The data was coded by COM and a portion of the anonymised data was also coded by a second researcher (KDM) to ensure consistency of coding. The data was analysed using thematic analysis, as set out by CLARKE et al. (2015). This method of qualitative analysis is a six step process; (i) familiarisation of the data, (ii) generating initial codes, (iii) searching for themes, (iv) reviewing themes, (v) defining and naming themes, (vi) producing the report.

### 2.7. Software

Audio recordings were made using a Dictaphone (Sony® ICD-PX240) and Mobile Device (OnePlus® Pro 7T) The transcribed interviews were analysed using NVivo® Version 12.

### 2.8. Guidelines

This study was written in accordance with the consolidated criteria for reporting qualitative research (COREQ) statement (Tong et al., 2007).

## 3. Results

18 interviews were completed. There were 6 patients, 5 hospital nurses and 7 community nurses.

Using thematic analysis detailed by CLARKE et al. (2015), four major themes were generated from the data, with a number of categories which are detailed below (see Table 2 below).

### 3.1. Improved patient experience

It was unanimously agreed by both patients and nurses interviewed, that the community service was of additional advantage to the patient. A number of reasons for this were put forward including; patient safety and efficiency, psychological impact, and fewer expenses and greater freedom from having services delivered in the patient's community or own home.

#### 3.1.1. Patient safety and efficiency

The hardship that patients go through during treatment was particularly noted, and nurses were keen to minimise this as much as possible. Nurses felt that patients were more comfortable in their own homes.

> "*I think they feel a lot safer at home, they're often pretty sick and exhausted …. I think the recovery is much better once they have someone coming into their own home or into a local health centre*". **CN3**

Nurses were aware of the clinical impact of patients travelling to a hospital setting, noting the increased risk of infection for these susceptible patients.

> "*We try and quarantine people, anyone with the superbugs and things like that. But there are other bugs and people come in with respiratory infections and they are exposed …. we've only two single rooms here so they are limited*" **HN3.**

**Table 2**
Major themes and categories identified.

| Themes | Categories |
|---|---|
| Improved patient experience | • Patient Safety and efficiency<br>• Psychological impact<br>• Expense and freedom<br>• Improved community nurse capabilities |
| Nurse- Patient relationship | • Many community nurses already known to patients 'cradle to grave' building on that relationship<br>• Education of nurses to ensuring they are competent in meeting their needs, giving patients confidence in their ability to assess and manage their care |
| The importance of location | • Urban vs rural<br>• West vs rest |
| Programme roadblocks | • Increased caseload<br>• Difficulty in release of staff for training<br>• Absence of recognition on taking on new roles<br>• Specialisation not always beneficial<br>• Increased support in hospital<br>• Knowledge gap |

*"They're sick patients and neutropenic and you don't want them to be going into the hospital and picking up something else"* **CN1.**

Moving the support services to the community allows for a more efficient service in the hospital, reducing time for treatment.

*"Certainly from the hospital point of view …. to be able to facilitate the likes of these disconnections and pumps and different things, enhances our job here …. allows for us to treat people quicker you know from the time of diagnosis that there is not that wait list"* **HN5.**

### 3.1.2. Psychological impact

Outside of the long travel times and the related difficulties in accessing the hospital service, patients faced psychological difficulties when confronted with the hospital environment. Patients already dealing with the mental trauma of their condition are particularly vulnerable and nurses were aware that there may be increased anxiety in patients who travel to hospital.

*"A lot of patients get anxious having to come in here. You know just the whole idea of coming into hospital?"* **HN2.**

Patients often had negative memories of the hospital, both related to their cancer and for other more personal reasons.

*"Well it just brings all your memories back of your diagnosis and operations and you're still there, you're not just finished in the hospital when you're going in and out. So it's not a pleasant experience a lot of the time, there's a lot facing you when you're going in"* **Pat1.**

*"I suppose the hospital setting itself is a bit more daunting … it's just a mental picture we have, going back to when we were kids"* **Pat6.**

Nurses in the hospital noted that the appearance and location of the day unit itself may have an impact. The day unit itself was described as uncomfortable for the patients, particularly while they were waiting.

*"Even to access the ground floor, they go down a flight of stairs you know so. I just think we could do more to make it more pleasant for them, I think a lot of them might dread coming here, just because of the look of it and where it is"* **HN4.**

*"The drawbacks for the patients would be probably because it's so busy and we've got an increase in patient number, the waiting area isn't big enough for a lot of patients even to wait around. Sometimes some of them are waiting on the steps waiting for treatment"* **HN5.**

Patients experienced longer waiting times in the hospital, and felt more uncomfortable doing so.

*"The waiting times can be a bit tedious and they can be very long sometimes … could be a wait of 3 or 4 hours …. And when you're waiting, there isn't a lot of room outside and just the room itself can be a bit uncomfortable. And when you're coming in you don't really want to be waiting around"* **Pat4.**

In contrast, attending the local health centre was familiar and easier for patients. Patients did not face the same mental barriers when accessing these facilities.

*"A lot of them enjoy coming here, it's probably mentally easier for them I imagine. Because going into the hospital sometimes had negative connotations with it, whereas we are not as hospitalised as the hospital"***CN4.**

### 3.1.3. Expense and freedom

Non-clinical outcomes such as the expense of travelling for patients was important. Related to this was the time and the fact that spending the day travelling to the hospital and long waiting times limited the patients and accompanying persons' freedom to work or carry on usual daily activities.

*"When I'm going to the hospital I usually get a taxi … The community centre is only a short ways away so it's not expensive, that's a big thing. Especially when you're older"* **Pat2.**

*"It's a day gone. For mothers it's a day gone from their kids, family at home"* **HN1.**

The time saving as well as the physical toll of car parking was important for the patients. Particularly ill patients being treated with chemotherapy could face a physically draining walk to access the day-ward, which wasn't the case in the community.

*"Well much better for parking, much better for time in general. There's never a problem finding a spot here, you could be ages in the hospital"* **Pat1.**

*"Definitely it's physically easier, because there is a designated car park for patients in the hospital, but it's away from the front door, down a hill. So if you are sick with having chemotherapy, you have to walk a good bit."* **CN4.**

A patient's ability to work might be impacted by the increased time spent travelling to the hospital.

*"I think the fact that they're at home and are free to do their daily basis and can get to work if they need to. Because most of them will want to work …. So when you take in travel time to the hospital and the long waits they'd have, and then it saves them from sitting in a sick bed when they're not actually sick. So freedom of movement almost"* **CN6.**

Patients would be less reliant on others to help them travel, sparing them from the guilt of burden that often arises from their condition.

*"I'd often not have the energy so I'd need someone else to bring me in and out which is a burden on them"* **Pat4.**

### 3.1.4. Improved community nursing capabilities

The training given to community nurses as part of the programme was universally lauded by those who had received it. As well as the obvious improvement in knowledge that the education provides, the course helped foster improved relationships between the two settings, allowing for better communication and improved patient care as a result.

*"I think your knowledge base really improves. I think we have a better relationship with our colleagues in the hospital compared to what we had. There's a lot more communication …. If I ever had a query for a patient it was easier to get through, I knew my way a bit better"* **CN3.**

The community nurses were more confident and felt more capable following their training. It allowed them to increase their knowledge of the condition and also familiarise themselves with the patient journey.

*"Once I did the programme, you visited all these sites and you saw exactly and you saw what exactly was decided and what happened the patient in the hospital setting.… And for different therapies, what happened there and how a different therapy was delivered. And even just the different cancers, you know, how they manifest themselves in the body, and all of that was touched on in the course. It was excellent, for me it was a great learning"* **CN7.**

The training the nurses received as part of the community oncology nursing programme allowed them to better appropriately assess and manage queries from the patients.

*"And then when the patients come in and they might question something or might describe an experience they had in the house you'd be in a position to understand it more, because you've done placements in the different areas as well"* **CN6.**

### 3.2. Nurse-patient relationship

In all responses there was a noticeable bond formed between the patient and nurses in both settings. Many nurses felt a sense of duty of care when caring for the patients.

> "*When you're seeing the same person every few weeks you really do get a sense of what they're going through and how tough it is. And with that you don't mind putting in the extra hour it might take to travel, you know if you're going into someone on the way home after you're supposed to finish. I'd have no problem doing that*" ***CN2.***

Patients were put at ease upon seeing a familiar face.

> "*You get to know them better, puts you more at ease and stuff like that. You see the same girl each time so you get to know them a bit more. It helps when you know who's coming*" **Pat2**.

Following the patient's journey from beginning to end of treatment provided a sense of satisfaction for nurses.

> "*You kind of get to see patients from the start of their diagnosis right through to completing their chemotherapy and so on. It's quite special really, it does make you appreciate the work that you're doing*" **HN5**.

The familiarity gained from repeated meetings provided benefits in the delivery of care.

> "*When you see them regularly, that's when you start to spot there's problems. They may be picked up sooner. That they're really starting to lose weight, that they're really struggling. That you can ring the unit and say I think this client needs to be reviewed*" **CN3.**

For patients, the ease of access to a local community nurse they knew enabled more direct and enhanced communication when needed.

> "*I can make a phone call to have it done in the morning. While if you go to (day ward), you can't do that …. And if I have any questions, I can ring and I know they'll answer me quickly. I have the nurses mobile number so I know if I'm ever not feeling well or need something, I can get her on the phone*" ***Pat6***.

This was different to the arduous process of getting through to hospital staff.

> "*They will say to you that they can ask questions, they feel safer, they feel happier, that they have a link so even when we take off the pump, the next day if there's a problem they have someone rather than trying to get through to the regional*" **CN3**.

### 3.3. The importance of location

#### 3.3.1. Urban versus rural

The divide between patients in a rural setting compared to those in a more urban setting was a central point in discussions. The long travel times from rural settings was a challenge for these vulnerable patients, a challenge exacerbated by treatment side-effects such as nausea. The more immediate access to a local community centre and nurse was a benefit for these patients.

> "*You'd be going nearly 100 km to get to your furthest patient. So if you're thinking of a sick patient travelling that distance, that's very hard on them …. And if you were up in Belmullet or somewhere like that, they have a nurse up there. Otherwise the patients would be coming down to Castlebar. Even some of them travel to Galway, not even to Castlebar. And that's too much to be asking of them*"**CN7**

Cost was another factor.

> "*We'd have a lot of people coming from various parts of the west and midland you know? So it reduces down their commute, it reduces their cost and again it gives them a bit of security to think that they have a local centre that they can go to*" **HN2**.

Patients in rural areas have an increased reliance on others for travel due to public transport limitations.

> "*They might have to ask their families. A lot of them would rely on their families and their families might have to take time off work. Especially if public transport doesn't suit timewise. For instance, to Castlebar, to get a bus you'd be gone at 9 and a bus might not be coming back until 4 in the afternoon*" **CN7.**

Patients in locations closer to the hospital did not experience as much difficulties with travel as those in rural areas, but did note that they were fortunate in this.

> "*I think it's great for people who live further out you know, I'd meet people inside in the hospital who've come from Belmullet and that's awful hard on them*" **Pat1.**

#### 3.3.2. West versus rest

Community nurses were aware that some of the problems faced by them might not be the case across the country. The more sparsely populated West of Ireland provided greater challenges to care when compared to other parts of the country, particularly to the capital Dublin.

> "*I suppose one thing is that it might be easier in other parts of the country. Like, for example, when I was in Dublin, it's much more compact and it might be easier to get to patients. And there's more staff there*" **CN6**.

Some community catchment areas in Galway and Mayo extend to islands, presenting a distinct challenge. Patients would have had to stay on the mainland due to travel restrictions back to their islands.

> "*I suppose when I started doing the course it was in Connemara, the difference for those clients was huge. Because you've got to remember they're travelling huge distances. When you work on the islands, it's even more so. A lot of these clients would have had to stay in town. When they have an oncology nurse on the island, they can stay home. So that was a huge benefit for them*" **CN3**

### 3.4. Programme roadblocks

The stakeholders universally found benefit in the programme, however some issues with its implementation and future prospects were raised.

#### 3.4.1. Increased caseload

Community nurses experienced an increased caseload while undergoing the accredited course. Nurses said that completing the course presented challenges due to the fact that it was extra work on an already busy schedule.

> "*Well it could be a drawback for us because it increases our workload …. it is difficult to get away from the work to do the course … there are some courses you can do here in the centre through the Galway Centre for Education but it's not always possible to attend those. And then there is the oncology nurse course. But again because our workload is so big, some of us wouldn't always be able to attend those courses.*" **CN6.**

Others noted that upon completing the course, they would have extra oncology services added on to their own caseload.

> "*Like if I was doing it for other nurses it's not like anything's being taken away from my caseload, it's just something that's added on for me*" **CN1.**

This increase in caseload, as well as a lack of places in the programme has meant that the roll-out in some areas has been limited, reducing the

number of trained community nurses.

> *"But there is only like 6 people, 6 PHN's that have done it this year now, there is more on board to do it. But, the roll-out of it in (here) has been pretty poor"* **CN4**

#### 3.4.2. Specialisation not always beneficial

One community nurse felt that by doing the course she had been shoehorned into a specific role, and that this may prevent other nurses from seeking this specialisation.

> *"If you've been able to do a course and you're specialised in it, you're nearly holed into that area if they're short. There are palliative care teams that help with the oncology as well, whereas is we do just this it covers us for our registration. But generally what happens is if you do anything extra, you could be pulled into other areas"* **CN6.**

Others felt differently, thinking it was a step in career progression.

> *"For the nurse, it makes you more competent and expands your scope of practice. Any nurse that gets an opportunity to improve themselves, in knowledge and prospectives, should do it"* **CN7.**

#### 3.4.3. Increased support in hospital

Nurses were noted to be more isolated in the community than in the hospital, presenting challenges. Where nurses in the hospital setting often had numerous colleagues, both nurses and other healthcare professionals, to have discussions and aid in queries, nurses in the community were often acting more on their own or in smaller groups.

> *"I think you'd have more of a support network in the hospital, compared to the community."* **CN4.**

Hospital nurses appreciated the extra security blanket that came from being surrounded by colleagues.

> *"There's a lot of us here so if we're ever stuck we can get someone around us to help, which is great when you're just starting. I know when I started you always like having the more experienced girls around to help out if you need it"* **HN1.**

For one patient, the hospital was a better location if something went wrong during their treatment.

> *"I guess I feel safer in one way. Whereas at home I think if something went wrong or if it wasn't done right, whereas a hospital I am kind of aware that it is done properly. If anything ever happened well I'm in the right place"* **Pat 4.**

This could be a particular problem in more isolated areas with less nurses. The limited allotment of places in the programme had left some nurses relying on the help of others to teach them.

> *"You learned on the job. Whoever had been doing it (oncology care) demonstrated it to you"* **CN2.**

#### 3.4.4. Knowledge gap

One community nurse was concerned that there may be a gap in knowledge between nurses in the two settings.

> *"Since I became a public health nurse, I have noticed a big gap in knowledge compared to nurses working in the hospital and public health nurses. I would know a lot about oncology, but some public health nurses don't because they are very generalised, they look after a lot of different patients"* **CN4.**

This nurse was concerned that patients might not be as confident in community nurses as they were with hospital nurses.

> *"Some patients might see us as more generalised not as specifically specialised in oncology nursing as they would be in the hospital. So I think that sometimes they are a bit afraid of coming to us, because they think oh Jesus they might not know what they are doing".*

This nurse saw the community oncology nursing programme as a big step in helping to bridge the gap.

> *"The community oncology programme would be massively beneficial to Public Health Nurses … if I had my way, I would make sure that they all had taken part in the community oncology nurse programme, because they really shouldn't be providing care for these patients if they don't know what they are doing".*

## 4. Discussion

This study provides an insight into the thoughts of those involved in community cancer services, the patients and community nurses, as well as the thoughts of nurses in the day ward who have experience with treating these same patients. Most evident in this study was the universal belief that community cancer care provided a benefit for the patient.

The development of a nurse-patient relationship over time has been previously reported. Wright et al. (2002) reported that the development of this relationship was the basis through which care was given. Nurses focused their care based on their observations from this relationship. Nurses in this study noted that increased familiarity can lead to improved care due to faster recognition of problem symptoms such as weight loss. Griffiths et al. (2013) reported the value patients place on this relationship and the psycho-social benefits they receive from home visits. Patients in this study found benefit in the increased familiarity they had with their primary care nurses, who they could contact more easily than the hospital nurses if needed. Being a short distance away and having more contact options such as a mobile phone number meant that the patients had more immediate access to the nurses in the community. Both patients and nurses felt that seeing the same nurse each time was another key factor in improving bonds between patient and nurse in the community. None of the patients stated any difference in knowledge or quality of care across the two settings and while one nurse in the community was concerned about a potential knowledge gap between nurses in hospitals as compared to nurses in the community, they also identified the education and learning provided by the programme as a manner of minimising this problem.

Given findings that show that between 23 and 30% of cancer patients develop some form of psychological need over the course of their treatment (Mitchell et al., 2011), reducing factors that may exacerbate this should be a part of cancer care. Both nurses and patients in this study noted the psychological impact that a journey to the hospital day ward can have on a patient. Patients' negative connotations of the hospital came from both their condition and prior personal convictions, such as negative thoughts of the "*daunting*" hospital from their childhood. Patients have been shown to prefer home care for reasons including less worry about childcare (Rayson and Ruedy, 2001) and finding the journey to hospital emotionally draining (Coates et al., 1983; Rischin et al., 2000). Tralongo et al. reported that 90% of cancer patients found hospital admission to be more distressing than home care (Tralongo et al., 2011).

This study was carried out in two counties in the West of Ireland, Galway and Mayo. This put a particular focus on the plight of patients in rural areas who had to travel to hospitals sometimes located more than 100 km away. For these patients, travel time saved was the most important value from the introduction of the community service. Nurses in both settings were aware of the physical and mental impact of these long journeys, when they described that this service was of particular benefit to those in more rural areas. Sláintecare, Ireland's health reform plan, aims "towards integrated primary and community care that is consistent with the highest quality of patient safety in as short a time-

frame as possible" (Burke et al., 2018). It aims to provide a health service accessible to all residents, showing the importance of primary care teams and cancer services in the more rural areas of the country.

Another aspect of Sláintecare is the increased focus on patient-centred care. The findings of this study show this type of care is evident in both settings. Both community and hospital nurses displayed sympathy for the patients' difficulties and it is clear they want to have a service that is the most beneficial for the patient and their families. All the nurses believed there was an advantage for the patient if their cancer care could be delivered in the community by trained community nurses and expressed that they believed that this is the service that should be offered.

For this programme to become successful and implemented as part of cancer care services nationally, the concerns raised by the community nurses in this study will have to be addressed. Concerns raised included:

i. Lesser support than their hospital counterparts
ii. The addition of study days
iii. Extra cancer oriented work on top of an already busy caseload

The nurses were appreciative of the training course and the increased capabilities it provided them, however there is concern that where only one nurse in a large catchment area might have cancer care training, they might be required to assist their colleagues should any cases arise. This problem may mitigate if more nurses are permitted to participate in the programme and upskill to allow them to be capable cancer care practitioners. There has been a limited number of nurses within regional areas who have been able to complete the programme, and often there is a reliance on other nurses who have more experience in cancer care to help teach them.

The original pilot study of the programme found no worsening of clinical outcomes compared to patients treated in the day ward (Hanan et al., 2014). Patients should be made aware of these findings when undergoing care in the community to assuage their worries about safety of treatment in the community versus the hospital. However, this non-worsening was reliant on the nurses in the community undergoing the training as part of the programme. For the desired clinical outcomes in the community, there should be an emphasis placed on an increased participation in the programme among primary care nurses.

A concurrent study that compares the cost of providing cancer services in the community and hospital was undertaken as part of the evaluation of the community oncology nursing programme. (O'Mahony (2020) #266) This found a significant increase of €6.86 ($p < 0.001$) in the cost of travel for the patient for each intervention. Patients' journeys were found to be an average of 34.67 min longer when travelling to hospital ($p < 0.001$). These findings lend credence to the claims of increased costs for patients travelling to hospital, as well as the concerns regarding arduous journey distances for these sick patients. Increased travel time has been shown to be a financial, time and practical hardship on patients (Payne et al., 2000; Zucca et al., 2011). Nurses interviewed in this study were keen to minimise patient difficulties as much as possible. Having care take place in the community has been shown to reduce the financial and travel hardship incurred by the patient, as well as any travel companions such as family/carers who often accompany cancer patients due to their illness.

### 4.1. Limitations

There was a risk of bias in the responses of the nurses in both settings, as they may have felt that it is important to put their work and environment in a good light. To the authors' best judgement this was not the case, as many of the nurses were critical of their own environment and reflected positively on their opposing setting. Patients may have been reticent to criticise some aspect of their care for fear of reprimand or embarrassment. This was mitigated by ensuring them that all interviews were confidential and that no detail of their interview would be shared with their cancer nurse unless requested by the patient themselves. Selection bias of interviewees was attempted to be minimised by the use of a sampling matrix to ensure representation. There was no prior relationship between the primary researcher and the interview participants. Some of the interviews with patients were shorter than expected, the shortest being 8 min in duration. While this may have led to a proportionally skewed response from some patient groups, the authors were confident that a sufficient level of detail was acquired from these interviews and were thus included.

### 4.2. Future work

The ultimate aim for the Health Service Executive is a national rollout of this programme. While this study aimed to be as generalisable to the rest of the country as possible, there may be some themes raised in other areas and new issues that need to be addressed before a full rollout can be undertaken. A quantitative method of examining patient and nurse satisfaction with the programme may be useful. Regular surveying of both patient and nurse satisfaction and enablement throughout the national implementation of the community oncology nursing programme would allow for timely identification and resolution of stakeholder concerns and region-specific issues that may not have arisen in this study or indeed any qualitative examination of the service.

## 5. Conclusion

The responses of both patients and nurses showed that the community oncology nursing programme has benefits for the quality of care provided for the patient. Benefits mentioned included reduced risk of infection, reduced stress, increased freedom, reduced cost, reduced waiting time and reduced reliance on others such as family for transport and support. The previously reported bond developed between cancer patient and nurse was once more evident, and was highlighted as allowing for an increased insight into the patient's condition. Ireland's health reform plan Sláintecare is aiming for an accessible healthcare system that has an increased focus on primary care. For this quality cancer care to continue to be delivered in the community, there seems to be a need for an increase in the number of nurses participating in the programme.

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## CRediT authorship contribution statement

**Cian O'Mahony:** Conceptualization, Methodology, Formal analysis, Writing - original draft, Project administration. **Stephen Byrne:** Conceptualization, Methodology, Validation, Writing - review & editing, Supervision. **Joe Aherne:** Writing - review & editing, Supervision, Project administration. **Terry Hanan:** Conceptualization, Writing - review & editing, Supervision. **Louise Mullen:** Writing - review & editing. **Maccon Keane:** Writing - review & editing. **Helen Browne:** Writing - review & editing. **Kevin D. Murphy:** Validation, Writing - review & editing, Supervision.

## Declaration of competing interest

The authors have no conflicts of interest to declare.

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## Appendix A. Supplementary data

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## Appendix J – Chapter 5 Ethics approval

COISTE EITICE UM THAIGHDE CLINICIÚIL
**Clinical Research Ethics Committee of the Cork Teaching Hospitals**

Tel: +353-21-4901901
Email: crec@ucc.ie

University College Cork
Lancaster Hall
6 Little Hanover Street
Cork
Ireland

**CREC Review Reference Number:** ECM 4 (c) 12/01/2021

**Date:** 13th January 2021

Professor Stephen Byrne
Professor of Clinical Pharmacy Practice
University College Cork
Cavanagh Building
College Road
Cork

**Study Title: A mixed methods analysis of the monitoring of oral anti-cancer therapies.**

Approval is granted to carry out the above study at:

| |
|---|
| South Infirmary Victoria University Hospital. |

The following documents have been approved:

| Document | Approved | Version | Date |
|---|---|---|---|
| Application Form | Yes | | Signed 26th November 2020 |
| Study Protocol | Yes | | |
| Proof of Insurance | Yes | | |
| CV for Chief Investigator | Yes | | |
| Participant Information Leaflets Qualitative and Quantitative | Yes | 1.0 | November 2020 |
| Consent Form Qualitative and Quantitative | Yes | 1.0 | November 2020 |
| Interview Topic Guide | Yes. | | |

***Please note that the Data Observation Sheets must be submitted for review and approval prior to use.***

We note that the co-investigator(s) involved in this project will be:

| Name | Appointment Details |
|---|---|
| Mr Cian O'Mahony | Research Pharmacist |
| Dr Kevin Murphy | Lecturer in Clinical Pharmacy Practice |
| Professor Denis O'Mahony | Professor of Geriatric Medicine. |

The date of this letter is the date of authorization of the study.

Please keep a copy of this signed approval letter in your study master file for audit purposes. The study must be carried out in accordance with General Data Protection Regulation and Health Research Regulation 2018.

You should note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submission of an Annual Progress Report/Annual Renewal Survey (due annually from the date of this approval letter). **We would encourage you to keep note of this date as the CREC will not issue a reminder.**

2. Report unexpected adverse events, serious adverse events or any event that may affect ethical acceptability of the study

3. Submit any change to study documentation (minor or major) to CREC for review and approval. Amendments must be submitted on an amendment application form and revised study documents must clearly highlight the changes and contain a new version number and date. Amendments cannot be implemented without written approval from CREC.

4. Notify CREC of discontinuation of the study

5. Submit an End of Trial Declaration Form and Final Study Report/Study Synopsis when the study has been completed.

Yours sincerely

Professor David Kerins
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

*The Clinical Research Ethics Committee of the Cork Teaching Hospitals, UCC, is a recognised Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, and is authorised by the Department of Health and Children to carry out the ethical review of clinical trials of investigational medicinal products. The Committee is fully compliant with the Regulations as they relate to Ethics Committees and the conditions and principles of Good Clinical Practice.*

Saolta
Grúpa Ollscoile Cúram Sláinte
University Health Care Group

Ospidéal na h-Ollscoile, Páirc Mheirlinne
*Merlin Park University Hospital*
GALWAY UNIVERSITY HOSPITALS

Clinical Research Ethics Committee
Room 59
1st Floor
HR Building
Merlin Park Hospital
Galway.

2nd December, 2020.

Mr. Cian O'Mahony
Cavanagh Building
University College Cork
College Road
Cork.

***Ref: C.A. 2521*** ***A Mixed Methods Analysis of the Monitoring of Oral Anti-Cancer Therapies***

---

Dear Mr. O'Mahony,
I have considered and reviewed the above submission, and I wish to confirm that I am happy to grant Chairman's approval to proceed. The following documentation was reviewed:

- Local Checklist and signatory declaration
- Signed Ethics Application
- Emails from University College Cork insurance officers Cathryn O'Driscoll and Muiris Dowling detailing insurance cover
- Study protocol
- PIL for focus group
- Consent form for focus group
- PIL for time recording
- Consent form for time recording
- Topic guide for focus groups
- CV of Principal Investigator, Prof. Stephen Byrne

*This submission has been reviewed from an ethical perspective only. It is the responsibility of the PI/sponsor/data controller and relevant Data Protection Officer to ensure and monitor compliance with any relevant legislation in the country where the study is due to take place or any local policy in the site where the study is due to take place.*

*Chairman's approval is normally ratified at the next Clinical Research Ethics Committee meeting. If any issues with your application are identified at the meeting we will contact you again.*

Yours sincerely,

B. Gerard Lyttus FRCPI,MD
Emeritus Professor of Paediatrics, NUI,Galway
Chair, Galway Clinical Research Ethics Committee.

c.c. Professor Stephen O'Byrne, Professor of Clinical Pharmacy Practice, School of Pharmacy, Cavanagh Building, University College Cork, College Road, Cork.

## Appendix K – Chapter 5 data collection sheet

| Monitoring date | |
|---|---|
| Please fill the time taken to complete tasks .<br>If the task was not completed please write n/a | |
| Task | Time |
| Patient collected-Patient discharged | |
| ECG | |
| Physical assessment | |
| Bloods returned-<br>bloods assesment and action complete | |
| Please identify if these issues arose and the time taken to deal with them. If no issue please write n/a | |
| Issue | Time |
| Toxicity identified with CTCAE | |
| Problem with bloods | |

# Appendix L – Chapter 5 topic guide

Background/experience:**

Current role

Length of time in role

** prior to recording beginning

What does providing this service entail for you?

How does delivery of this service differ to other chemotherapy services you deliver?

How do you feel about this service being provided as it currently is being delivered?

Are there any consistent difficulties you encounter when delivering this service?

over/underdispensing, unwell patient taking time

What do you think are the potential barriers to providing this level of service?

What do you think would facilitate and enable the nurses to provide the service?

Views on key skills/training and knowledge nurses require in order to provide these services to cancer patients:

- What knowledge do you think nurses need in order to safely provide this service?
- Is there a need for specialisation with this service?

In your opinion, would nurses need training in to safely provide this service?

- What format do you think the training should be in?

How do you find communication with healthcare professionals in the community as part of this service?

Has there been any effect of the pandemic on this service?

Virtual assessment difficulties

What do you envision for the future of this service?

In an ideal world, what resources do you think nurses or patients will need in order to provide this service?

Are there any other recommendations you would give for this safe delivery of this service?

Is there anything you would like to add on these services being provided?

## Appendix M – Chapter 3 CHEERS statement

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| **Title and abstract** | | | |
| Title | 1 | Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared. | Yes |
| Abstract | 2 | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | Yes |
| **Introduction** | | | |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| Background and objectives | 3 | Provide an explicit statement of the broader context for the study. | Yes |
| | | Present the study question and its relevance for health policy or practice decisions. | Yes |
| **Methods** | | | |
| Target population and subgroups | 4 | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | Yes |
| Setting and location | 5 | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| Study perspective | 6 | Describe the perspective of the study and relate this to the costs being evaluated. | Yes |
| Comparators | 7 | Describe the interventions or strategies being compared and state why they were chosen. | Yes |
| Time horizon | 8 | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | Yes |
| Discount rate | 9 | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | Yes |
| Choice of health outcomes | 10 | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | n/a |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| Measurement of effectiveness | 11a | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | n/a |
| | 11b | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | n/a |
| Measurement and valuation of preference based outcomes | 12 | If applicable, describe the population and methods used to elicit preferences for outcomes. | n/a |
| Estimating resources and costs | 13a | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | its unit cost. Describe any adjustments made to approximate to opportunity costs. | |
| | 13b | *Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | n/a |
| Currency, price date, and conversion | 14 | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | converting costs into a common currency base and the exchange rate. | |
| Choice of model | 15 | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | n/a |
| Assumptions | 16 | Describe all structural or other assumptions underpinning the decision-analytical model. | n/a |
| Analytical methods | 17 | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | methods for handling population heterogeneity and uncertainty. | |
| **Results** | | | |
| Study parameters | 18 | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | Yes |
| Incremental costs and outcomes | 19 | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| Characterising uncertainty | 20a | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | Yes |
| | 20b | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | n/a |
| Characterising heterogeneity | 21 | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | or other observed variability in effects that are not reducible by more information. | |
| **Discussion** | | | |
| Study findings, limitations, generalisability, and current knowledge | 22 | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | Yes |
| **Other** | | | |
| Source of funding | 23 | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | of the analysis. Describe other non-monetary sources of support. | |
| Conflicts of interest | 24 | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | Yes |

# Appendix N – Chapter 4 COREQ statement

**COREQ (COnsolidated criteria for REporting Qualitative research) Checklist**

| /A. **Topic** | **Item No.** | **Guide**<br><br>**Questions/Description** | | **Detail** |
|---|---|---|---|---|
| **Domain 1: Research team and reflexivity** | | | | |
| *Personal characteristics* | | | | |
| Interviewer/facilitator | 1 | Which author/s conducted the interview or focus group? | | COM |
| Credentials | 2 | What were the researcher's credentials? E.g. PhD, MD | | MD |
| Occupation | 3 | What was their occupation at the time of the study? | | PhD student |
| Gender | 4 | Was the researcher male or female? | | Male |

| | | | |
|---|---|---|---|
| Experience and training | 5 | What experience or training did the researcher have? | NVIVOQDA training |
| *Relationship with participants* | | | |
| Relationship established | 6 | Was a relationship established prior to study commencement? | No |
| Participant knowledge of the interviewer | 7 | What did the participants know about the researcher? e.g. personal goals, reasons for doing the research | For PhD thesis and publication |
| Interviewer characteristics | 8 | What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic | No bias, motivation for research was PhD thesis |
| **Domain 2: Study design** | | | |
| *Theoretical framework* | | | |

| | | | |
|---|---|---|---|
| Methodological orientation and Theory | 9 | What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis | Thematic analysis |
| *Participant selection* | | | |
| Sampling | 10 | How were participants selected? e.g. purposive, convenience, consecutive, snowball | Purposive |
| Method of approach | 11 | How were participants approached? e.g. face-to-face, telephone, mail, email | Face to face |
| Sample size | 12 | How many participants were in the study? | 20 |
| Non-participation | 13 | How many people refused to participate or dropped out? Reasons? | None |

| | | | |
|---|---|---|---|
| *Setting* | | | |
| Setting of data collection | 14 | Where was the data collected? e.g. home, clinic, workplace | Workplace, primary care centre and home |
| Presence of non-participants | 15 | Was anyone else present besides the participants and researchers? | No |
| Description of sample | 16 | What are the important characteristics of the sample? e.g. demographic data, date | Discussed in sampling framework |
| *Data collection* | | | |
| Interview guide | 17 | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Yes |
| Repeat interviews | 18 | Were repeat interviews carried out? If yes, how many? | No |

| | | | |
|---|---|---|---|
| Audio/visual recording | 19 | Did the research use audio or visual recording to collect the data? | Yes |
| Field notes | 20 | Were field notes made during and/or after the interview or focus group? | Yes |
| Duration | 21 | What was the duration of the interviews or focus group? | Median 13 mins |
| Data saturation | 22 | Was data saturation discussed? | Yes |
| Transcripts returned | 23 | Were transcripts returned to participants for comment and/or correction? | No |
| **Domain 3: analysis and findings** | | | |
| *Data analysis* | | | |
| Number of data coders | 24 | How many data coders coded the data? | 2 |

| | | | |
|---|---|---|---|
| Description of the coding tree | 25 | Did authors provide a description of the coding tree? | No |
| Derivation of themes | 26 | Were themes identified in advance or derived from the data? | Data |
| Software | 27 | What software, if applicable, was used to manage the data? | NVIVO |
| Participant checking | 28 | Did participants provide feedback on the findings? | No |
| *Reporting* | | | |
| Quotations presented | 29 | Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number | Yes |

| | | | |
|---|---|---|---|
| Data and findings consistent | 30 | Was there consistency between the data presented and the findings? | Yes |
| Clarity of major themes | 31 | Were major themes clearly presented in the findings? | Yes |
| Clarity of minor themes | 32 | Is there a description of diverse cases or discussion of minor themes? | Yes |

# Appendix O – Chapter 5 COREQ statement

**COREQ (COnsolidated criteria for REporting Qualitative research) Checklist**

| /A. **Topic** | **Item No.** | **Guide**<br><br>**Questions/Description** | | **Detail** |
|---|---|---|---|---|
| **Domain 1: Research team and reflexivity** | | | | |
| *Personal characteristics* | | | | |
| Interviewer/facilitator | 1 | Which author/s conducted the interview or focus group? | | COM |
| Credentials | 2 | What were the researcher's credentials? E.g. PhD, MD | | MD |
| Occupation | 3 | What was their occupation at the time of the study? | | PhD student |
| Gender | 4 | Was the researcher male or female? | | Male |

| | | | |
|---|---|---|---|
| Experience and training | 5 | What experience or training did the researcher have? | NVIVOQDA training |
| *Relationship with participants* | | | |
| Relationship established | 6 | Was a relationship established prior to study commencement? | No |
| Participant knowledge of the interviewer | 7 | What did the participants know about the researcher? e.g. personal goals, reasons for doing the research | For PhD thesis and publication |
| Interviewer characteristics | 8 | What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic | No bias, motivation for research was PhD thesis |
| **Domain 2: Study design** | | | |
| *Theoretical framework* | | | |

| | | | |
|---|---|---|---|
| Methodological orientation and Theory | 9 | What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis | Thematic analysis |
| *Participant selection* | | | |
| Sampling | 10 | How were participants selected? e.g. purposive, convenience, consecutive, snowball | Purposive followed by snowball |
| Method of approach | 11 | How were participants approached? e.g. face-to-face, telephone, mail, email | Videoconferencing and phone |
| Sample size | 12 | How many participants were in the study? | 11 |
| Non-participation | 13 | How many people refused to participate or dropped out? Reasons? | None |

| | | | |
|---|---|---|---|
| *Setting* | | | |
| Setting of data collection | 14 | Where was the data collected? e.g. home, clinic, workplace | Virtually |
| Presence of non-participants | 15 | Was anyone else present besides the participants and researchers? | No |
| Description of sample | 16 | What are the important characteristics of the sample? e.g. demographic data, date | All nurses responsible for monitoring |
| *Data collection* | | | |
| Interview guide | 17 | Were questions, prompts, guides provided by the authors? Was it pilot tested? | Yes |
| Repeat interviews | 18 | Were repeat interviews carried out? If yes, how many? | No |

| | | | |
|---|---|---|---|
| Audio/visual recording | 19 | Did the research use audio or visual recording to collect the data? | Yes |
| Field notes | 20 | Were field notes made during and/or after the interview or focus group? | Yes |
| Duration | 21 | What was the duration of the interviews or focus group? | Median 23 mins |
| Data saturation | 22 | Was data saturation discussed? | Yes |
| Transcripts returned | 23 | Were transcripts returned to participants for comment and/or correction? | No |
| **Domain 3: analysis and findings** | | | |
| *Data analysis* | | | |
| Number of data coders | 24 | How many data coders coded the data? | 2 |

| | | | |
|---|---|---|---|
| Description of the coding tree | 25 | Did authors provide a description of the coding tree? | No |
| Derivation of themes | 26 | Were themes identified in advance or derived from the data? | Data |
| Software | 27 | What software, if applicable, was used to manage the data? | NVIVO |
| Participant checking | 28 | Did participants provide feedback on the findings? | No |
| *Reporting* | | | |
| Quotations presented | 29 | Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number | Yes |

| | | | |
|---|---|---|---|
| Data and findings consistent | 30 | Was there consistency between the data presented and the findings? | Yes |
| Clarity of major themes | 31 | Were major themes clearly presented in the findings? | Yes |
| Clarity of minor themes | 32 | Is there a description of diverse cases or discussion of minor themes? | Yes |

## Appendix P – Chapter 6 CHEERS statement

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| **Title and abstract** | | | |
| Title | 1 | Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared. | Yes |
| Abstract | 2 | Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions. | Yes |
| **Introduction** | | | |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| Background and objectives | 3 | Provide an explicit statement of the broader context for the study. | Yes |
| | | Present the study question and its relevance for health policy or practice decisions. | Yes |
| **Methods** | | | |
| Target population and subgroups | 4 | Describe characteristics of the base case population and subgroups analysed, including why they were chosen. | Yes |
| Setting and location | 5 | State relevant aspects of the system(s) in which the decision(s) need(s) to be made. | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| Study perspective | 6 | Describe the perspective of the study and relate this to the costs being evaluated. | Yes |
| Comparators | 7 | Describe the interventions or strategies being compared and state why they were chosen. | Yes |
| Time horizon | 8 | State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate. | Yes |
| Discount rate | 9 | Report the choice of discount rate(s) used for costs and outcomes and say why appropriate. | Yes |
| Choice of health outcomes | 10 | Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed. | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| Measurement of effectiveness | 11a | *Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data. | Yes |
| | 11b | *Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data. | n/a |
| Measurement and valuation of preference based outcomes | 12 | If applicable, describe the population and methods used to elicit preferences for outcomes. | n/a |
| Estimating resources and costs | 13a | *Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | its unit cost. Describe any adjustments made to approximate to opportunity costs. | |
| | 13b | *Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs. | Yes |
| Currency, price date, and conversion | 14 | Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | converting costs into a common currency base and the exchange rate. | |
| Choice of model | 15 | Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended. | Yes |
| Assumptions | 16 | Describe all structural or other assumptions underpinning the decision-analytical model. | Yes |
| Analytical methods | 17 | Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | methods for handling population heterogeneity and uncertainty. | |
| **Results** | | | |
| Study parameters | 18 | Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended. | Yes |
| Incremental costs and outcomes | 19 | For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios. | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| Characterising uncertainty | 20a | *Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective). | Yes |
| | 20b | *Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions. | Yes |
| Characterising heterogeneity | 21 | If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | or other observed variability in effects that are not reducible by more information. | |
| **Discussion** | | | |
| Study findings, limitations, generalisability, and current knowledge | 22 | Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge. | Yes |
| **Other** | | | |
| Source of funding | 23 | Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting | Yes |

| Section/item | Item No | Recommendation | Reported |
|---|---|---|---|
| | | of the analysis. Describe other non-monetary sources of support. | |
| Conflicts of interest | 24 | Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations. | Yes |