



**Trinity College Dublin**

Coláiste na Tríonóide, Baile Átha Cliath

The University of Dublin

**A theory-based exploration of the  
medicines management process provided  
to older people residing in the nursing  
home setting in the Republic of Ireland**

A thesis submitted for the degree of

**Doctor of Philosophy**

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By

**Asil Sadeq (B.Sc.)**

Under the supervision of

Professor Cristin Ryan MPharm, PhD, PGCHET, FHEA, MPSI

Associate Professor Tamasine Grimes Ph.D., M.Sc., B.Sc., M.P.S.I.

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## **Abstract**

### **Introduction**

While the population is ageing globally, this does not necessarily mean that they are living healthier. The multimorbidity and polypharmacy in the older population (age > 65 years) increases their risk of experiencing medication-related problems and undesirable consequences. Coupled with the increased dependency of older people on carers and the lack of services to keep them in their own homes, this cohort often resides in nursing homes (NHs). The medicines management process (MMP) in the NH setting is reported to be complex due to various factors including the high prevalence of polypharmacy, frailty in this cohort and the involvement of multiple carers in various settings. The aim of the research programme was to explore the interprofessional MMP services which are provided in the Irish NH setting, using a theoretical basis.

### **Methods**

A systematic review and meta-analysis was conducted to explore the effectiveness of interprofessional MMP interventions, involving pharmacists and provided to older people in NHs. The care team and their roles, and stages of MMP targeted were identified. Assessment of the effectiveness of interventions on the most reported outcomes was undertaken. The findings of this study supported undertaking interviews with care team of NH residents in the Republic of Ireland (RoI) to explore perceptions of MMP services. This was conducted using the Systems Engineering Initiative for Patient Safety (SEIPS) 3.0 model, to identify work systems and their components (elements, external environment, interactions and outcomes) that influence the MMP journey. Further exploration of the MMP was conducted from Health Information and Quality Authority (HIQA)'s NH inspection reports using mixed methods secondary analysis of over a four-year period. The reporting of MMP-related regulations was quantitatively described, and the SEIPS 3.0 was applied to qualitatively explore work systems and their components; and finally qualitative and quantitative results were triangulated.

### **Results**

Eighteen studies were included in the systematic review and highlighted (i) that medication reviews were the most reported interventions and demonstrated a beneficial effect on improving the prescribing appropriateness; (ii) the involvement of informal carers as a part of the care team; and (iii) the lack of reporting of any theoretical underpinning. Seventeen interviews were conducted with the care team and identified eight work systems MMP journey featuring one central work system, namely, Internal NH. Barriers to achieving desirable outcomes included inconsistent communication and ambiguity in service provision and role clarity. The use of technology that was



triggered by the COVID-19 was identified to facilitate desirable outcomes. The findings were synthesised to create the first NH resident MMP journey map in the RoI. The mixed methods secondary research analysed 319 NH inspection reports published for 119 NHs in the RoI. Quantitative findings analysis suggested that (i) > 50% of NHs were compliant with Regulation 29 (Medicines and Pharmaceutical Services); (ii) There was no statistically significant association between reporting and compliance with Regulation 29 and NH characteristics; and (iii) administration was the most frequently inspected MMP stages followed by storage across the four years. The qualitative analysis explored the internal NH setting work system and identified (i) inconsistent interprofessional collaboration; and (ii) majority of reports inspected described administration stage of the MMP. Triangulation of quantitative and qualitative findings identified that (i) some stages of MMP that are inspected in the free text are not a part of Regulation 29; (ii) Pharmacist records were inspected in 25-35% of NHs, however, the free text identified that records inspected are not limited to pharmacists interventions but to all other relevant HCPs; (iii) work system elements that facilitated compliance and desirable outcomes: people, tasks, organisational, tools and technologies, external environment; and finally (iv) Barriers to the MMP contributing to non-compliance and undesirable outcomes include organisational, physical and external environments interactions.

### **Discussion/Conclusion**

The need to improve interprofessional MMP practice for older people residing in NHs is widely acknowledged. To our knowledge, this is the first study to explore the interprofessional MMP practice provided to older people in the RoI from different perspectives. Initially, a systematic review and meta-analysis was conducted to report on the nature and impact of interprofessional MMP interventions, involving a pharmacist and provided to older people in NHs. The outcome of the systematic review involving a pharmacist in interprofessional MMP provision to older NH residents is beneficial to improving some outcomes. However, there is an absence of reporting the theoretical basis of these interventions. Exploration of the extent of MMP services in the RoI using SEIPS 3.0 model provided evidence that the MMP is a complex process, with opportunities to overcome barriers. The SEIPS analysis facilitated identifying dimensions of the MMP that can be used by researchers to develop a complex interprofessional MMP intervention. Deeper exploration of additional work systems and their components that contribute to the complexity of the MMP will complement the work presented in this thesis and further serve to optimise patient safety in the RoI. The gap in a consolidated approach to interprofessional MMP in the RoI could encourage national and international regulators to refine the current suggested approach to the MMP in the Irish NH setting and therefore improve outcomes experienced both by NH residents and HCPs.

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## **List of abbreviations**

ABS	Aggressive Behaviour Scale
ADE	Adverse Drug Events
ADL	Activities of Daily living
AHRQ	Agency for Healthcare Research and Quality
APID	Appropriate Psychotropic drug use In Dementia
AS	Asil Sadeq
BNF	British National Formulary
C	Compliant
CB	Connie Brennan
CG	Control Group
CI	Confidence Interval
CINAHL	Cumulated Index to Nursing and Allied Health Literature
CMAI	Cohen-Mansfield Agitation Inventory
COREQ	Consolidated Criteria for Reporting Qualitative Research
CPS	Cognitive Pharmaceutical Services
CR	Cristin Ryan
DQI	Dementia Quality-of-Life instrument
DRS	Depression Rating Scale
ELSA	English Longitudinal Study of Ageing
EMBASE	Excerpta Medica database
EMTREE	Elsevier Life Science Thesaurus
EPOC	Cochrane Effective Practice and Organization of Care Review Group
EQ-5D-3L	3-level version of the EuroQol-5D
FOI	Freedom of Information
GDPR	General Data Protection Regulations
GMS	General Medical Services
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
GRAM	Geriatric Risk Assessment MedGuide
HCP	Healthcare Professionals
HIQA	Health Information and Quality Authority
HR	Hazard Ratio

HRB	Health Research Board
HSE	Health Services Executive
$I^2$	Heterogeneity
ICC	Interdisciplinary Case Conferences
ICGP	Irish College of General Practitioners
IG	Intervention Group
IOM	Institute Of Medicine
IP	Interprofessional Practice
KT	Knowledge Translation
MA	Maryam AlMutairi
MAI	Medication Appropriateness Index
MDT	Multidisciplinary Team
MEDLINE	Medical Literature Analysis and Retrieval System Online
MeSH	Medical Subject Headings
MMP	Medicines Management Process
MMS	Medicines Management System
MMSE	Mini-Mental State Examination
MR	Medication Review
MRC	Medical Research Council
MRP	Medication Related Problem
MRS GRACE	Medication Regimen Simplification Guide for Residential Aged Care
MS	Monica Strugaru
NC	Not Compliant
NH	Nursing Home
NHBPS	Nursing Home Behaviour Problem Scale
NHI	Nursing Home Ireland
NICE	National Institute for Health and Clinical Excellence
NICOLA	Northern Ireland Cohort for the Longitudinal Study of Ageing
NIHR	National Institute of Health Research
NJ	Not Judged
NMBI	Nursing and Midwifery Board of Ireland
NORGEF	Norwegian General Practice
NPI-NH	Neuropsychiatric Inventory–Nursing Home Version
NPI-Q	Neuropsychiatric Inventory – Questionnaire

NR	NR
OBRA	Omnibus Budgetary Reconciliation Act
OR	Odds Ratios
PAG	Programme Advisory Group
PIC	Person in Charge
PIM	Potentially Inappropriate Medications
PIP	Potentially Inappropriate Prescribing
PPI	Public and Patient Involvement
PPO	Potentially Prescribing Omission
PRISMA-P	Preferred Reporting Items for Systematic Reviews and Meta-Analyses- Protocol
PROSPERO	International Prospective Register of Systematic Reviews
PSI	Pharmaceutical Society of Ireland
QoL-AD	Quality of Life in Alzheimer’s Disease
RCI	Resident Classification Instrument
RCT	Randomised Controlled Trial
RevMan	Review Manager
RoI	Republic of Ireland
SC	Substantially Compliant
SD	Standard Deviation
SEIPS	Systems Engineering Initiative for Patient Safety
SF	Short Form
SIB-S	Severe Impairment Battery
SMD	Standard Mean Difference
SMMSE	Standardised Mini-Mental State Examination
SMPA	Swedish Medical Product Agency
START	Screening Tool to Alert to Right Treatment
STOPP	Screening Tool of Older Person’s Prescriptions
STRIP	Systematic Tool to Reduce Inappropriate Prescribing
TARA	Trinity Access to Research Archive
TCD	Trinity College Dublin
TCS	Theory Coding Scheme
TDF	Theory Domain Framework
TG	Tamasine Grimes
TILDA	The Irish Longitudinal Study on Ageing



UK	United Kingdom
US	United States
WHO	World Health Organization
WS	Work System

## **List of Publications**

### Manuscripts

Sadeq A, Strugaru M, Almutairi M, Stewart D, Ryan C, & Grimes T. (2022). Interprofessional Interventions Involving Pharmacists and Targeting the Medicines Management Process Provided to Older People Residing in Nursing Homes: Systematic Review and Meta-Analysis of Randomised Controlled Trials. *Drugs & aging*, 39(10), 773–794. <https://doi.org/10.1007/s40266-022-00978-3>

### *Conference abstracts*

Sadeq A, Strugaru M, Grimes T, Ryan C. (2019). Interprofessional Interventions Involving Pharmacists and Targeting the Medicines Management Process Provided to Older People Residing in Nursing Homes: A Protocol of Systematic Review and Meta-Analysis of Randomised Controlled Trials [Conference: All Ireland Schools of Pharmacy Conference, Trinity College Dublin, Ireland: Poster presentation]

Sadeq A, Strugaru M, Almutairi M, Stewart D, Ryan C, Grimes T. (2020). Interprofessional Interventions Involving Pharmacists and Targeting the Medicines Management Process Provided to Older People Residing in Nursing Homes: Systematic Review and Meta-Analysis of Randomised Controlled Trials [Trinity Health & Education International Research Conference, Trinity College Dublin, Ireland: Oral presentation]

Sadeq A, Ryan C, Brennan C, Shanagher D, Walsh K, Kennelly S, Noonan C, Grimes T. (2022). Work system analysis to explore the medicines management process in the nursing home setting in Ireland: A qualitative study using the Systems Engineering Initiative for Patient Safety model [Healthcare Systems Ergonomics and Patient Safety Conference, Delft University, Netherlands: Oral Presentation]

Sadeq A, Ryan C, Brennan C, Shanagher D, Walsh K, Kennelly S, Noonan C, Grimes T. (2023) Work system analysis to explore the medicines management process in the nursing home setting in Ireland: A qualitative study using the Systems Engineering Initiative for Patient Safety model International Conference on Pharmacy and Biomedical Sciences, Al Ain University, United Arab Emirates: Poster and Oral Presentation]\*

\*The PhD candidate has won the Second place in the 'Best Presenter' poster award

# **Chapter 1**

## General Introduction

### 1.1. THE AGING POPULATION

It is widely acknowledged that the population is ageing globally. Current predictions are that there will be 1.5 billion older adults ( $\geq 65$  years) in the world by 2050, a stark rise from 525 million in 2010 (Figure 1.1) [3]. In other words, one in six people globally will be aged over 65 years by 2050, an increase from the current figure of one in 11 [4]. In the Republic of Ireland (RoI), 14% of the current older population is aged 65 years or older and this percentage will double by the year 2040 (Figure 1.2) [5].

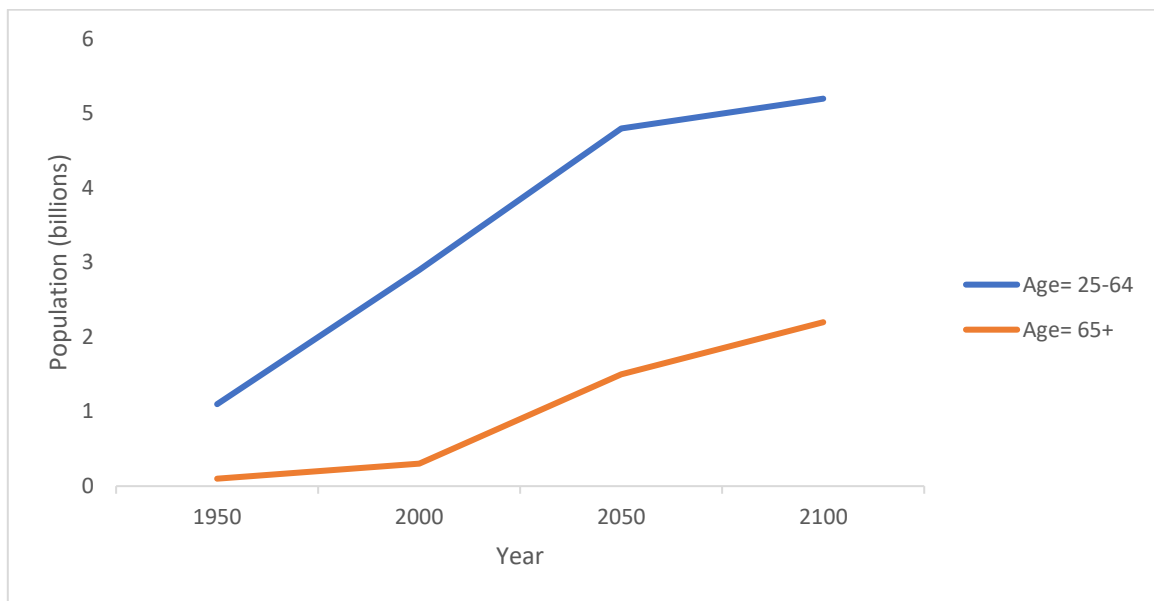


Figure 1. 1 Estimated and projected global population by age group [3]

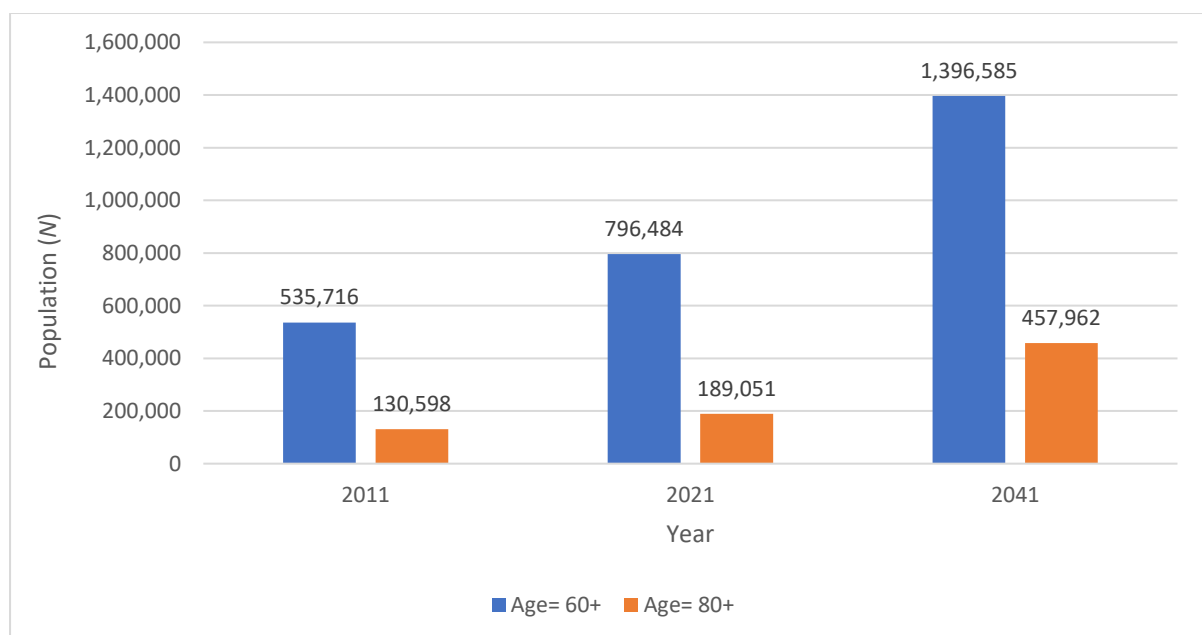


Figure 1. 2 : Estimated and projected global older population in the Republic of Ireland [6]

There are several known reasons for the predicted rise in the older population. Firstly, life expectancy at birth is increasing. In 2021, the life expectancy for the European population was 80.5 years for women and 73.6 years for men [7]. The life expectancy at birth for residents in the RoI in 2018 was reported slightly higher; 80.4 years at birth for men and 84 years for women, a rise by approximately two years since 2008 [8, 9]. The increased life expectancy, coupled with improved diagnostics, preventative therapies, treatments and management strategies greatly contribute to the ageing population. This in turn results in increased longevity, but also an increase in morbidity and frailty [10].

Older age has traditionally been defined by a numerical value, as  $\geq 65$  years. Categorisation of older age is now common, with adults referred to as *young old* if they aged between 65 and 74 years, *old* if they are aged between 75 and 84 years and *very old* if they are 85 years or older [11]. Ageing is defined as a stage of life when the body observes “*a decrease in physiological reserves, while still supporting acceptable functioning in the steady state*” and cannot adapt to any additional stress. The ageing process results in homeostatic/hemodynamic dysregulation [12]. It is this characterisation of ageing that results in the occurrence of age-related morbidities.

#### *Effect of aging of medicines*

The nature of ageing is associated with changes in body systems which result in a decline of their functions [13]. For instance, the development of physiological impairments such as a decrease in organ functions, for instance (i) cardiac (*i.e.*, change in heart size and muscle weakness and reduced blood volume and normal distribution of red blood cells) [14], (ii) respiratory (*i.e.*, muscle atrophy, tissue stiffness and changes in respiratory tract structure) [15], and metabolic function. These physiological impairments result in the presence of diseases, such as cardiovascular disease (*e.g.*, hypertension, hyperlipidaemia), diabetes, impaired renal function and others [16, 17]. These diseases exist in more than 20% of the older population [18]. The World Health Organization (WHO), described cardiovascular diseases as the leading cause of mortality in older people globally [19] and the European Cardiovascular Disease Statistics reported that up to 45% of the recorded deaths in European older adults in 2021 were caused by cardiovascular diseases [20]. It is also reported that up to 80% of older people in the US of age > 60 years have cardiovascular disease [21] and each have more than 90% risk of hypertension [22]. In the RoI, more than half of the older population have hypertension with a higher prevalence reported in females compared to males [23]. On the contrary, more than 15.3% of older men had a heart attack compared to 5% of older women [23]. Cardiovascular diseases are also associated with diabetes; where more than 500 million people

internationally were diagnosed with diabetes [24, 25]. Six to eleven percent of the older population in the RoI are diagnosed with diabetes [23].

Multiple conditions are associated with the deterioration of kidney function and other complications such as diabetic retinopathy, peripheral neuropathy or stroke. For instance, it has been reported that up to 40% of older people with Type 2 diabetes suffer from chronic kidney diseases [26, 27]. Coupled with the decline of liver functions such as structure and blood flow and imbalanced hepatic enzymes level, older people are at risk of reduced drug metabolism and alterations in the pharmacokinetics factors such as absorption (*i.e.*, increase bioavailability and plasma concentration), excretion (*i.e.*, decrease in blood flow and increase in liver enzymes), elimination (*i.e.*, reduced glomerular filtration rate and creatinine clearance) and volume of distribution of medications consumed [28]. As a result, medications tend to have either lower optimum effects in older people or an increase in medications' concentration in the body, causing increased risk of side effects such as falls, contributing to increased hospitalisation rate [29]. Greenblatt and colleagues explain that medication with long elimination half-life (*i.e.*, benzodiazepines) potentially accumulate in older people with impaired pharmacokinetics factors, resulting in a significant impact on falls and hospitalisation rates [30]. Other medications, for example, medications with low volume of distribution (*i.e.*, arrhythmia controlling medicine and some antibiotics) can accumulate in blood, increasing the blood serum levels in this cohort and impaired creatinine clearance [31, 32]. Some medicines that undergo hepatic metabolism are also influenced [33]. This in turn places older people at higher risk of increased drug toxicity levels, and their susceptibility to a series of side effects ranging from treatable side effects (*i.e.*, abdominal discomfort) to serious side effects (*i.e.*, mortality) [34]. These medications are categorised as inappropriate in the Screening Tool of Older Person's Prescriptions (STOPP) criteria [35], more details of inappropriate prescribing and tools to improve prescribing is provided in Section 1.2. Thus, medications prescribed for this cohort may need medication dose adjustments depending on the level of their kidney disease and/or pharmacokinetics impairment, and an appropriate choice of medication prescribed [29, 36]. Not only that, but also changes to the evidence-based pharmaceutical formulation of medicines can alter the appropriateness of drug administration, for example, crushing of medicines (where appropriate), pill splitting and/or changing route of administration [37].

Another common physiological impairment associated with ageing is the loss of bone density and osteoporosis. For instance, a systematic review and meta-analysis by Salari *et al.*, reported that the prevalence of osteoporosis was 23.1 and 11.7 among older women and men of age range between 15-105 in five global continents, respectively [38] and Barnsley *et al.*, discuss the prevalence of osteoporosis risk which increases with aging due to reductions in bone-mass density [39]. Osteoporosis is largely associated with gender where up to 50% of older females in the RoI are living

with osteoporosis compared to 20% of men [23]. Frailty is also associated with increasing age [40]. Frailty is a syndrome characterised by a physiological decline in reserve and resistance against stressors, where even a minor illness may trigger a dramatic change in health status [41]. It encompasses weakness, slowness, low levels of physical activity, exhaustion and loss of weight [42]. It is associated with walking disabilities, a high risk of falls and cognitive conditions such as dementia [43, 44]. Approximately 36% of the global population aged  $\geq 50$  years is frail, and the incidence of frailty will rise with an ageing population [45]. In the RoI, 55% of older people are characterised as frail [46]. Equally, the prevalence of cognitive impairment and dementia also increases with age [47, 48]. Dementia is defined as a syndrome that involves conditions characterised by damage or death of brain neurons, resulting in memory, behavioural, and physical challenges [49]. Therefore, dementia is not a 'single disease', it is a group of conditions [49, 50]. There are a number of causes for dementia, including Alzheimer's disease (the most common cause; up to 80%), vascular dementia, dementia with Lewy bodies and mixed causes of dementia [50]. Jorm and Jolley's meta-analysis on the incidence of dementia reported a direct association between ageing and higher incidents of dementia, where the prevalence of dementia in the 65-69 years age range is 1.3%, compared to 40.8% in people of age  $>90$  years [51, 52]. More than fifty thousand people in the RoI are living with dementia, and an escalation of these numbers is expected in the next 30 years, where 141,200 people are expected to have dementia (1.1% in 2018, compared with 2.3% in 2050 of the overall Irish population) [53]. Similar projections are reported for older people in the United States (US) and the United Kingdom (UK) [5, 54].

### *Research on aging*

Some research projects have focused on examining key components of health in older adults, in order to understand more about healthy aging. For example, The Irish Longitudinal Study on Ageing (TILDA) in the RoI is a large-scale nationwide longitudinal study for people aged 50 years and above [55]. A longitudinal study is a type of research study where data on the same variables are collected at multiple points in time [56]. TILDA is a project run by Trinity College Dublin (TCD) with other institutions cooperating such as University College Dublin and Cork, the Royal College of Surgeons in Ireland, Queens University Belfast and others [57]. The TILDA project includes approximately 8000 participants that are representative of Irish older adults of age more than 50 years [58]. TILDA collects data on various topics on ageing, including socio-economic data (*i.e.*, pension, education, *etc.*), health behaviours (*i.e.*, drinking, smoking, *etc.*), and health assessments on cognitive functions, bone density and cardiovascular parameters [59]. To date, the TILDA project has been ongoing for 5 continuous waves, starting from 2009-2011 (wave 1). In wave 1, data were collected on health assessment. In wave 2 (2012-2013) data were collected from the same participants in wave 1, adding new questions

on personality. Wave 3 took place from 2014-2015; more than 6500 participants undertook the questionnaire that included new questions on cognitive, physical and cardiovascular health. Wave 4 was conducted in 2016 and recorded the same questions with the addition of health education and childhood health-related questions. In 2018, wave 5 was completed with similar questions and wave 6 TILDA is now ongoing. It is worth mentioning that waves 2, 4 and 5 did not include health assessments [60]. Likewise in the UK, the Northern Ireland Cohort for the Longitudinal Study of Ageing (NICOLA) and the English Longitudinal Study of Ageing (ELSA) are widespread longitudinal studies for older adults of age more than 50 years residing in Northern Ireland and England, respectively [61, 62]. All these projects aid policymakers to plan improvements to services provided to older people, and help researcher understand key factors that contribute to healthy aging. Outcomes from research projects are used to inform public and health policy, and disease management and prevention strategies.

## **1.2. MULTIMORBIDITY AND POLYPHARMACY IN OLDER ADULTS**

Ageing is typically associated with the development of multiple chronic conditions or multimorbidity (the co-existence of one or more chronic conditions). The WHO defines a chronic condition as a condition that is the result of “a combination of genetic, physiological, environmental and behaviours factors” [63, 64]. Anderson and colleagues describe chronic conditions as conditions that typically last more than one year and cannot be cured but rather controlled with medications or other interventions [65]. More than 60% of older people worldwide have multimorbidity [66]. A European-wide study by Palladino *et al.*, reported that hypertension, arthritis and cardiovascular disease were the most recorded conditions in more than 55 thousand older adults (aged > 50 years, mean age= 66 years) [67]. In the ROI, Larkin and colleagues’ cross-sectional study on TILDA participants demonstrated that approximately 60% of the older participants (age >50 years) were multimorbid [68]. The same study also reported that more than half of the included older adults of age >70 years were multimorbid [68]. This cohort with multimorbidity is more likely to have risks of hospitalisations, mortality and decreased quality of life [69]. A retrospective cohort study conducted on more than 400,000 patients demonstrated that multimorbidity accounts for more than 55% of hospital admissions in the UK [70]. It has been reported by Jacob *et al.*, that fall risks are higher in multimorbid older adults compared to the non-multimorbid sample in Irish TILDA participants [71].

Consequently, the older, multi-morbid population is more likely to be prescribed multiple medications or ‘polypharmacy’ to treat their chronic conditions [72, 73]. There are variations in how polypharmacy is defined, ranging from a numerical value of prescribing 2 to more than 11 medications, or a description of the process *i.e.*, the prescribing of many medications [74]. Using a numerical value to



describe polypharmacy is traditionally associated with negative connotations, as the greater the number of medications prescribed, the more likely the patient is to suffer from an adverse event associated with their medications. The term ‘too many’ is often used to describe this. It is now widely accepted that older people will be prescribed several medications because of the number of age-related conditions they have. This is fuelled by evidence-based guidelines that advocate for the prescribing of multiple medications to treat multiple conditions. [74-76] However, studies continue to use a numerical value to describe polypharmacy to allow for comparisons to be made between studies, using values as low as four or more regular medications [74]. Up to 27% and 40% of older people are prescribed polypharmacy in the RoI and North America, respectively [77-79].

As with multimorbidity in ageing, polypharmacy can be safe when all medications are prescribed appropriately. However, polypharmacy can also be associated with medication related problem (MRP) “an event or circumstance involving a patient’s drug treatment that actually, or potentially, interferes with the achievement of an optimal outcome”. MRPs include adverse drug reactions, drug-drug interactions, medication errors and potentially inappropriate prescribing (PIP). Adverse drug reactions are described by the WHO as “*Unintended, harmful reactions to medicines*”[80]. The discussed changes in physiology of the human body occurring naturally with ageing (Section 1.1), altering the metabolism of medications [81]. Coupled with polypharmacy and complex medication regimens, this cohort is vulnerable to adverse drug reactions [82]. PIP refers to the prescribing of potentially inappropriate medications (PIM), *i.e.*, the prescribing of medications when the clinical risk outweighs the clinical benefit (*e.g.*, no clinical indication or a duplicative medication) and potential prescribing omissions (PPOs) *i.e.*, when a medication is clinically indicated but not prescribed [83-86]. These in turn can result in negative outcomes such as hospitalisations, increased morbidity and mortality and an increase in falls [87].

The commonly reported occurrence of inappropriate polypharmacy has led to a wealth of research into ways of reducing inappropriate polypharmacy, or as referred to by the Health Information and Quality Assessment (HIQA) as ‘*problematic polypharmacy*’ and defined as “*prescribing of multiple medications inappropriately, or where the intended benefit of the medication is not realised*” [88]. Multiple methods of reducing inappropriate medications have been studied [88]. Of these methods, deprescribing has been described in many ways in the literature. For example, Lyer *et al.*, identified deprescribing as ‘medication withdrawal’ [89] and others such as Le Couteur *et al.*, described it as ‘cessation of long-term therapy’ [90]. Reeve and colleagues' systematic review on deprescribing presented a new definition ‘the process of tapering or withdrawing drugs with the goal of managing polypharmacy and improving outcomes’ [91]. Various systematic reviews provide evidence in support of deprescribing interventions provided by healthcare professionals (HCPs) to older adults (age >65

years). Such interventions have been associated with reduced death rates and a reduction in PIP [92, 93].

Other ways of reducing inappropriate prescribing of medication have been developed in response to the high percentage of MRPs amongst older adults, including the use of tools and criteria to aid HCPs to detect and address PIP and improve the overall quality of medications prescribed to older people [92, 93]. These include the use of prescribing recommendations from the National Institute for Health and Clinical Excellence (NICE) guidelines [94], explicit tools such as Beers criteria [95] and the STOPP/Screening Tool to Alert to Right Treatment (START) criteria [35], and implicit tools such as the Medication Appropriateness Index (MAI) [96]. Some other tools were developed for the management of prescribing in targeted areas of prescribing, for instance, Lavan and colleagues developed the STOPPFRAIL criteria, which targets specific categories of older adults with limited life expectancy [97] and Rogntad and colleagues developed the Norwegian General Practice (NORGEP) criteria, that was developed for the older NH cohort [98].

These tools are now being widely used to identify and reduce the number MRPs experienced by older people and their linked consequences. For instance, Lopez-Rodriguez and colleagues' undertook a cross-sectional study in Spanish primary care using the MAI to identify PIP and reported that the prescribing of proton pump inhibitors in older adults of age between 65 and 74 years was the most commonly encountered instance of PIP [99]. Hamilton *et al.*, noted that 56.2% of patients have at least one PIM at hospital admission, identified using the STOPP criteria [100]. Gallagher and O'Mahoney noted that the STOPP criteria identify more PIMs than the Beers criteria [101]. Abu Hammour and colleagues used the STOPP criteria at hospital admission and noted that the most commonly encountered instance of PIP was using medicines 'beyond the recommended duration'[102]. Deliens and colleagues' study in the hospital setting for older adults with cancer reported a significant reduction in the number of PIM detected when compared between admission and discharge [103]. A study conducted in Argentina by Fajreldines *et al.*, reported a reduction of approximately 20% in the occurrence of MRPs following the use of STOPP/START as an intervention [104].

### **1.3. THE POPULATION RESIDING IN NURSING HOMES**

In the RoI, 6% (n=22,761) of the total older population reside in nursing homes (NHs) [77, 105]. A NH is also referred to in the literature as a care home, long-term care facility, or skilled nursing facility and is internationally defined as "*a facility with a domestic-styled environment that provides 24-hour functional support and care for persons who require assistance with Activities of Daily Living and who*

*often have complex health needs and increased vulnerability*" [12]. Several factors are associated with older people becoming NH residents. Concerns about patients' physical and cognitive decline most often result in referrals to NH by patients' care teams (HCPs and family members). These concerns result from night-induced anxiety and depression, malnutrition, marital status (*e.g.*, divorced or widowed) and increased physical injuries in the community [106-108]. The lack of available medical and emotional support in the community setting had also contributed to patients being transitioned to NHs [106, 107]. More than 70% of NH residents are reported to require mobility assistance in their daily living and high fall rates in this cohort is one of the major causes of NH admissions [109, 110]. Kojima and colleagues' systematic review and meta-analysis reported that the level of frailty in older adults is also a factor contributing to NH admissions [111]. A large-scale analysis of British NH residents undertaken by Zafeiridi *et al.*, reported that frequent hospitalisations and long inpatient stays in hospital are significant contributory factors to NH admissions [108]. Equally in the RoI, factors that contribute to older people's admission to NHs include decline in physical abilities and lack of informal carers to care for them in their own homes where this cohort would need 24-hours' assistance in performing their daily habits such as eating, drinking, dressing and taking their medications [112-115]. Two-thirds of older NH residents have dementia [116]. Rolland *et al.* reported that approximately 50 thousand NH residents in France live with dementia, 60% of whom are women [117]. A recent national survey of the RoI reported that more than half of the NH residents have high to maximum dependency levels with a 3.65 years average length of stay per long-term resident [118], the Irish NH setting is further described in detail in Chapter 3, Section 3.1.1.

The presence of multimorbidity in NH residents is high. For instance, one study undertaken in New Zealand reported that 64.1% of NH adults have multimorbidity [119]. Heinrich and colleagues' study in the Irish NH setting reported that included NH residents had a mean number of 5.5 conditions [120]. Dilles *et al.*, report that 60% of NH older adults experience a MRP with a reported mean of two adverse drug events per resident [121]. Similarly, results in Norway demonstrated that 82.7% of the included NH population had an average of three MRPs per resident [122]. The characteristics and complications of aging described in earlier sections are no different than older people residing in NHs. However, this cohort is more likely to be prescribed medicines than those residing in the community settings [72, 73]. Fog *et al.*, reported that 60% of identified MRPs resulted from PIP with an average of 6.8 medication per resident in Norwegian NHs [122]. A recent Irish study reported that NH residents are five times more likely to be prescribed multiple antipsychotics than community older adults [123]. A large-scale American study reported a mean of eight oral medications per day prescribed to more than 11 thousand NH residents [124]. These drugs can include psychotropic medications, antihypertensives, antidiabetics, anticoagulant/antiplatelet, proton pump inhibitors and pain killers

[125-127]. Diez and colleagues reported the prevalence of polypharmacy was approximately 80% of older NH residents in Spain [128]. Additionally, multiple medications from the same class can be prescribed to a single resident and contribute to further adverse effects. For instance, a systematic review and meta-analysis conducted by Jester and colleagues reported that NH residents with dementia can be prescribed up to three psychotropic medications in addition to other chronic medications [129]. Notably, many of these MRPs can be avoidable, these are referred to as medication errors [130] (described in Section 1.4). Another large scale mixed methods study in Belgium reported that more than 85% of older people prescribed polypharmacy are on medicines for cardiovascular, gastrointestinal, and neurological conditions [131]. Similar results were reported in Scottish NHs for older people prescribed more than 10 medications [132]. In addition to prescribed medications, NH residents are also provided other medications such as over the counter medications, vitamins, and medical herbs [133]. Furthermore, Hamadani *et al.*'s study in a NH in the UK identified at least 5 medication administration errors per week for people prescribed polypharmacy, making the process of managing adverse effects and improving patient safety more complex [134]. The prevalence of PIP amongst NH residents has been documented in a variety of studies undertaken in NHs. For example, two studies conducted in the NH settings in two European countries reported that 50% of the older population residing in NHs had at least one incidence of PIP [135, 136]. Other researchers reported on the prevalence of patients prescribed PIP/PIM, for instance, a systematic review conducted by Morin and colleagues which included NHs from 18 different countries, reported that PIM was detected in 43.2% of NH older people using various screening tools and criteria such as STOPP/START, Beers, and NORGEF [137]. The same systematic review included two studies conducted in Irish NHs, reporting the existence of PIMs and PPOs in more than 50% and 40% of the total NH older adults of age more than 65 years, respectively [138, 139].

Some types of medications are more commonly associated with PIP than others. For example, an Australian study reported that three medication classes were associated with PIP in 96% of the older NH sample, namely cardiovascular, central nervous system and gastrointestinal medications [140]. Similarly in the Irish NH setting, Heinrich *et al.*, identified more than 30% of PIM were from PPIs, blood pressure lowering medications and vitamin D prescriptions [120]. Van der Spek and colleagues' cross-sectional study assessed the prescribing of antipsychotics in the Dutch NH setting using a tool called the Appropriate Psychotropic drug use In Dementia (APID) Index, which described that the prescribing of antipsychotics is often inappropriate [141]. The APID index was developed from the MAI implicit tool that targets the use of antipsychotic medications in older people with dementia residing in NHs [142]. Several factors affect the prescribing of antipsychotics in NH residents, including the interprofessional working dynamic, level of HCPs' skills and regulatory guidance, as reported by Walsh

*et al.*, in a systematic review investigating the influences on decision-making regarding antipsychotic prescribing in nursing home residents with dementia [143].

#### **1.4. THE MEDICINES MANAGEMENT PROCESS**

As mentioned above (Section 1.2), appropriate prescribing is a concern in the NH setting but is only one facet of the entire process by which medications are supplied to residents. There are other stages in this process, known as the medicines management process (MMP) that also contribute to patient safety and risk of undesirable outcomes. The MMP is a process that involves several stages, encompassing assessing the resident on admission, prescribing, dispensing, delivering medications from the pharmacy and storing medications in the NH, administering them, reviewing, monitoring medication related outcomes, and disposal of out-of-date medications [144]. The MMP is crucial in providing quality care to patients and preventing the occurrence of MRPs [145]. The term MMP is often used interchangeably with the term ‘medication optimisation’ which is defined as “a patient-focused approach to getting the best from investment in and use of medicines that requires a holistic approach, an enhanced level of patient-centred professionalism, and partnership between clinical professionals and a patient” [146]. While both terms define similar concepts, the term MMP will be used throughout this thesis as it refers to an overall process encompassing subprocesses and stages related to ensuring patients get the best quality care relating to their medicines and related outcomes. Complications of ageing, multimorbidity, MRPs and the complex medication prescribed for NH residents increases the complexity of the MMP practices provided by stakeholders and makes the process more challenging [147, 148].

##### *Medication error*

Medication error is one type of MRP that is evident in many clinical settings and can happen at any stage of the MMP [149]. Medication error is defined as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional or patient” [150]. Although the prescribing stage of the MMP accounts for the highest prevalence of errors [151], the literature also provides evidence for the occurrence of errors at other stages. For instance, a systematic review conducted by Sutherland *et al.*, reported that 50% of medications administered via the intravenous route are inappropriately administered in the hospital setting in the UK [152]. Another mixed methods study by Gracia *et al.*, identified more than 300 medication administration errors of antibiotics and noradrenaline-containing medications in a Spanish intensive care unit using the Global Medication Error Index [153]. Similarly in the NH setting, Zimmerman and colleagues’ observational study in the American NHs identified more than 40% of

administered medications had errors [154]. Gurwitz and colleagues also reported that medication errors occur in the monitoring stage of the MMP in 70% of older people in NHs [155].

While medication error is a serious issue in healthcare settings, many of these errors are deemed avoidable when appropriate approaches and practices, using for example standard operating procedures, are in place [156-159]. In this regard, various guidelines and standards for MMP in NHs have been developed to ensure NH residents avail of optimum person-centred medicines management services [160]. For instance, the UK's NICE issued guidance on managing medicines in care homes in 2014, which highlights the importance of medicines management provided by all HCPs to NH residents [161]. Likewise in the RoI, HIQA, the statutory regulator, set guidance for providing medicines management to NH older people in their bespoke *Medicines Management Guidance, 2015* and also in the *National Standards for Residential Care Settings for Older People in Ireland, 2016* [160, 162, 163]. HIQA, their standards and the *Medicines Management Guidance* are further described in Chapter 4.

## **1.5. HEALTHCARE PROFESSIONALS WORKING IN NURSING HOMES**

NH residents are under the care of onsite nurses who help with medication needs such as administering medications and monitoring outcomes from medications. The primary HCPs involved in caring for older people in NHs are prescribers (*i.e.*, general practitioners (GPs) and geriatricians), pharmacists and nurses [163, 164]. The prescribers and pharmacists, on the other hand, are primarily off-site contractors having a unique set of MMP-related roles [165].

HCP roles include those outlined by legislation, for example, the Medicinal Products (Prescription and Control of Supply) Regulations in Ireland, and the regulations specifically for the care of older people in residential care, to ensure the safe delivery of MMP, such as the UK's National Service framework for older people and the *National Standards for Residential Care Settings for Older People* in RoI [166] [113]. These standards contribute to both the medication and non-medication aspects of care, to ensure best care practice by HCPs is delivered to NH residents. However, despite these regulations and standards, the nuances of each professional group's role may vary between regions and even between NHs [167, 168].

Other factors can influence the HCP's role, for instance, the geographic location of external HCPs to the NH where the dispersed emplacement of HCPs in different organisations (*i.e.*, NH, hospital, practice, or community) can create deficits in the communication and structured system between them [169]; organisational culture such as NH facility's own policies and availability of tools that can influence roles; the funding structure [12, 170]; and the level of collaboration (*interprofessional*

*practice*) between these multiple HCPs. Some NHs have HCPs working individually, who may or may not be a formal member of a team but are opportunistically working together in the shared interest of a single NH resident [167] [171]. The term Interprofessional practice will be used throughout this thesis to refer to the 'collaborative', 'multidisciplinary' and 'team working' interplay between HCPs.

Interprofessional practice is defined as a patient-centred practice that can enhance outcomes experienced by both service users (patients/residents) and service providers (HCPs) [144, 172]. Researchers in this area suggest that interprofessional practice can have an influence on medicines-related outcomes and processes [173]. For instance, Zwarenstein and colleagues' systematic review suggest that interprofessional collaboration can improve health-related outcomes and improve some stages of the MMP such as prescribing [174]. McDebry *et al.*, also suggest that a strong relationship between pharmacists, prescribers, nurses and residents helps prevent MRPs [175]. Furthermore, many national and international organizations including the World Health Organization have recognised interprofessional practice and its importance [176]. Similarly in the RoI, HIQA guides HCPs on the desired interprofessional approach to the MMP [144].

## **1.6. CORONAVIRUS IN THE REPUBLIC OF IRELAND**

Globally, more than five million people were diagnosed with coronavirus disease (COVID-19) caused by a highly infectious SARS-Cov-2 virus that affects the respiratory system [177, 178]. COVID-19 was declared a global pandemic in March 2020 after its wide spread in more than 200 countries [179]. This disease is often transmitted via coughing, sneezing, talking and physical surface contact. COVID-19 caused mild symptoms such as high body temperature and sore throat. Some other cases reported more serious symptoms such as breathing difficulties, pain and death [180]. Some factors were associated with exacerbation of the severity of the disease including an age-related decline in body system functions in older adults (age>65 years), multimorbidity (*e.g.*, cancer, low immunity and respiratory diseases) and polypharmacy [181, 182]. In the RoI, more than seven thousand older adults of age 65+ years tested positive for COVID-19, up to 11.4% were hospitalised and 23.7% have lost their lives to the virus and its complications [183].

In response to the global pandemic, the majority of governments internationally undertook measures and recommendations to stop the spread of the virus. These included isolations to avoid direct physical contact and hand hygiene [184]. Likewise in the RoI, several strategies were undertaken as a response to the COVID-19 outbreak. For instance, the Irish government declared a lockdown in the country which involved travel restrictions, physical distancing measures, closure of outpatient clinics and isolation of residential care settings such as NHs. The Department of Health, the Health Service Executive (HSE) and local public health authorities in the RoI have worked closely to stop, restrict and

overcome the infection. Any person testing positive for COVID-19 or who had direct contact (face-to-face within a distance of 2 meters) with a COVID-19 patient had to remain isolated for a period of 14 days or until symptoms subsided. This measure also applied to HCPs working in NHs or other essential healthcare settings. The Health Protection Surveillance Centre (HPSC) in the RoI (the local surveillance agency for all infectious diseases) reported that 32% of COVID-19 involved those who were HCPs. This has resulted in variances in HCPs' level of staffing (*i.e.*, low staffing burnout) and psychological challenges which contributed to increased pressure on healthcare systems and decreased provision of health-related services [180].

### **1.6.1. COVID-19 and the Irish nursing home context**

In the Irish NH context, the first case of the virus was recorded on 13 March 2020 [185]. The number of cases continued to increase and the 2021 report from the HPSC reported that more than 16 thousand positive cases of COVID-19 were recorded in NHs with a 2.2% mortality prevalence [183]. Management of COVID-19 was challenging in this cohort for many reasons, these include (i) their ageing, multimorbidity complications, (ii) the fact that their frailty level limited their ability to communicate their symptoms to relevant HCPs, (iii) lack of guidance on the disease at the time of the outbreak, (iv) organisational context such as the level of staffing, and (v) the physical structure of NHs (*i.e.*, multi-occupancy rooms or lack of isolation rooms) that contributed to the internal transmission of the disease [185].

HIQA, being the regulators of NHs and services provided to NH residents, have maintained the support given to NHs to manage the pandemic, these included the provision of personal protective equipment, provision of up-to-date information and national guidance on virus management, answering concerns from people working and living in NHs (through a developed Infection Prevention and Control Hub), and facilitating testing for COVID-19 disease [185]. NHs in the country were isolated and visits from family and/or nonessential workers were restrained. Not only that but also inspections against standards and regulations performed by HIQA inspectors were deferred during the pandemic to limit the spread of the virus in this setting [185] (details about HIQA, standards and inspections are provided in Chapter 4, Section 4.1.3). At the same time, HIQA continued supervising NH services through close contact by phone and conducting risk assessments for NHs affected by the virus [185]. HIQA had also worked with the National Public Health Emergency Team (NPHE), a team from the Department of Health in Ireland, to develop strategies and refine national guidance for infection control in response to the COVID-19 outbreak, namely the *Interim Public Health, Infection Prevention & Control Guidelines on the Prevention and Management of COVID-19 Cases and Outbreaks in Residential Care Facilities* [186]. This guidance encompasses areas in terms of staffing, safety and quarantine measures and



COVID-19 testing. Additionally, HIQA have also published a *Regulatory assessment framework of the preparedness of designated centres for older people for a COVID-19 outbreak* report for unaffected NHs to prevent and prepare for the outbreak [187]. Within the report, NH providers are required to self-assess their facilities against 15 regulations that were noted as essential [187]:

Regulation 4: *Written policies and procedures;*

Regulation 5: *Individual assessment and care plan;*

Regulation 6: *Health care;*

Regulation 7: *Managing behaviour that is challenging;*

Regulation 8: *Protection;*

Regulation 9: *Residents' rights;*

Regulation 10: *Communication;*

Regulation 11: *Visits;*

Regulation 14: *Persons in charge;*

Regulation 15: *Staffing;*

Regulation 16: *Training and staff development;*

Regulation 23: *Governance and management;*

Regulation 26: *Risk management;*

Regulation 27: *Infection control;*

HIQA inspectors confirm adherence to and compliance with these regulations via talking with the NH provider, validating the availability of documentation and where appropriate, observations in NH (details on observations and compliance judgment are provided in Chapter 4, section 4.1.3). These were conducted via phone and/or onsite [187].

The COVID-19 pandemic in the RoI has highlighted (i) the gap in clinical attention provided to NHs and (ii) the need to improve health regulations under relevant legislation, to ensure the safety and welfare of older people residing in NHs and maintain person-centred care [185]. It is also worth highlighting that medicines-related regulations were not the focus of inspections during the pandemic despite the published evidence on multimorbidity and MRPs (*i.e.*, polypharmacy) in older adults in all clinical settings including the NH setting that is associated with being infected with COVID-19, worsening of symptoms and leading to death [188, 189]. For instance, Illoanusi and colleagues' systematic review reported that medications used for the treatment of psychotic problems, can result in undesirable outcomes in older adults who tested positive for COVID-19 [190].

### 1.6.2. Technology use in COVID-19

The COVID-19 pandemic had provoked the use of health technologies globally to support remote diagnosis, treatment and reviews (also referred to as telemedicine) and electronic transmission of records [191, 192]. These health technologies had shown beneficial in limiting the transmission of the disease between individuals, triggering countries to change the health legislation and regulations towards facilitating the greater use of these tools to overcome COVID-19 restrictions [193, 194]. Similarly in the RoI during the pandemic, policy makers and relevant legislators authorised the use of virtual consultations (telemedicine) and electronic transfer of medicine-related documents such as prescriptions, using a secure email service, called “Healthmail” [195-197].

Telemedicine has been introduced in the last decade globally, and in the Republic of Ireland. However, it did not come into routine practice until the COVID-19 pandemic for the purpose of balancing the aim to reduce the spread of virus infection and maintain healthcare. Studies have reported interest and acceptance of telemedicine since the pandemic. For instance, Hong and colleagues reported a statistically significant correlation ( $p < 0.001$ ) between the number of identified COVID cases and search trends of telemedicine [198]. Hincapie and colleagues’ systematic review describes the wide acceptance of telemedicine practices by doctors and patients [199]. In the NH setting, telemedicine has been reported to facilitate older NH residents’ access to clinical experts during the pandemic to reduce the number of community and hospital visits [200, 201]. Tan and colleagues systematic review demonstrated multiple challenges with telemedicine in the NH setting, for instance, the extra workload put on nurses to communicate medicine-related information to prescribers and/or clinical experts; and the unforeseen technological problems in using a digital platform [202]. Another qualitative study conducted in NHs in Singapore added that the extent of telemedicine skills by NH staff are inadequate [203]. In light of that, a recent study conducted by Banburry and colleagues investigated NH staff telemedicine training demands and concluded that broad training on telemedicine skills is needed to overcome challenges and preserve telemedicine use in this setting [204].

Healthmail is defined by the HSE as “*a secure clinical email service that allows health care providers to send and receive clinical patient information in a secure manner*”. Healthmail was established in the RoI in 2014 but the use of it was limited and it was not officially a legal route for prescription transmission or a main practice of communication between HCPs or settings [195, 205]. Gleeson *et al.*’s cross-sectional study in the RoI reported that between 49-73% of responders (*i.e.*, GPs and pharmacists) perceived health technologies positively, reporting a potential improvement in interprofessional practice [206]. Nevertheless, the components and extent of MMP interprofessional

practice in NH facilities are not yet well described in the literature but are reported to be inconsistent and complex [168, 207].

## **1.7. APPROACHES ADOPTED IN THIS THESIS**

### **1.7.1. Guidance from the Medical Research Council**

This PhD follows the Medical Research Council (MRC) framework for complex interventions [208] [209]. The most recent MRC framework- commissioned by the National Health Institute of Health Research (NIHR) in the United Kingdom (UK)- consists of four stages: development or identification stage; feasibility testing of research design; evaluation and understanding of the process; and implementation (Figure 1.3) [208]. These stages share a set of core elements which should be recognised within and throughout the framework stages. The core elements are: considering context; developing, refining and testing programme theory; engaging stakeholders; identifying fundamental uncertainty; refining interventions; and economic considerations (refer to definitions in Table 1.1) [208].

This PhD followed the previous 2008 MRC framework for complex interventions as it was the latest version published at the time of the project's conception (Figure 1.4)[209]. This framework consists of four stages, beginning at the development stage, moving to feasibility testing of processes, then evaluating and understanding the process and finally implementation [209]. This project is tailored to the development stage of the MRC framework, which involves identifying the evidence base, and identifying/developing theory and modelling process and outcomes (Figure 1.4) [209]. In 2022, the MRC-NIHR framework (Figure 1.3) was updated; consisting of similar components with the addition of core elements to be considered as explained above and also in Table 1.1 [208]. The design of this PhD project adapts to these core elements recommended for identifying the basis for intervention development; namely context, theory (section 1.7.2), stakeholders and uncertainties. The MRC recommends steps required to construct successful health interventions, beginning with a systematic review study, in this case, to identify and determine whether existing evidence of interprofessional practice, involving pharmacists and targeting MMP, results in beneficial effects (Chapter 2). Secondly, primary data collected from interviews (qualitative research methodology), or questionnaires (quantitative research methodology) consists of stakeholders' opinions which can be used to explore the MMP, gaps and potential improvements (Chapter 3). Finally, further mixed method analysis (qualitative and quantitative) was applied to NH inspection reports from the statutory regulator in the RoI, *i.e.*, HIQA, to explore the MMP work system in the Irish NH setting from that perspective (Chapter 4).

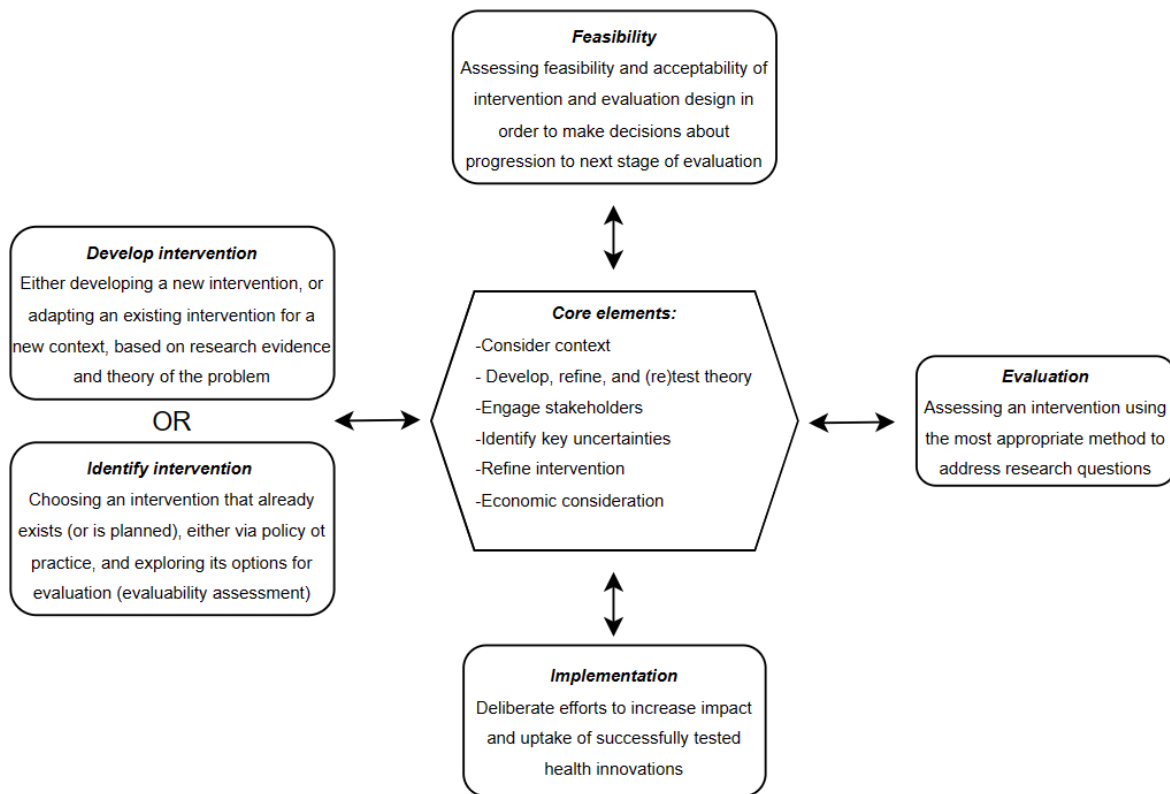


Figure 1. 3 Medical Research Council Framework for design and evaluation of complex interventions (MRC-NIHR), 2022 [208].

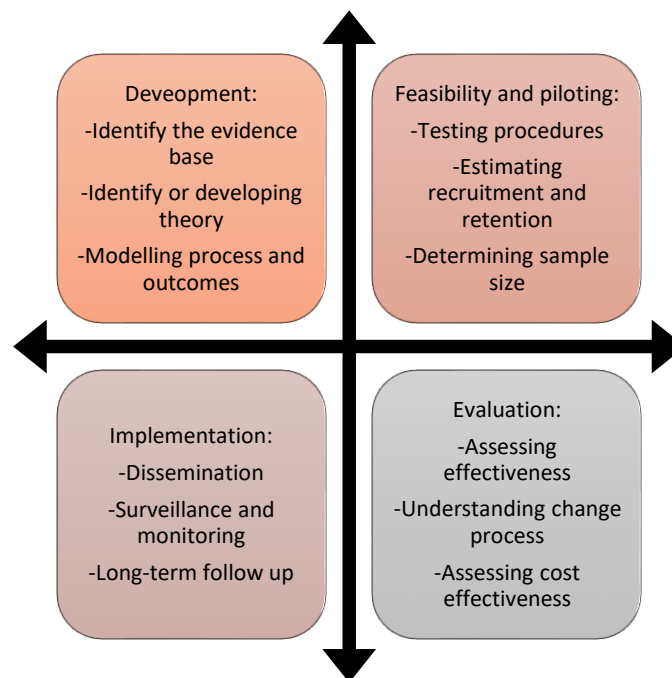


Figure 1. 4 Medical Research Council framework for design and evaluation of complex interventions (MRC), 2008 [209].

Table 1. 1 Core elements description (adapted from the Medical Research Council framework, 2022) [208].

Core elements components	Description
<b>Context</b>	Any feature of the circumstances in which an intervention is conceived, developed, evaluated, and implemented.
<b>Programme theory</b>	Describes how an intervention is expected to lead to its effects and under what conditions—the programme theory should be tested and refined at all stages and used to guide the identification of uncertainties and research questions.
<b>Stakeholders</b>	Those who are targeted by the intervention or policy, involved in its development or delivery, or more broadly those whose personal or professional interests are affected (that is, who have a stake in the topic)—this includes patients and members of the public as well as those linked in a professional capacity.
<b>Uncertainty</b>	Identifying the key uncertainties that exist, given what is already known and what the programme theory, research team, and stakeholders identify as being most important to discover—these judgments inform the framing of research questions, which in turn govern the choice of research perspective.
<b>Refinements</b>	The process of fine tuning or making changes to the intervention once a preliminary version (prototype) has been developed.
<b>Economic considerations</b>	Determining the comparative resource and outcome consequences of the interventions for those people and organisations affected.

### 1.7.2. Use of Theory in Research

Recent guidelines developed by the MRC support the use of theory when developing interventions to ‘understand how change is brought about, including the interplay of mechanisms and context’ [208]. Theory is defined as a ‘*a set of interrelated concepts, definitions and propositions that present a systematic view of events or situations by specifying relations among variables, to explain or predict the events or situations*’ [210]. Meleis *et al.*, also define theory as ‘*a symbolic depiction of aspects of reality that are discovered or invented for describing, explaining, predicting, or prescribing responses, events, situations, conditions, or relationships*’ [211]. Theories that relate to pharmacy practice research originate from different disciplines such as psychology, sociology, anthropology and biomedical sciences [212]. Theory also helps explain if the intervention works or not and the possible effect of an intervention on findings [210]. Theory in research can be used in:

- 1) justifying the rationale for the research;
- 2) constructing the aim of the research;

3) considering the theories of qualitative (narrative, phenomenology, ethnography, grounded theory and case studies) and quantitative (randomised controlled trials (RCTs), cohort studies, case-control studies and cross-sectional surveys) approaches:

4) developing data collection tools such as questionnaires and interview topic guides; and

5) analysing data (or theoretical analysis) and interpreting results [213]. The use of theory in intervention development intensifies the robustness and rigour of research [214].

The theory adopted in Chapters 3 and 4 of this thesis is a system-based approach using a human factors/ergonomics model that aids in the identification and analysis of complex processes such as the resident's MMP journey in order to achieve outcomes for both residents and carers/stakeholders. Refer to Chapter 3, section 3.1.2 for a more detailed explanation of this approach.

### **1.7.3. Public and Patient Involvement in Health Research**

The UK MRC guidance and Health Research Board (HRB) in Ireland recommend involving relevant stakeholders (patients, users of interventions or the public) in the development stage, also referred to as Patient and Public Involvement (PPI) (Figure 1.5) [215, 216]. PPI has become an essential component of health research prompted by policies as it enhances rigorous analysis, appropriateness of outcomes and 'successful research results into practice' [217]. PPI in health research can be utilised in various stages of a study. These stages include (i) developing and defining a research question; (ii) development of study design; (iii) interpretation of findings; (iv) dissemination of findings and (v) funding [218]. Accordingly, this PhD project has created a PPI panel by *identifying users, carers and providers* of the MMP services in the NH settings to boost the robustness and quality of findings. Thus, PPI contributors included two pharmacists; an advanced nurse practitioner; a clinical nurse expert; a general practitioner; a consultant geriatrician; a previous director of nursing in a NH, a current director of a NH representative body in Ireland; and a family member of an older adult residing in a NH in Ireland. The PPI contributors:

- Have *supported the design* of the project by (i) refining the study proposal; (ii) supporting the choice of suitable methods such as research design, sampling methods, and supporting the design of the topic guides used; and (iii) assisting in the recruitment of participants eligible for participation in chapter 3 of this thesis.
- Will support the *dissemination* of study findings as an article, a presentation or a poster.

The involvement of a PPI contributor who is a NH resident was not applicable due to difficulties in reaching older people residing in NHs. However, having a family member and HCPs supported

this gap as they acted as great representatives of NH residents both professionally and emotionally. To our knowledge, this is the first multifaceted PPI panel created to explore the MMP and the residents' journey in the NH setting in the RoI.

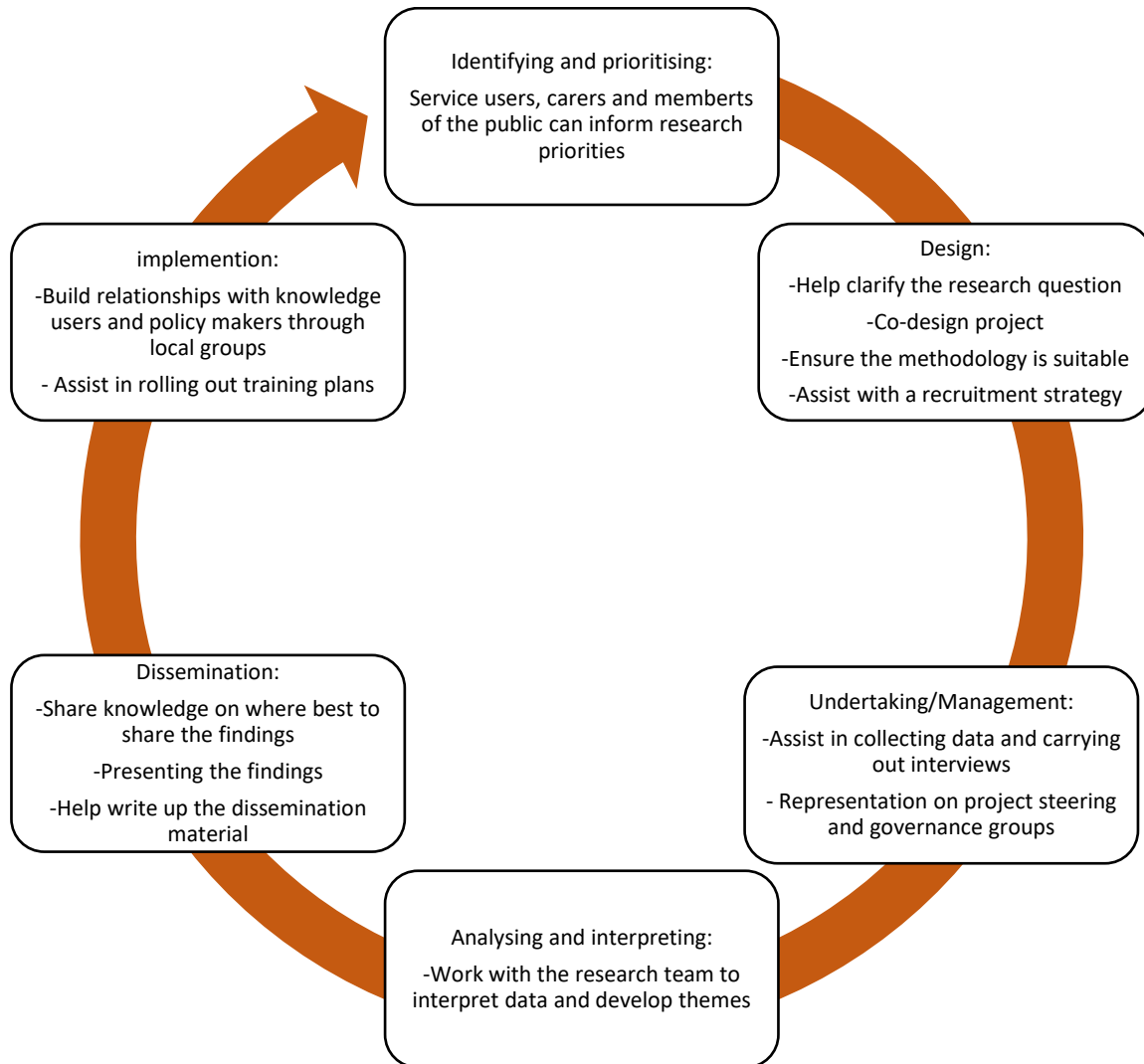


Figure 1. 5 Public and Patient Involvement (PPI) in Research

## 1.8. OVERVIEW OF RESEARCH PRESENTED IN THIS THESIS

### 1.8.1. The overall aim

The aim of this PhD was to explore the MMP provided to older people residing in the Irish NH setting.

### 1.8.2. Research Objectives

The objectives were to:

- Identify and determine the current evidence of interprofessional MMP interventions involving pharmacists, in the NH setting.
- Describe a theoretical underpinning of these MMP interventions.
- Undertake a theoretical exploration and analysis of the MMP and its components provided in NHs in the RoI.
- Identify stakeholders' perceived barriers and facilitators to the safe and efficient provision of MMP and outcomes experienced by residents in NHs in the RoI.
- Describe the MMP in the Irish NH setting using a journey map.
- Explore the extent of MMP compliance and reporting from the statutory regulators from perspective.
- Suggest future improvements for a complex interprofessional MMP intervention that can be implemented by researchers and guide policy makers to improve MMP practices.

### **1.8.3. Overview of thesis chapters**

To address the above key research objectives, the project was divided into three phases. The findings from each phase are outlined in chapters 2-4 of this thesis:

- Chapter 2** Interprofessional interventions involving pharmacists and targeting the medicines management process provided to older people residing in nursing homes: A systematic review and meta-analysis of randomised controlled trials.
- Chapter 3** Work system analysis to explore the medicines management process in the nursing home setting in Ireland: a qualitative study using the Systems Engineering Initiative for Patient Safety model.
- Chapter 4** An exploration of the medicines management process in the Irish nursing home setting: A secondary mixed methods analysis of the National Inspection Reports.
- Chapter 5** General discussion and conclusion: Triangulation of findings.



## **Chapter 2**

Interprofessional interventions involving pharmacists and targeting the medicines management process provided to older people residing in nursing homes:

A systematic review and meta-analysis of randomised controlled trials

## 2.1. INTRODUCTION

This chapter focuses on a systematic review conducted in line with the development stage of the United Kingdom (UK) Medical Research Council (MRC) framework for complex interventions as described in Chapter 1, Section 1.7.1 [208]. The study reported in this chapter sought to systematically identify and describe interprofessional interventions involving pharmacists that target the medicines management process (MMP) in the nursing home (NH) setting to improving outcomes experienced by patients.

### 2.1.1. Overview of the Current Evidence Base

As discussed in Chapter 1, section 1.1, the older population is ageing; older people ( $\geq 65$  years) currently represent 9% of the global population in 201 countries and these figures are expected to double in the coming decades[3]. NHs are also referred to in the literature as care homes, long-term facilities or skilled nursing facilities [116]. Older NH residents tend to have more complex medication needs than those in the community due to age-related cognitive and physical impairments such as dementia and malnutrition [116, 117, 148]. As described in Chapter 1 (Section 1.4), this cohort is more likely to be prescribed multiple medications (polypharmacy) than those of a younger age due to the co-existence of one or more chronic diseases (*i.e.*, multimorbidity). In addition to their age-related changes, they are potentially pre-disposed to medication-related problems (MRPs) which contribute to potentially inappropriate prescribing (PIP), hospitalization, mortality and falls [72, 84, 219, 220]. PIP is a frequent issue in all clinical settings, including NHs [221]. For example, a systematic review undertaken to determine the prevalence of potentially inappropriate medication use in older adults living in nursing homes by Morrin *et al.*, reported that 43% of approximately 550,000 NH residents in more than four continents (including Europe) had at least one PIP [137]. Like other MRPs, PIP is associated with a high mortality risk, hospitalisations and increased medication cost [222-224]. A detailed description of MRPs, multimorbidity, polypharmacy and their consequences to other adults in all clinical settings, including the NH setting are provided in Chapter 1.

As discussed in Chapter 1 (Section 1.5), the MMP is a process that covers a number of stages and encompasses assessing, prescribing, dispensing, delivering and storing, administering, reviewing and monitoring medicines [225]. Medication errors may occur at any stage of the MMP, thus, making the provision to MMP services challenging [84, 226]. A systematic review undertaken by Ferrah and colleagues to determine the prevalence of medication errors that result in hospitalisation of NH residents, demonstrated that up to 27% of the older NH cohort are vulnerable to medication errors, with 31% of these detected during the hospital transfer [227]. These medication errors were reported to occur during the prescribing and monitoring (59-100%), and ordering (20- 53%) components of

MMP [227]. Consequences of medication errors in this cohort can range from mild to severe, resulting in hospital admission and even mortality [228, 229]. Thus, appropriate management of each stage of the MMP is essential to ensure patients achieve maximum therapeutic benefits from their medications [230].

### **2.1.2. Interprofessional MMP Practice**

The MMP is complex for several reasons, including the variety of healthcare professionals (HCPs) caring for NH residents at each stage of the process, either *individually* or *collectively* as an *interprofessional group* from various disciplines and organizations [220, 231]. For example, in Northern Ireland, Scott and colleagues reported that interprofessional working in the form of integrated MMP led to improvements in the safety of medicines, the occurrence of morbidity and mortality in hospitalised patients, and issues occurring during and after discharge of hospital patients [232]. Loganathan and colleagues' systematic review of prescribing interventions reported improvements in the appropriateness of prescribing in NH residents [233]. Bergkvist and colleagues' intervention targeting the assessing, monitoring and review stages showed a significant reduction in the number of inappropriate medicines prescribed in the Swedish hospital settings for patients aged 65 years and above [234]. Davidsson *et al.* demonstrated the positive effect of interprofessional medication reviews which targeted the prescribing, monitoring and review stage in reducing MRPs in NH residents [220], and in the same way, Kaboli and colleagues reported similar results when targeting the same and other stages (*e.g.*, assessing) in hospitalised patients [235].

Nevertheless, providing interprofessional practice in the NH setting has been reported to be challenging for a variety of reasons: the lack of HCPs' being co-located in the NH facility, limited communication between multiple HCPs caring for a single resident, [236, 237] and the absence of a formal system to help with medication-related issues [238]. These factors may lead to an increase in HCPs' workload and increase the risk of MRPs [239].

Other factors challenging interprofessional practice involve the considerable international variation in the provision of MMP services to NH residents. For example, variation in individual country's regulatory requirements for undertaking medication reviews; the guidance provided by the professional bodies to provide medicines management service; the contractual relationship between HCPs and NHs (*e.g.*, pharmacists might have a supply-only contract or a contract that also stipulates the undertaking of medicines review); the number, types and roles of HCPs involved in caring for patients; and the payment model for services provided [159, 240].

Pharmacists provide a variety of services to NH residents that are key to the MMP. For example, pharmacists are the core HCP group who provide dispensing services to NH residents, without them, medications would not be supplied. Pharmacists also have a variety of roles in the review of medicines prescribed to NH residents, although these roles are not standardised [145, 241]. A recent systematic review by Salahudeen *et al.*, suggested that interventions by pharmacists can result in a degree of success in optimising anticholinergic drug prescribing in older adults [242]. Although pharmacists' contributions within an interprofessional team have not been formally structured, previous studies have demonstrated the importance of pharmacists' interprofessional involvement in reducing MRPs and improving the overall quality of care in different clinical settings through medication reviews [145, 243-245]. A recently published before-and-after study in the NH setting identified an association between pharmacist's involvement in an interprofessional medication review with the direct impact of reducing medication risk in residents [246]. Although it is known that pharmacists' involvement in an interprofessional intervention expands other HCP's knowledge of medicines, nevertheless, there is a lack of guidance on their involvement within the interprofessional practice to provide the MMP service and enhance resident outcomes in the NH settings [247]. A recently published before and after study in the NH setting concluded that having a pharmacist involved in an interprofessional medication review, resulted in a reduction in the risk associated with medicines for NH residents [246].

### **2.1.3. Theory Use in Intervention Development**

Recent guidelines developed by the MRC support the use of theory in developing interventions (*e.g.*, psychological theory) [208]. As discussed in Chapter 1 (Section 1.7.2), theory has been described as 'a set of interrelated concepts, definitions and propositions that present a systematic view of events or situations by specifying relations among variables, in order to explain or predict the events or situations' [248]. In other words, theory may help predict behaviours, guide the intervention design, development, evaluation and explain the reported outcomes [248]. The use of theory in intervention development also allows the understanding of the intervention's mechanisms of action [249]. To systematically determine the extent to which interventions are theory-driven, Michie and colleagues have developed the theory coding scheme (TCS) (Table 2.1), which allows researchers to identify and describe the theoretical basis of interventions [249]. The TCS consist of 19 items across six categories, where categories 1-3 assess the extent to which interventions are theory-based and categories 4-6 describe theory testing and refinement.

The TCS has been helpful in providing a clear understanding of the role of theory in the development of an intervention. The same author added that experts in this area acknowledge the role of theory in explaining the impact of interventions on outcomes assessed [249]. For instance, a previously

conducted systematic review undertaken by Lau and colleagues investigated digitalised self-medication management for older people with neurological disorders and used the TCS to assess theory reported in ten included studies [250]. The same study reported significant effects in favour of interventions reporting the use of the cognitive behaviour theory on improving depression, anxiety, and fatigue [250].

Other systematic reviews that have used the TCS have found a lack of detailed descriptions of the included interventions, rendering it difficult to apply the TCS to its full capacity. Additionally, some systematic reviews note the scarcity of theory informed interventions, despite the use of theory being explicitly recommended by the MRC's framework for complex intervention development [208]. Therefore, determining the impact of theoretically designed interventions over interventions that are not theoretically designed can be challenging. For example, Patton and colleagues set out to investigate the effectiveness of theory-based interventions aimed at improving adherence in patients prescribed polypharmacy [251]. Whilst the review authors included five studies in their review, the included studies were too heterogenic to allow for meaningful conclusions to be drawn. Similarly, O'Gorman and colleagues aimed to establish the overall effectiveness of theoretically derived interventions on improving appropriate polypharmacy and also found few theoretically derived studies and therefore the overall effectiveness of these interventions could not be established [252].

To date, no systematic review has investigated theories underpinning the development of interprofessional interventions, involving a pharmacist addressing the MMP provided to older people residing in the NH setting using the TCS. The effectiveness of such interventions has not been established either. This chapter provides an overview of the methodology and findings from a systematic review and meta-analysis that aimed to identify and address gaps in the literature and aid in future development of a novel interprofessional intervention in this area. This systematic review and meta-analysis have been published in the peer-reviewed journal *Drugs and Aging* [253] (Appendix 2.1). Details of contributions made by all authors are noted in section 2.3.2 of this chapter.

Table 2. 1 Theory Coding Scheme (TCS)[249]

TCS category	Items of TCS	Description
<b>Category 1: Is the theory mentioned?</b>	<p>TCS item 1: Theory/model of behaviour mentioned.</p> <p>TCS item 2: Targeted/psychological construct mentioned as behaviour predictor.</p> <p>TCS item 3: Intervention based on a single theory.</p>	<p>Theories/models that specify relations among variables to explain or predict behaviour are mentioned, even if the intervention is not based on this theory.</p> <p>Evidence that the psychological construct relates to (correlates/predicts/causes) behaviour should be presented within the introduction or method.</p> <p>The intervention is based on a single theory (rather than a combination of theories or predictors).</p>
<b>Category 2: Are relevant theoretical constructs targeted by the intervention?</b>	<p>TCS item 2: Targeted Targeted/psychological construct mentioned as behaviour predictor.</p> <p>TCS item 5: Theory/predictors used to select/develop intervention techniques. <i>Intervention techniques(s) linked to theory-relevant construct(s).</i></p> <p>TCS item 7: All intervention techniques are explicitly linked to at least one theory-relevant construct/predictor.</p> <p>TCS item 8: At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/predictor.</p> <p>TCS item 9: Group of techniques are linked to a group of constructs/ predictors. <i>Theory-relevant construct(s) linked to intervention techniques(s).</i></p>	<p>Evidence that the psychological construct relates to (correlates/predicts/causes) behaviour should be presented within the introduction or method.</p> <p>The intervention is explicitly based on a theory or predictor or combination of theories or predictors.</p> <p>Each intervention technique is explicitly linked to at least one theory-relevant construct/predictor.</p> <p>At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/ predictor.</p> <p>A cluster of techniques is linked to a cluster of constructs/ predictors.</p>

TCS category	Items of TCS	Description
	<p>TCS item 10: All theory-relevant constructs/predictors are explicitly linked to at least one intervention technique.</p> <p>TCS item 11: At least one, but not all, of the theory relevant constructs/predictors are explicitly linked to at least one intervention technique.</p>	<p>Every theoretical construct within a stated theory, or every stated predictor (see item 5), is linked to at least one intervention technique.</p> <p>At least one, but not all, of the theoretical constructs within a stated theory or at least one, but not all, of the stated predictors (see item 5) are linked to at least one intervention technique.</p>
<p><b>Category 3: Is theory used to select intervention recipients or tailor interventions?</b></p>	<p>TCS item 4: Theory/predictors used to select recipients for the intervention.</p> <p>TCS item 6: Theory/predictors used to tailor intervention techniques to recipients.</p>	<p>Participants were screened/selected based on achieving a particular score/level on a theory-relevant construct/ predictor.</p> <p>The intervention differs for different sub-groups that vary on a psychological construct (e.g., stage of change) or predictor at baseline.</p>
<p><b>Category 4: Are the relevant theoretical constructs measured?</b></p>	<p>TCS item 12: Theory-relevant constructs/predictors are measured.</p> <p>TCS item 13: Quality of measures.</p>	<p>a) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured post-intervention.</p> <p>b) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured pre- and post-intervention.</p> <p>a) All of the measures of theory-relevant constructs/predictors had some evidence for their reliability.</p> <p>b) At least one, but not all, of the measures of theory relevant constructs/predictors had some evidence for their reliability.</p> <p>c) All of the measures of theory relevant constructs/predictors have been previously validated.</p> <p>d) At least one, but not all, of the measures of theory relevant constructs/predictors have been previously validated.</p> <p>e) The behaviour measure had some evidence for its reliability.</p> <p>f) The behaviour measure has been previously validated.</p>
<p><b>Category 5: Is theory tested?</b></p>	<p>TCS item 12: Theory relevant constructs/predictors are measured.</p>	<p>a) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured post-intervention.</p> <p>b) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured pre- and post-intervention.</p>

TCS category	Items of TCS	Description
	<p>TCS item 13: Quality of measures.</p> <p>TCS item 14: Randomisation of participants to condition.</p> <p>TCS item 15: Changes in measured theory-relevant constructs/ predictors.</p> <p>TCS item 16: Meditational analysis of constructs/predictors.</p> <p>TCS item 17: Results discussed in relation to theory.</p> <p>TCS item 18: Appropriate support for theory.</p>	<p>a) All of the measures of theory-relevant constructs/predictors had some evidence for their reliability.</p> <p>b) At least one, but not all, of the measures of theory relevant constructs/predictors had some evidence for their reliability.</p> <p>c) All of the measures of theory relevant constructs/predictors have been previously validated.</p> <p>d) At least one, but not all, of the measures of theory relevant constructs/predictors have been previously validated.</p> <p>e) The behaviour measure had some evidence for its reliability.</p> <p>f) The behaviour measure has been previously validated.</p> <p>a) Do the authors claim randomisation?</p> <p>b) Is a method of random allocation to condition described (<i>e.g.</i>, random number generator)?</p> <p>c) Was the success of randomisation tested?</p> <p>d) Was the randomisation successful (or baseline differences between intervention and control group statistically controlled)?</p> <p>The intervention leads to significant change in at least one theory-relevant construct/predictor (vs. control group) in favour of the intervention.</p> <p>In addition to 15, do the following effects emerge?</p> <p>a) Mediator predicts DV? (Or change in mediator leads to change in DV)</p> <p>b) Mediator predicts DV (when controlling for IV)?</p> <p>c) Intervention does not predict DV (when controlling for mediator)?</p> <p>d) Mediated effect statistically significant?</p> <p>Results are discussed in terms of the theoretical basis of the intervention.</p> <p>Support for the theory is based on appropriate mediation OR refutation of the theory is based on obtaining appropriate null effects (i.e., changing behaviour without changing the theory-relevant constructs).</p>
<b>Category 6: Is theory refined?</b>	TCS item 19: Results used to refine theory.	The authors attempt to refine the theory upon which the intervention was based by either (1) adding or removing constructs to the theory, or (2) specifying that the interrelationships between the theoretical constructs should be changed and spelling out which relationships should be changed.



## 2.2. AIM AND OBJECTIVES

The aim of this systematic review was to systematically identify and describe interprofessional interventions involving pharmacists that target the MMP for older people residing in NHs.

The objectives were to:

- Describe published interprofessional interventions and the role of pharmacists within the interprofessional team;
- Describe the effect of these interventions;
- Describe the MMP stages targeted by the interventions;
- Identify any reported theoretical underpinning of the intervention.

## 2.3. RESEARCH DESIGN AND METHODS

### 2.3.1. Protocol

This systematic review followed a protocol using methods established by the Cochrane collaboration methodology [254] and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Protocol (PRISMA-P). The systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) [Ref: CRD42020181744].

### 2.3.2. Published manuscript

The review findings and meta-analysis have been reported in accordance with the (PRISMA) statement [255] and Cochrane collaboration methodology [254]. The completed PRISMA checklist can be found in Appendix 2.2. The PhD candidate led all components of the review process.

The following list describes each author's individual contribution to the published manuscript.

- *Screening of titles and abstract:* Asil Sadeq (AS), Monica Strugaru (MS) and Maryam AlMutairi (MA);
- *Screening of full text:* Asil Sadeq (AS), Monica Strugaru (MS) Maryam AlMutairi (MA), Tamasine Grimes (TG), Cristin Ryan (CR), and Connie Brennan (CB);
- *Data extraction and assessments:* Asil Sadeq (AS), Monica Strugaru (MS), Tamasine Grimes (TG), and Maryam AlMutairi (MA);
- *Manuscript writing and refinements:* Asil Sadeq (AS), Tamasine Grimes (TG), Cristin Ryan (CR) and Derek Stewart (DS).

### **2.3.3. Eligibility criteria**

#### Types of studies

All types of randomised controlled trials (RCTs), including cluster and pilot trials, were considered eligible for inclusion in this study. RCTs were chosen as they present the highest level of evidence in health research; bias is minimised with the unique nature of randomisation that allows balanced attribution between participants and outcomes in an intervention [256].

#### Types of participants

This review included trial participants of age >65 years or a population mean (median) age of 65 years or older.

#### Types of interventions

Any interprofessional intervention targeting at least one stage of the MMP (assessing, prescribing, dispensing, delivering and storing, administering, and reviewing and monitoring of medicines), was eligible for inclusion. Interventions had to involve a pharmacist amongst the intervention providers. The interventions had to target NH residents.

#### Types of setting

Only interventions undertaken in the NH setting were eligible for inclusion.

#### Types of outcomes

Studies were not restricted or excluded based on outcomes measured.

### **2.3.4. Search strategy**

Seven databases were searched: Excerpta Medica database (EMBASE), Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulated Index to Nursing and Allied Health Literature (CINAHL), PsycINFO, Scopus, Web of Science and The Cochrane Library for randomised controlled trials, from the date of the database inception to August 2021. Elsevier Life Science Thesaurus (EMTREE) headings, Medical Subject Headings (MeSH) and free text terms were used and developed in accordance with a subject librarian. These search terms explored two key areas:

1. Medicines management: *“medication therapy management” OR “medication therapy assessment” OR “medicine management” OR “medicine therapy assessment” OR “medicine therapy management” OR “drug therapy management” OR “medication review\*” OR “drug*

*utilisation management” OR “drug utilisation management” OR “drug therapy service\*” OR “medication management” OR “medication optim\*” OR “medication use” OR “medication system” OR “deprescri\*”*

2. Nursing home: *“nursing home” OR “long term care” OR “long-term care” OR “residential home\*” OR “skilled nursing facility\*” OR “skilled-nursing facility\*” OR “aged-care facility\*” OR “aged care facility\*” OR “geriatric facility\*” OR “geriatric care facility\*” OR “residential care home\*”*

Search terms were adapted according to the relevant databases’ linguistic particularities, and an English language filter was applied. The Cochrane recommended RCTs filters were used in EMBASE and PsychINFO [257]. The full search strategy is provided in Table 2.2.

*Table 2. 2 The Search Strategy*

<b>Data base</b>	<b>Search Strategy</b>
<b>EMBASE</b>	<ul style="list-style-type: none"> <li>• [#1]: ‘medication therapy management’/exp</li> <li>• [#2]: ‘medication therapy management’:ti,ab OR ‘medication therapy assessment’:ti,ab OR ‘medicine management’:ti,ab OR ‘medicine therapy assessment’:ti,ab OR ‘medicine therapy management’:ti,ab OR drug therapy management’:ti,ab OR ‘medication review*’ :ti,ab OR ‘drug utilisation management’:ti,ab OR ‘drug utilisation management’:ti,ab OR ‘drug therapy service*’ :ti,ab OR ‘medication management’:ti,ab OR ‘medication optim*’:ti,ab OR ‘medication use’:ti,ab OR ‘medication system’:ti,ab OR ‘deprescri*’:ti,ab</li> <li>• [#3]: [#1] OR [#2]</li> <li>• [#4]: ‘nursing home’/exp</li> <li>• [#5]: ‘nursing home’:ti,ab OR ‘long term care’:ti,ab OR ‘long-term care’:ti,ab OR ‘residential home’:ti,ab OR ‘skilled nursing facility’:ti,ab OR ‘skilled nursing facilities’:ti,ab OR ‘skilled-nursing facility’:ti,ab OR ‘skilled-nursing facilities’:ti,ab OR ‘aged-care facility’:ti,ab OR ‘aged-care facilities’:ti,ab OR ‘aged care facility’:ti,ab OR ‘aged care facilities’:ti,ab OR ‘geriatric facility’:ti,ab OR ‘geriatric facilities’:ti,ab OR ‘geriatric care facility’:ti,ab OR ‘geriatric care facilities’:ti,ab OR ‘residential care home’:ti,ab OR ‘residential care homes’:ti,ab</li> <li>• [#6]: [#4] OR [#5]</li> <li>• [#7]: [#3] AND [#6]</li> <li>• [#8] ‘crossover procedure’:de OR ‘double-blind procedure’:de OR ‘randomized controlled trial’:de OR ‘single-blind procedure’de OR random*:de,ab,ti OR</li> </ul>

	<p>factorial*:de,ab,ti OR crossover*:de,ab,ti OR ((cross NEXT/1 over*):de,ab,ti) OR placebo*:de,ab,ti OR ((doubl* NEAR/1 blind*):de,ab,ti) OR ((singl* NEAR/1 blind*):de,ab,ti) OR assign*:de,ab,ti OR allocat*:de,ab,ti OR volunteer*:de,ab,ti</p> <ul style="list-style-type: none"> <li>• [#9]: [#7] AND [#8]</li> </ul>
<b>Medline and CINAHL</b>	<ul style="list-style-type: none"> <li>• MJ medication management in older adults</li> <li>• OR</li> <li>• “AB ( “medication therapy management” OR “medication therapy assessment” OR “medicine management” OR “medicine therapy assessment” OR “medicine therapy management” OR “drug therapy management” OR “medication review*” OR “drug utilisation management” OR “drug utilisation management” OR “drug therapy service*” OR “medication management” OR “medication optim*” OR “medication use” OR “medication system” OR “deprescri*” )</li> <li>• OR</li> <li>• TI ( “medication therapy management” OR “medication therapy assessment” OR “medicine management” OR “medicine therapy assessment” OR “medicine therapy management” OR “drug therapy management” OR “medication review*” OR “drug utilisation management” OR “drug utilisation management” OR “drug therapy service*” OR “medication management” OR “medication optim*” OR “medication use” OR “medication system” OR “deprescri*” )</li> <li>• And</li> <li>• MJ ( nursing homes or care homes or long-term care or residential care or aged care facility )</li> <li>• OR</li> <li>• AB ( “nursing home” OR “long term care” OR “long-term care” OR “residential home*” OR “skilled nursing facilit*” OR “skilled-nursing facilit*” OR “aged-care facilit*” OR “aged care facilit*” OR “geriatric facilit*” OR “geriatric care facilit*” OR “residential care home*” )</li> <li>• OR</li> <li>• TI ( “nursing home” OR “long term care” OR “long-term care” OR “residential home*” OR “skilled nursing facilit*” OR “skilled-nursing facilit*” OR “aged-care facilit*” OR “aged care facilit*” OR “geriatric facilit*” OR “geriatric care facilit*” OR “residential care home*” )</li> </ul>
<b>PsycInfo</b>	<ul style="list-style-type: none"> <li>• MJ medication management in older adults</li> <li>• OR</li> <li>• “AB ( “medication therapy management” OR “medication therapy assessment” OR “medicine management” OR “medicine therapy assessment” OR “medicine therapy management” OR “drug therapy management” OR “medication review*” OR “drug</li> </ul>

	<p>utilisation management" OR "drug utilisation management" OR "drug therapy service*" OR "medication management" OR "medication optim*" OR "medication use" OR "medication system" OR "deprescri*")</p> <ul style="list-style-type: none"> <li>• OR</li> <li>• "AB ( "medication therapy management" OR "medication therapy assessment" OR "medicine management" OR "medicine therapy assessment" OR "medicine therapy management" OR "drug therapy management" OR "medication review*" OR "drug utilisation management" OR "drug utilisation management" OR "drug therapy service*" OR "medication management" OR "medication optim*" OR "medication use" OR "medication system" OR "deprescri*")</li> <li>• AND</li> <li>• MJ ( nursing homes or care homes or long-term care or residential care or aged care facility )</li> <li>• OR</li> <li>• AB ( "nursing home" OR "long term care" OR "long-term care" OR "residential home*" OR "skilled nursing facilit*" OR "skilled-nursing facilit*" OR "aged-care facilit*" OR "aged care facilit*" OR "geriatric facilit*" OR "geriatric care facilit*" OR "residential care home*" )</li> <li>• OR</li> <li>• TI ( "nursing home" OR "long term care" OR "long-term care" OR "residential home*" OR "skilled nursing facilit*" OR "skilled-nursing facilit*" OR "aged-care facilit*" OR "aged care facilit*" OR "geriatric facilit*" OR "geriatric care facilit*" OR "residential care home*" )</li> <li>• AND</li> <li>• (randomized controlled trials OR MH double-blind studies OR MH single-blind studies OR MH random assignment OR MH pretest-posttest design OR MH cluster sample OR TI (randomised OR randomized) OR AB (random*) OR TI (trial) OR (MH (sample size) AND AB (assigned OR allocated OR control)) OR MH (placebos) OR PT (randomized controlled trial) OR AB (control W5 group) OR MH (crossover design) OR MH (comparative studies) OR AB (cluster W3 RCT)) NOT ((MH animals+ OR MH animal studies OR TI animal model*) NOT MH human)</li> </ul>
<b>SCOPUS</b>	<ul style="list-style-type: none"> <li>• TITLE-ABS-KEY ( "medication therapy management" OR "medication therapy assessment" OR "medicine management" OR "medicine therapy assessment" OR "medicine therapy management" OR "drug therapy management" OR "medication review*" OR "drug utilisation management" OR "drug utilisation management" OR "drug therapy</li> </ul>

	<p>service*" OR "medication management" OR "medication optim*" OR "medication use" OR "medication system" OR "deprescri*")</p> <ul style="list-style-type: none"> <li>• AND</li> <li>• TITLE-ABS-KEY ( "nursing home" OR "long term care" OR "long-term care" OR "residential home*" OR "skilled nursing facilit*" OR "skilled-nursing facilit*" OR "aged-care facilit*" OR "aged care facilit*" OR "geriatric facilit*" OR "geriatric care facilit*" OR "residential care home*" )</li> </ul>
<b>Cochrane Library</b>	<ul style="list-style-type: none"> <li>• [#1]: MeSH descriptor: [Nursing Homes]</li> <li>• [#2]: ("nursing home" OR "long term care" OR "long-term care" OR "residential home*" OR "skilled nursing facilit*" OR "skilled-nursing facilit*" OR "aged-care facilit*" OR "aged care facilit*" OR "geriatric facilit*" OR "geriatric care facilit*" OR "residential care home*"):ti,ab,kw</li> <li>• [#3]: [#1] OR [#2]</li> <li>• [#4]: ("medication therapy management" OR "medication therapy assessment" OR "medicine management" OR "medicine therapy assessment" OR "medicine therapy management" OR "drug therapy management" OR "medication review*" OR "drug utilisation management" OR "drug utilisation management" OR "drug therapy service*" OR "medication management" OR "medication optim*" OR "medication use" OR "medication system" OR "deprescri*"):ti,ab,kw)</li> <li>• [#5]: [#3] AND [#4]</li> </ul>
<b>Web of science</b>	<ul style="list-style-type: none"> <li>• nursing home OR long term care OR long-term care OR residential home OR skilled nursing facility OR skilled nursing facilities OR skilled-nursing facility OR skilled-nursing facilities OR aged-care facility OR aged-care facilities OR aged care facility OR aged care facilities OR geriatric facility OR geriatric facilities OR geriatric care facility OR geriatric care facilities OR residential care home OR residential care homes (Title)</li> <li>• OR</li> <li>• nursing home OR long term care OR long-term care OR residential home OR skilled nursing facility OR skilled nursing facilities OR skilled-nursing facility OR skilled-nursing facilities OR aged-care facility OR aged-care facilities OR aged care facility OR aged care facilities OR geriatric facility OR geriatric facilities OR geriatric care facility OR geriatric care facilities OR residential care home OR residential care homes (Abstract)</li> <li>• AND</li> <li>• medication therapy management OR medication therapy assessment OR medicine management OR medicine therapy assessment OR medicine therapy management OR drug therapy management OR medication review OR medication reviews OR drug utilisation management OR drug utilisation management OR drug therapy service OR drug therapy services OR medication management OR medication optimisation OR</li> </ul>

	<p>medication optimization OR medication use OR medication system OR deprescribe OR deprescribing OR de-prescribe or de-prescribing (Title)</p> <ul style="list-style-type: none"> <li>• OR</li> <li>• medication therapy management OR medication therapy assessment OR medicine management OR medicine therapy assessment OR medicine therapy management OR drug therapy management OR medication review OR medication reviews OR drug utilisation management OR drug utilisation management OR drug therapy service OR drug therapy services OR medication management OR medication optimisation OR medication optimization OR medication use OR medication system OR deprescribe OR deprescribing OR de-prescribe or de-prescribing (Abstract)</li> </ul>
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All retrieved references were exported into a reference management tool: EndNote X9, where duplicates were removed. Records were then imported into a systematic review management tool: Covidence.org, where de-duplication was repeated with the remaining titles left available for screening. All identified references were screened firstly at the title and abstract stage by two of three reviewers (AS, MS, MA), and then full-text reviews were independently undertaken by two of six reviewers (AS, MS, TG, MA, CB, CR) and judged for eligibility for inclusion. One reviewer (AS) screened all references, and the second screening of each record was divided amongst the remaining five reviewers. Any disagreements or concerns were resolved by discussion. The full-text screening included an individual screening of full-text articles, and any protocol or design articles were also searched to look for reporting of a theoretical basis for included interventions.

### **2.3.5. Data extraction and assessment**

A data extraction form (Appendix 2.3) was developed in accordance with the Cochrane Effective Practice and Organization of Care Review Group (EPOC) Data Collection Checklist template [258]. The extraction form was piloted, and refinements were made before the data extraction commenced to improve usability. This form guided extraction of the study characteristics (author, study design, the geographic region, sample size); study population characteristics (mean age, sex, comorbidity rate and index, dementia, depression), intervention characteristics (aim, HCPs involved, frequency and duration of delivery, location of intervention delivery, guidelines followed and follow-up time); the role of the pharmacist within the intervention; MMP stage(s) targeted; specific medication(s)/ condition(s) targeted; theory reporting and all outcomes assessed. Data were independently extracted by two of four reviewers (AS, MS, TG, MA); where the PhD student AS extracted all and second reviewer extraction was done by one of the 3 reviewers (MS, TG, MA), and any discrepancies were resolved by discussion.

### Quality assessment

The quality of individual studies was assessed using the tool developed by Jadad *et al.*, [259] available online as the Oxford Quality Scoring System [260]. Studies were scored as ‘high quality’ (score  $\geq 3$ ) or ‘low quality’ (score  $\leq 2$ ) across three domains: randomisation, blinding and drop-outs/withdrawals. The total score was obtained by answering yes or no questions, where ‘yes’ adds 1 point and ‘no’ either deducts 1 point or gives no point, according to the question (Table 2.3). A dual assessment of quality was undertaken by the same reviewers during the data extraction stage; where the PhD student AS extracted all and the second reviewer extraction was completed by one of the 3 reviewers (MS, TG, MA).

Table 2. 3 Jadad *et al.*, quality scoring or Oxford Quality scoring system [259]

Items	Score details
Was the study described as Randomised?	Yes= +1 No= 0
Was the method of randomisation described and appropriate?	Yes= +1 No= -1 Unclear= 0
Was the study described as double-blinded?	Yes= +1 No= 0
Was the method of blinding described and appropriate?	Yes= +1 No= -1 Unclear= 0
Was there a clear description of withdrawal and dropouts?	Yes= +1 No= -1 Unclear= 0
Score	Sum scores out of 5

### Risk of bias assessment

An assessment of bias risk was completed for all included studies by two reviewers during the data extraction stage; where the PhD student AS extracted all and the second reviewer assessment was undertaken by one of the three reviewers (MS, TG, MA), using the Cochrane Collaboration’s tool risk of bias tool [261]. The risk of bias tool assesses RCTs to determine the overall bias risk according to the following aspects:

- Sequence generation: selection bias (*were participants allocated randomly to intervention or control group?*);
- Allocation concealment: selection bias (*could intervention allocations have been predicted prior to, or during enrolment?*);



- Blinding of participants or personnel: performance bias (*were participants and personnel blinded to knowledge of which intervention participants received?*);
- Blinding of outcome assessments: detection bias (*were outcome assessors blinded to knowledge of which intervention participants received?*);
- Incomplete outcome data: attrition bias (*how complete is the outcome data including attrition and exclusions?*); and
- Selective reporting: reporting bias (*were all the pre-specified outcomes reported in the study results?*).

Included studies were judged for ‘high,’ ‘low’ or ‘unclear’ risk of bias for each component.

### Certainty of evidence

The overall certainty level of evidence for the five most commonly reported outcomes across the included studies was determined. These were scored as ‘high,’ ‘moderate’ or ‘low’ certainty level using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) tool within GRADEpro GDT [262].

Outcomes were assessed for ‘serious,’ ‘not serious’ or ‘very serious’: bias risk, inconsistency, indirectness, imprecision, and publication bias. For each ‘serious’ score, the level of certainty was downgraded by one unit.

### Theory

The same extraction process was used to identify the theoretical underpinning using the TCS (Table 2.1), which consists of 19 items across six categories [249].

- Categories 1-3 assess the extent to which the reported intervention was theory-based (‘Is theory mentioned’; ‘Are relevant theoretical construction targeted by the intervention’; ‘Is theory used to select interventions recipients or tailor interventions?’)
- Categories 4-6 describe theory testing and refinement (‘Are the relevant theoretical constructs measured’; ‘Is theory tested’; ‘Is theory refined’)

### **2.3.6. Data analysis**

The effect of the interventions on the five most commonly measured outcomes in the included trials was analysed: ((i) appropriateness of prescribing, (ii) frequency of prescribing—the number of medicines prescribed per resident/ residents prescribed medications, (iii) falls, (iv) hospitalisations and (v) mortality).

Where adequate data for meta-analysis at 12-months follow-up was reported, the odds ratios (ORs) for dichotomous outcomes or standard mean differences (SMDs) for continuous outcomes, both with 95% confidence intervals (Cis) and two-sided *p*-values for each outcome, was reported. A *p*-value < 0.05 was considered significant. Statistical heterogeneity ( $I^2$ ) between studies was quantified using the Chi-squared ( $\chi^2$ ) test and the  $I^2$  statistic. A fixed-effects model was used to calculate the pooled effect estimate for outcomes with no significant heterogeneity. Where substantial and considerable heterogeneity ( $I^2 > 50\%$ ) was present, a random-effects model was applied. Meta-analyses were conducted using Review Manager (RevMan) [Computer program] Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

#### *Narrative summary*

Where there was significant heterogeneity of the outcomes measured between studies, not all studies or outcomes could be meta-analysed. Thus, a narrative synthesis was undertaken.

## **2.4. RESULTS**

The literature search identified 18,635 references after removing duplicates ( $n = 4,081$ ) (Figure 2.1). Following the title and abstract screening of 14,554 reports, a total of 145 full-text articles were retrieved and screened for eligibility. Of these, 115 reports were excluded due to various reasons such as wrong study design, wrong intervention, (*e.g.*, no involvement of a pharmacist in the intervention), wrong population, wrong setting, trial not completed, a further duplicate found not detected earlier, and non-English language reports. Nineteen manuscripts [1, 263-280] were deemed eligible for inclusion. Two papers [1, 280] reported the same intervention with different follow-up times, therefore 18 interprofessional interventions were included, involving a total of 19 manuscripts.

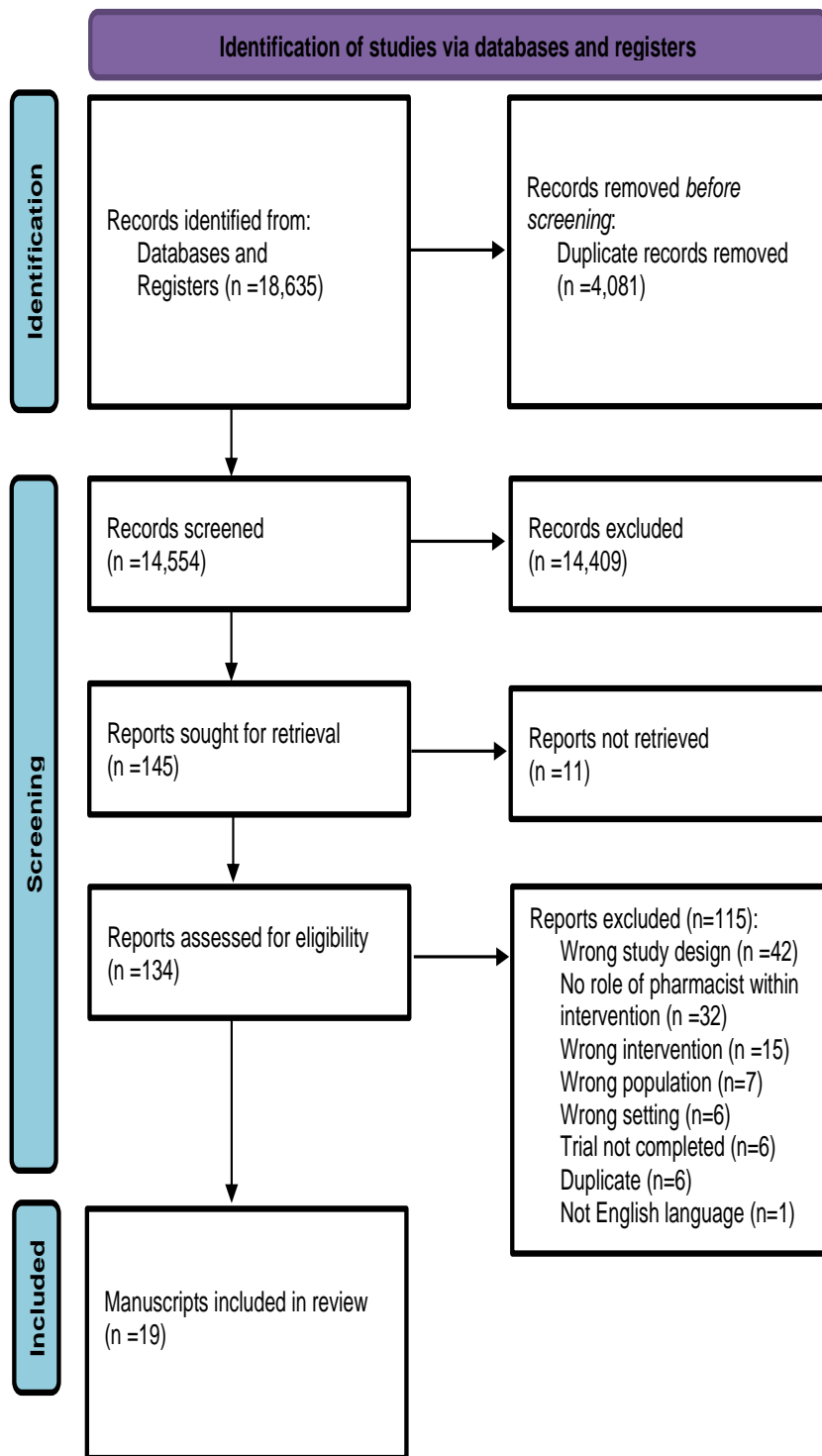


Figure 2. 1 PRISMA diagram

The included interventions employed cluster randomisation by NH (n=12) and individual participant randomisation (n=6). These interventions were conducted in Europe (n= 6) [270-272, 276, 277, 279], Australia (n= 4) [1, 263, 264, 269, 280] (two manuscripts referenced are for one intervention), the UK (n= 3) [268, 273, 274], Canada (n= 2) [266, 278], United States of America (n= 1) [267], Asia (n=1) [275], and the Middle East (n= 1) [265], and were published from 1998 to 2021 (Table 2.4) .

#### **2.4.1. Characteristics of participants**

A total of 27,001 NH residents were recruited across all included 18 RCTs (experimental n=13,823 and control n=13,178). The mean age of participants was ≥65 years as per the inclusion criteria. Female gender constituted approximately 70% of the total study population in fourteen included RCTs that reported sex [1, 263-266, 268, 270-273, 275-277, 280]. The prevalence of dementia ranged from 26.8% [275] to 100% [271, 276] amongst included residents, which was reported in fourteen studies [1, 263-265, 267, 270-278, 280]. The mean number of medicines prescribed per resident ranged from two to thirteen medicines, as reported in nine studies [264-268, 270-273]. Regarding comorbidities, four trials [267, 268, 275, 277] reported the mean number of comorbidities in their included population (mean= 3.8 to 6) and 3 trials [1, 265, 272] reported Charlson Comorbidity Index, as a measure of comorbidity (mean= 2) (Table 2.5).

#### **2.4.2. Characteristics of interventions**

Interprofessional interventions were described in 13 of the included interventions (reported in 14 manuscripts) as; *multidisciplinary* (n=9) [1, 263, 269-272, 275, 276, 280], *interdisciplinary* (n=2) [266, 277], *multiple healthcare professionals* (n=2) [274, 278], and *interprofessional* (n=1) [279]. Other included articles described interprofessional interventions but without reporting a specific term for the collective working between professions [264, 265, 267, 268, 273] (Table 2.4).

Pharmacists' direct-patient care roles were: to recognise PIP and MRPs [263, 265, 266, 268, 269, 271-277]; improve prescribing, identify and monitor drug use and interactions [267-271, 274, 275]; medication simplification (Box 2.1) [1, 280]; flag high-risk patients through accessing residents' records and medication charts [266]; provide educational sessions [279] or academic detailing (Box 2.1) [264, 278]; participate in interdisciplinary case conferences [263, 277] and discuss medicines related recommendations with resident/family representative [1, 268, 273, 275, 280]. Other roles included the supply of medicines [277] and organising interprofessional meetings [270] (Table 2.4).

Table 2. 4 Characteristics of included RCTs with intervention description

Author year region	Sample Size of IG	Study Aim	Interprofessional team contributors	Pharmacist's role within the intervention	Frequency of delivery	Location	Tools / Guidelines followed	MMP stage (s) targeted
Cateau 2021 [279], Europe	1248	'Design and trial deprescribing interventions to reduce the use of potentially inappropriate medications'	Physician, pharmacist, and NH staff	Provision of educational sessions	Once and follow-up after 4 months	NH	Beers Criteria, NORGEP-NH	Prescribing
Crotty 2004 [263], Australia	154	'Evaluate the impact of multidisciplinary case conferences on the management of residents with medication problems and difficult behaviours (pain- and dementia-related) in high-level residential aged care facilities'	GP, geriatrician, pharmacist, NH staff, and representative of the Alzheimer's Association of South Australia	1. Attending case conferences 2. MR to identify PIP	Once a month for 12 months	NH	GPs medical records and case notes prepared by NH staff	Prescribing
Crotty 2004 [264], Australia	665	'Examine the impact of an outreach visit intervention, targeting falls reduction and stroke prevention in a residential care setting'	Physician, pharmacist and nurse	1. Academic detailing visit to physicians at the surgery. 2. Educational sessions for nurses at the facility	One, 30 minutes academic detailing to physician + 4 sessions, 2 hours each educational visit to the facility. 4- and 7-months follow-up	GP practice/ surgery and NH	WHO guidelines + Southeast Institute of Public Health	Prescribing, administering, monitoring
Desborough 2020 [274], UK	826	'Determine the clinical and cost-effectiveness of a multi-professional medication review (MPMR) service in care homes for older people'	GP, pharmacist, pharmacy technician, NH staff, and resident/family	90- Pharmaceutical care plan: identify interactions and PIP, assess unmet pharmaceutical needs, and make dose/medication adjustments. 2- Participation in Multidisciplinary MR meeting to discuss recommendations	0 and 6 months, follow-up at 12 months	NH	START criteria	Prescribing
Frankenthal 2014 [265], Middle east	306	'Assess the effect of a Screening Tool of Older Persons potentially inappropriate Prescriptions/ Screening Tool to Alert doctors to Right Treatment (STOPP/START) medication intervention on clinical and economic outcomes'	Physician and pharmacist	MR to identify PIP and PPO	Every 6 months for 12 months	NH	STOPP/ START criteria	Prescribing

Author year region	Sample Size of IG	Study Aim	Interprofessional team contributors	Pharmacist's role within the intervention	Frequency of delivery	Location	Tools / Guidelines followed	MMP stage (s) targeted
Kennedy 2015 [266], Canada	5,478	'Examined the effectiveness of a multifaceted, interdisciplinary KT intervention for improving the prescribing of vitamin D, calcium and osteoporosis medications over 12-months'	Physicians, pharmacists, nurses, and other staff such as nutritionists and physiotherapists	1-Flag residents with a high risk of falls and fractures 2-Participation in interdisciplinary action planning meetings	Every 6 months for 12 months	NH	-Ontario Osteoporosis Strategy (in educational component) -2010 Osteoporosis Canada Clinical Practice Guidelines (in MR component)	Prescribing and monitoring
Kua 2020 [275], Asia	295	'Examine the effectiveness of a pharmacist-led 5-step team-care deprescribing intervention (comprising Beers and STOPP criteria) in a nursing home setting in primarily reducing falls (fall risks and fall rates) and secondarily reducing pill burden, mortality, number of hospitalised residents, medication cost, and assessing the deprescribing acceptance rate.'	Physician, pharmacist, nurse and resident/family member	1. MR. 2. Initiation of deprescribing 3- Discuss with NH staff and resident/family members	Once weekly or fortnightly, follow-up at 3-, 6-, and 12-months	NH	Beers and STOPP criteria	Prescribing and monitoring
Lapane 2011 [267], United States	3321	'Determine the extent to which the use of the GRAM clinical tool would reduce the incidence of potential delirium, falls, hospitalisations potentially due to ADEs, and mortality.'	Pharmacist, nurse and nurse assistants	1-MR using GRAM software 2-Share reports with nurses	Once a month for 12 months	NH	GRAM software	Monitoring.
Patterson 2010 [268], United Kingdom	334	'Test the adapted model in a cluster randomised controlled trial in which the primary outcome was a change in the proportion of residents who received inappropriate psychoactive medication.'	Physician, pharmacist, NH staff and resident's family	1- Visit NH monthly, 2- Collect clinical information 3- Assess the pharmaceutical care needs by interviewing residents/family 4- PIP and MRP identification and monitoring recommendations recorded. 5- Discuss recommendations with NH staff, family	Once a month for 12 months	NH	OBRA nursing home Reform Act recommended guidelines, USA.	Prescribing and monitoring
Roberts 2001 [269], Australia	2325	'Evaluate whether a yearlong clinical pharmacy program involving the development of professional relationships, nurse education on medication issues, and individualised MRs could change drug use, mortality	GPs, pharmacists, nurses	1.MR. 2. Educational sessions for NH staff during facility visits	Eleven and 26 hours of nurse education and pharmacist visit, respectively, over the 12 months study period	NH	Not reported	Prescribing, monitoring and administering

Author year region	Sample Size of IG	Study Aim	Interprofessional team contributors	Pharmacist's role within the intervention	Frequency of delivery	Location	Tools / Guidelines followed	MMP stage (s) targeted
		and morbidity in nursing home residents.'						
Schmidt 1998 [270], Europe	1854	'Evaluate the impact of regular multidisciplinary team interventions on the quantity and quality of psychotropic drug prescribing in Swedish nursing homes'	Physician, pharmacist, nurses, and nurse assistant	1.Organising the interprofessional team meetings 2. Participation in the monthly interprofessional MR meeting to improve prescribing and minimise non-recommended drugs	Once a month for 12 months	NH	SMPA	Prescribing
Sluggett 2020 [1, 280], Australia	242	'The impact of structured medication regimen simplification on medication administration times falls, hospitalisation, and mortality at 8 residential aged care facilities (RACFs)'	GP, pharmacist, nurse and resident/family	Medication simplification and discussing recommendations with other stakeholders	One MR for each resident and follow-up at -4, -8, -12 months	NH	MRS GRACE	Administering
Smeets 2020 [276], Europe	380	'Evaluate the effect of the PROPER intervention in nursing home residents with dementia on (1) the prevalence of psychotropic drug use prescribed for neuropsychiatric symptoms and on (2) the occurrence of neuropsychiatric symptoms'	Prescriber, pharmacist, nurse, nurse assistant, and resident representative.	Provision of pharmacological information during the MR	Not specified, follow-up every 6 months for 18 months	NH	STRIP, START, STOPP and Guideline for problem behavior of the Dutch Association of Elderly Care Physicians and social geriatrician (verenso)	Prescribing
Strauven 2019 [277], Europe	1507	'Describe the impact of a complex multifaceted intervention, developed in the COME-ON study, on the appropriateness of prescribing for NH residents'	GP, pharmacist and nurse	Supply of medicines*	Every 4 months for 12 months	NH	STOPP, START, Beer's criteria	Prescribing
Tadrous 2020 [278], Canada	5363	'Evaluate the real-world effectiveness of an academic detailing intervention in nursing homes across Ontario targeting appropriate prescribing of antipsychotics and the management of behavioral and psychological symptoms of dementia'	Pharmacist and nurses	Academic detailing	Mean 6.2 presentations and meetings held per NH during 12 months	NH	Principles of Educational Outreach ('Academic Detailing') to address challenges and opportunities for improving prescribing of antipsychotics	Prescribing and dispensing

Author year region	Sample Size of IG	Study Aim	Interprofessional team contributors	Pharmacist's role within the intervention	Frequency of delivery	Location	Tools / Guidelines followed	MMP stage (s) targeted
Van Der Spek 2018 [271], Europe	380	'Study the impact of a structured repeated multidisciplinary MR on the appropriateness of psychotropic drug prescriptions'	Physician pharmacist, nurse and Dutch Institute for Rational Use of Medicine (IVM)	1- Participation in multidisciplinary MR to provide pharmaceutical information and knowledge.	Every 6 months for 18 months	NH	Guideline for problem behaviour of the Dutch Association of Elderly Care Physicians and Social Geriatricians (Verenso) for education and STOPP, START, STRIP for a MR	Prescribing
Wouters 2017 [272], Europe	992	'Assess whether multidisciplinary systematic MRs increase successful discontinuation of inappropriate medication use, improve prescribing in other respects, and improve clinical outcomes in nursing home residents.'	Physician, pharmacist, NH staff and resident/family	1.MR to improve prescribing. 2.Meeting with the prescriber to make pharmacotherapeutic decisions	One time then follow-up after 4 months	Not reported	START, STOPP, Beer's criteria	Prescribing and monitoring.
Zermansky 2006 [273], United Kingdom	331	'Measure the impact of pharmacist-conducted clinical MR with elderly care home residents'	GP, pharmacist and resident/carer	90- MR of GP clinical records 2- Consult with the resident/carer	Not specified, after 6 months	NH	Not reported	Prescribing and administering

IG: Intervention Group; MMP: Medicines Management Process; NH: Nursing Home; NORGEP-NH: Norwegian General Practice – Nursing Home; GP: General Practitioner; MR: Medication review; PIP: Potentially Inappropriate Prescribing; WHO: World Health Organization; START: Screening Tool to Alert doctors to Right Treatment; STOPP: Screening Tool of Older Person's potentially inappropriate Prescriptions; PPO: Potentially Prescribing Omission; KT: Knowledge translation; GRAM: Geriatric Risk Assessment MedGuide; ADE: Adverse Effect; MRP: Medication-Related Problem; OBRA: Omnibus Budgetary Reconciliation Act; SMPA: Swedish Medical Product Agency; MRS GRACE: Medication Regimen Simplification Guide for Residential Aged Care; STRIP: Systematic Tool to Reduce Inappropriate Prescribing.

\*Pharmacist role was reported to be limited to the supply of medicines in the intervention, despite being described in the intervention description on their involvement in interprofessional.



Table 2. 5 Participant characteristics

Characteristic/ Author year, region	Number of residents	Age <sup>1</sup>	Sex %	Number of comorbidities <sup>1</sup>	Charlson Comorbidity Index	Dementia %	Depression %
<b>Cateau Europe</b> 2021,	Average IG=48 CG=35	Not reported	Not reported	Not reported	Not reported	Not reported	
<b>Crotty Australia</b> 2004,	IG=50 CG=54	Age mean IG=85.5 CG= 83.6	Male IG= 44 CG: 43	Not reported	Not reported	IG= 67 CG=74	IG=29 CG=28
<b>Crotty Australia</b> 2004,	IG=381 CG=334	Age mean IG=84.7 CG=83.4	Female IG=85.5 CG=82	Not reported	Not reported	IG=42.7 CG=33.4	IG=17.8 CG=19.2
<b>Desborough UK</b> 2020,	IG=381 CG=445	Age mean IG=88.4 CG=86	Male IG=20.5 CG=27.2	Not reported	Not reported	IG=45.9 CG=53.3	Not reported
<b>Frankenthal Middle east</b> 2014,	IG=183 CG=176	Age mean 65–74 IG=29 CG=36	Female IG=70.5 CG=62.5	Not reported	IG=44.3 CG=50.6	IG=53.6 CG=56.3	IG=23.9 CG=25.5
		75–84 IG=63 CG=63					
		≥85 IG=91 CG=77					
<b>Kennedy Canada</b> 2015,	IG=2185 CG=3293	Age mean IG=84 CG=84.6	Female mean <sup>2</sup> IG=70.4 CG=71.1	Not reported	Not reported	Not reported	Not reported
<b>Kua 2020, Asia</b>	IG=448 CG=437	Age mean IG=80.57 CG=80.02	Female IG=58 CG=52.8	Mean IG=6.01 CG=5.99	Not reported	IG=26.8 CG=36.62	IG=13.07 CG=7.7
<b>Lapane United States</b> 2011,	IG=1711 CG=1492	Age 65–74 IG=16.3% CG=15.8%	Female IG=72.3 CG=68.2	4–5 IG=30.4% CG=31.3% ≥6 IG=37.3% CG=45.4%	Not reported	IG=35.4 CG=43.4	Not reported
		75–84 IG=35.9% CG=35.3%					
		≥85 IG=39.7% CG=36.4%					
<b>Patterson United Kingdom</b> 2010,	IG=173 CG=161	Age mean IG=82.6 CG=82.9	Female IG=72.3 CG=73.4	Mean IG=4.1 CG=3.8	Not reported	Not reported	Not reported
<b>Roberts Australia</b> 2001,	IG=1258 CG=549	<60 IG=2.0% CG=2.6%	Not reported	Not reported	Not reported	Not reported	Not reported
		60-69 IG=6.6% CG=5.4%					
		70-79 IG=21.9% CG=22.3%					
		80-89 IG=47.4% CG=46.7%					
		90-99 IG=20.7% CG=21.1%					
<b>Schmidt Europe</b> 1998,	IG=626 CG=1228	Age mean IG=83 CG=84	Female IG=70 CG=67	Not reported	Not reported	IG=42 CG=37	IG=7 CG=6
<b>Sluggett Australia</b> 2020,	IG=99 CG=143	Age mean IG=85.5	Female IG=78.3	Not reported	Mean IG=2	Mean <sup>2</sup> IG=54	Not reported

Characteristic/ Author year, region	Number of residents	Age <sup>1</sup>	Sex %	Number of comorbidities <sup>1</sup>	Charlson Comorbidity Index	Dementia %	Depression %
		CG=86.5	CG=67.7		CG=2	CG=77	
<b>Smeets 2020, Europe</b>	IG=222 CG=158	Age mean IG=84 CG=83	Female IG=72 CG=78	Not reported	Not reported	Alzheimer's dementia IG=41 CG= 23 Vascular dementia IG=12 CG=18 Mixed Alzheimer's/vascular dementia IG=10 CG=12 Other dementia IG=37 CG=46	Not reported
<b>Strauven 2019, Europe</b>	IG=847 CG=957	Age mean IG=87 CG=88	Female IG=71.3 CG=69.7	Mean IG=25 CG=24	Not reported	IG=56.1 CG=56	Not reported
<b>Tadrous 2020, Canada</b>	IG=2303 CG=3060	Age mean IG=86 CG=85	Men IG=29.3 CG=31.7	Not reported	Not reported	IG=88.8 CG=88.5	DRS mean <sup>2</sup> IG= 2.81 CG=2.18
<b>Van Der Spek 2018, Europe</b>	IG=222 CG=158	Age mean IG=84 CG=83	Female IG=77.9 CG=72.2	Not reported	Not reported	Alzheimer's dementia IG=40.5 IG=23.4 Vascular dementia IG=2712.2 CG=18.4 Mixed Alzheimer's/vascular dementia IG=9.9 CG=12.0 Other dementia IG=37.4 CG=46.2	
<b>Wouters 2017, Europe</b>	IG=233 CG=193	Age mean IG=83.7 CG=83.2	Female IG=65 CG=71	Not reported	IG=2 CG=2	IG=43 CG=45	Not reported
<b>Zermansky 2006, United Kingdom</b>	IG=331 CG=330	Age mean IG=85.3 CG=84.9	Male IG=75 CG=79	Not reported	Not reported	Not reported	Not reported

IG: Intervention group, CG: Control group, DRS: Depression Rating Scale

1: Numbers are reported in either age mean or percentage (%) as per original manuscript reporting.

2: These studies the reporting of sex, dementia and depression in (mean).

HCPs that contributed to interventions included: pharmacists (in all interventions being an inclusion criterion), general practitioners (GPs), specialist physicians and nurses [263-267, 269, 270, 278, 279]. Eight interventions reported that in addition to HCP groups, resident/family member or their representative were consulted on any changes before the final decision to change or otherwise was made [1, 268, 271-276, 280] (Table 2.4).

Stages of the MMP that were targeted include: prescribing (n=16) [263-266, 268-279]; monitoring (n=7) [264, 266-269, 272, 275], administration (n=4) [1, 264, 269, 273, 280] and dispensing (n=1;[278]). One intervention described the education of nurses on the topic of ‘medicines management’, but there was no description of the stage(s) of the MMP that were addressed during the education [264] (Table 2.4).

Seventeen interventions were provided in the NH, one of which was also provided in the GP practice. One study, however, did not report the intervention location, but it was provided to older people residing in the NH setting [272] (Table 2.4).

***Box 2.1 Definitions of interventions, as defined by authors of RCTs.***

**Medication simplification:** “consolidating the number of administration times through strategies such as administering medications at the same time, using long-acting formulations where available, and switching from multiple single-ingredient to combination formulations, without changing the therapeutic intent of the medication regimen” [1]

**Academic detailing:** “is an outreach education technique that combines the direct social marketing traditionally used by pharmaceutical representatives with unbiased content summarising the best evidence for a given clinical issue” [2]

*Medication review interventions*

Twelve interventions involved medication review (MR), either solely by a pharmacist (n= 6)[263, 265, 267, 269, 273, 275] whose recommendations were then discussed with a physician for decision making; or in an interprofessional MR meeting (n=6) [266, 270-272, 276, 277] where a pharmacist, physician and nurse met at the same time to agree on therapeutic actions (Table 2.4). Prior to the provision of MRs, two manuscripts reported holding interdisciplinary case conferences where GPs, pharmacists, and NH staff identified PIP [277] and cases that required discussions from the NH staff’s perspective [263] (Table 2.4).

Four MR interventions [266, 269, 271, 276] preceded an educational component that was provided by either specialist physicians to other stakeholders on osteoporosis prevention [266] or experts to physicians, pharmacists and nurses on psychotropic drug use and how to conduct MRs [271, 276]. One study delivered education on over-the-counter medicines, psychoactive and antibacterial medications to nurses but reported that these sessions were supported by pharmacists’ visits [269] (Table 2.4).

One study described '*pharmaceutical care*' [268], where the intervention was provided by pharmacists to assess pharmaceutical care needs, identify MRPs, assess prescribing and monitor drug use; recommendations were discussed by other NH staff, family members and GPs. Another study reported the provision of pharmaceutical care by a pharmacist independent of the interprofessional MR meeting that involved a pharmacist discussing the pharmaceutical care plan recommendations with a GP, NH staff, and a pharmacy technician to agree on an action plan [274] (Table 2.4 ).

All MR interventions varied in prescribing evidence-based criteria/tool/guidance used. The indicators employed were the Swedish Medical Product Agency recommendation guidelines on psychotropic drug use [270]; Screening Tool of Older Persons potentially inappropriate Prescriptions/ Screening Tool to Alert doctors to Right Treatment (STOPP/START) [265, 272, 274, 275]; Beer's criteria [272, 275, 279]; Geriatric Risk Assessment Medguide (GRAM): electronic reporting software [267]; Medication Regimen Simplification Guide for Residential Aged Care (MRS GRACE) [1]; Norwegian General Practice – Nursing Home criteria (NORGEP-NH) [279]; and algorithms on appropriate prescribing from Omnibus Reconciliation Act (OBRA) [268].

#### Medication simplification interventions

Both of Sluggett *et al.*'s manuscripts (reporting the same interventions at different follow-up times) [1, 280] reported a medication simplification intervention delivered by a pharmacist and subsequently discussed with the resident, family member, nursing staff and GP. The medication regimens in this intervention were 'simplified' using the Medication Regimen Simplification Guide for Residential Aged Care (MRS GRACE) (Table 2.4).

#### Education interventions

Three interventions [264, 278, 279] were education through academic detailing (n= 2) [264, 278] and quality circles based education (n=1) [279]. Academic detailing was provided by a pharmacist to physicians on fall prevention, management of hypertension [264]; to both physicians and nurses on stroke risk management [264] and psychotropic drug use management and reduction [264, 278]. Cateau *et al.*'s intervention involved educational sessions provided by the study investigators to pharmacists on considerations regarding polypharmacy, potentially inappropriate medicines (PIM) and deprescribing measures. Information regarding supportive tools and guidelines for prescribing in older people was provided. Information was also provided on the appropriate prescribing of specific classes of medicines in the older cohort (*e.g.*, proton-pump inhibitors, antipsychotics, antihypertensive, etc.) [279] (Table 2.4).

### 2.4.3. Quality assessment

Seven interventions [1, 264, 265, 268, 272, 275, 279, 280] were scored as ‘high’ quality and the remaining 11 [263, 266, 267, 269-271, 273, 274, 276-278] as ‘low’ quality. Two studies [1, 270] did not clearly report how randomization was undertaken. None of the studies were double-blinded (Table 2.6).

Table 2. 6 Quality assessment using Jadad et al., scale [259]

Reference Items:	Score details:	Cateau et al. [279]	Crotty et al. [263]	Crotty et al. [264]	Desborough et al. [274]	Frankenthal et al. [265]	Kennedy et al. [266]	Kua et al. [275]	Lapane et al. [267]	Patterson et al. [268]	Roberts et al. [269]	Schmidt et al. [270]	Sluggett et al. [1, 280]	Smeets et al. [276]	Strauven et al. [277]	Tadrous et al. [278]	Van der Spek et al. [271]	Wouters et al. [272]	Zermansky et al. [273]
		Was the study described as Randomised?	Yes= +1 No= 0	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Was the method of randomization described and appropriate?	Yes= +1 No= -1 Unclear= 0	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y
Was the study described as double-blinded?	Yes= +1 No= 0	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Was the method of blinding described and appropriate?	Yes= +1 No= -1 Unclear= 0	UN	N	Y	Y	Y	N	Y	N	Y	N	N	UC	N	N	Y	N	UC	N
Was there a clear description of withdrawal and dropouts?	Yes= +1 No= -1 Unclear= 0	Y	Y	N	N	N	Y	Y	N	Y	N	Y	Y	Y	N	N	N	Y	Y
Score	Sum scores out of 5	3	2	3	2	3	2	4	1	4	1	0	3	2	0	2	1	3	1




Y: Yes; N: No; UN; Unclear

#### 2.4.4. Risk of Bias

The risk of bias summary is displayed in Figure 2.2. All the included studies had a moderate risk of bias. The blinding of participants and personnel (performance bias) was identified as ‘high’ risk for 10 interventions [1, 264, 267, 270, 273-277, 279, 280] and ‘unclear bias risk’ for the other eight [263, 265, 266, 269-272, 278]. The blinding of outcome assessment (detection bias) was identified in seven studies as ‘low risk’ of bias [268, 273-278], in five studies as ‘unclear risk’ [264, 266, 269, 271] and in six studies as ‘high risk’ [1, 263, 265, 267, 272, 279, 280]. Two studies [264, 279] had a ‘high risk’ of bias for selective outcome data and the remainder were ‘low risk’. Random sequence generation (selection bias) was identified as ‘low’ risk of bias across all included RCTs.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Cateau 2021	+		-	-	+	-
Crotty* 2004	+	+			+	
Crotty 2004	+		-	-	+	-
Desborough 2020	+	-	-	+	+	+
Frankenthal 2014	+	+		-	+	+
Kennedy 2015		+			+	
Kua 2020	+		-	+	-	+
Lapane 2011	+	+	-	-	+	+
Patterson 2010	+	+	-	+	+	+
Roberts 2001	+				+	+
Schmidt 1998	+	+	-	-	+	
Sluggett 2020	+	+	-	-	+	+
Smeets 2020	+	+	-	+	+	
Strauven 2019	+		-	+	+	+
Tadrous 2020	+	-		+	+	+
Van Der Spek 2018	+				-	+
Wouters 2017	+			-	+	+
Zermansky 2006	+	-	-	+	+	+

Figure 2. 2 Risk of bias assessment

 LOW RISK    
  HIGH RISK    
  UNCLEAR RISK

## 2.4.5. Certainty of evidence

The overall certainty of evidence of the five outcomes at 12 months follow-up was qualified (Table 2.7). The certainty level of evidence was downgraded in four outcomes due to the high heterogeneity and low sample size. Hospitalisation as an outcome, was the only outcome with high certainty.

Table 2.7 Certainty of evidence assessment

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	interprofessional interventions involving pharmacist	usual care	Relative (95% CI)	Absolute (95% CI)		
<b>Appropriateness of prescribing (follow-up: median 12 months)</b>												
3	Randomised trials	Not serious	Not serious	Not serious	Serious <sup>a</sup>	None	449	480	-	SMD <b>0.2 SD lower</b> (0.33 lower to 0.07 lower)	⊕⊕⊕○ Moderate	CRITICAL
<b>Falls (follow-up: median 12 months)</b>												
3	Randomised trials	Not serious	Serious <sup>b</sup>	Not serious	Not serious	None	768	869	-	SMD <b>0.12 SD lower</b> (0.32 lower to 0.08 higher)	⊕⊕⊕○ Moderate	CRITICAL
<b>Hospitalization (follow-up: median 12 months)</b>												
4	Randomised trials	Not serious	Not serious	Not serious	Not serious	None	9175	9769	-	SMD <b>0 SD</b> (0.02 lower to 0.03 higher)	⊕⊕⊕⊕ High	
<b>Mortality (follow-up: median 12 months)</b>												
5	Randomised trials	Not serious	Serious <sup>c</sup>	Not serious	Not serious	None	633/11687 (5.4%)	646/10970 (5.9%)	<b>OR 0.99</b> (0.79 to 1.24)	<b>0 fewer per 100</b> (from 1 fewer to 1 more)	⊕⊕⊕○ Moderate	CRITICAL
<b>Frequency of prescribing (follow-up: median 12 months)</b>												

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	interprofessional interventions involving pharmacist	usual care	Relative (95% CI)	Absolute (95% CI)		
3	Randomised trials	Not serious	Rerious <sup>d</sup>	Not serious	Not serious	Publication bias strongly suspected <sup>e</sup>	1182	1831	-	SMD 0.28 SD higher (0.15 lower to 0.7 higher)	⊕⊕○○ Low	CRITICAL

\*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; OR: odds ratio; SMD: standardised mean difference

#### GRADE Working Group grades of evidence

**High certainty:** we are very confident that the true effect lies close to that of the estimate of the effect.

**Moderate certainty:** we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

**Low certainty:** our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

**Very low certainty:** we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

**Explanations:** a. one study has a small sample size, b. Heterogeneity= 74%, c. Heterogeneity= 60%, d. Heterogeneity= 96%, e. 2/3 studies had unclear selective reporting bias which may have affected publication

#### 2.4.6. Theory coding scheme

Item 1 in category 1 of the TCS describes whether a theory is mentioned (Section 2.3.5) (Table 2.1). None of the included interventions mentioned ‘theory’ or ‘model’ in intervention development either in the description of the published full-text manuscripts or in the study’s protocol, if written as a separate study. Thus, further assessment using the remaining items and categories of the TCS tool was not possible, as none of the included interventions described using theory in their development.



### 2.4.7. Effect of interprofessional interventions on outcomes measure

The included studies measured the intervention effect at 3 [275], 4 [1, 263, 272, 277, 279], 6 [265, 266, 271, 273-275, 278], 8 [277, 280], 12 [264-270, 274, 275, 277, 278, 280], and 18 [271, 276] months' follow-up. Eleven studies in total reported adequate data for the meta-analysis (standard mean difference and odds ratio variables) on the following outcomes: appropriateness of prescribing (n=3), frequency of prescribing (n=3), fall rate (n=3), mortality rate (n=5) and incidence of hospitalisation (n=4) (Appendix 2.4). Outcomes with insufficient data for meta-analysis and heterogeneity in outcomes measurements were narratively reported; onset of delirium, quality of life, neuropsychiatric symptoms and care-need and disability, summarised in Table 2.8).

Table 2. 8 Outcomes measured for narrative summary.

Study	Intervention type	Outcomes Measured	Quality of life	Behavior assessment	Neuropsychiatric symptoms	Care-need and disability	Onset of delirium
<i>Crotty et al.</i>	Medication review + education	Method of measurement Results		NHBPS  No significant change*			
<i>Frankenthal et al.</i>	Medication review	Method of measurement  Results	SF-12 health survey and expressed in two scores: physical component summary and cognitive component summary  No significant change*				
<i>Lapane et al.</i>	Medication review	Method of measurement Result					Incident rate per 1000 residents Reduced (rate for IG= 36.4 and CG= 99.1post-

Study	Intervention type	Outcomes Measured	Quality of life	Behavior assessment	Neuropsychiatric symptoms	Care-need and disability	Onset of delirium
<i>Roberts et al.</i>	Medication review + education	Method of measurement Result				RCI  No significant change*	intervention with HR0.42(0.35-0.52))
<i>Sluggett et al.</i>	Medication simplification	Method of measurement Result	QoL-AD scale score  No significant change at follow-up (IG=33.9 and CG=34.1)*				
<i>Smeets et al.</i>	Medication review + education	Method of measurement Result				Difference in slopes per 6 months for NPI-Q and CMAI scores. No significant change between intervention and control group*	
<i>Tadrous et al.</i>	Education	Method of measurement Result	ADL score after 24 months No significant change (IG=15.43 and CG=15.08)*	ABS score at 6 months follow-up No significant change (IG=1.56 and CG=1.56)			
<i>Van Der Spek et al.</i>	Medication review + education	Method of measurement Result	Physical function: EQ-5D-3L and DQI utilities score -Cognitive function: SIB-S score and MMSE score. -Physical function: No significant change				

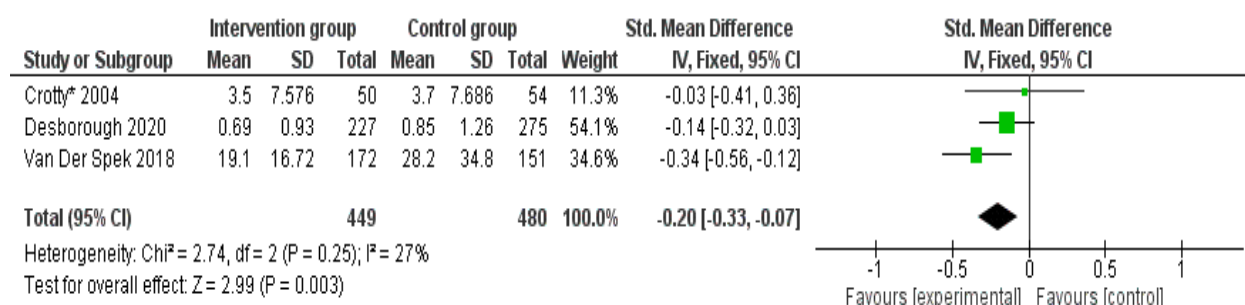
Study	Intervention type	Outcomes Measured	Quality of life	Behavior assessment	Neuropsychiatric symptoms	Care-need and disability	Onset of delirium
			(EQ-5D-3L: IG= 0.41 and CG= 0.33) DQI: IG=0.46 and IG= 0.34) -Cognitive function: No significant change (SIS-S: IG= 30.1 and CG= 27.3) MMSE: IG= 11.1 and CG= 9.2)				
<i>Wouters et al.</i>	Medication review	Method of measurement Result			NPI-NH score  No significant change (IG= 14 and CG= 22.2)		
<i>Zermansky et al.</i>	Medication review	Method of measurement  Results	-Physical function: Barthel activities of Daily Living Index -Cognitive function: SMMSE -Physical function: No significant change* -Cognitive function: No significant change*				

NHBPS: Nursing Home Behaviour Problem Scale; SF: Short form; IG= Intervention Group; CG: Control Group, HR: Hazard Ratio, CI= Confidence Interval; RCI: Resident Classification Instrument; QoL-AD: Quality of Life in Alzheimer's Disease; NPI-Q: Neuropsychiatric Inventory – Questionnaire; CMAI: Cohen-Mansfield Agitation Inventory; ADL: Activities of Daily Living; ABS: Aggressive Behaviour Scale; EQ-5D-3L: 3-level version of the EuroQol-5D instrument; DQI: Dementia Quality-of-Life Instrument; SIB-S: Severe Impairment Battery; MMSE: Mini-Mental State Examination; NPI-NH: Neuropsychiatric Inventory–Nursing Home Version; SMMSE: Standardised Mini-Mental State Examination.

\*  $p > 0.05$

### Appropriateness of prescribing

Of the eight studies that measured the appropriateness of prescribing [263, 265, 268, 271, 272, 274, 277, 279], three interventions [263, 271, 274] reported continuous data at 12 months and a meta-analysis for these were undertaken. A significant impact in favor of the intervention was identified (SMD -0.20; 95% CI -0.33 to -0.77;  $I^2= 27\%$ ;  $p$ -value= 0.003, Figure 2.3).



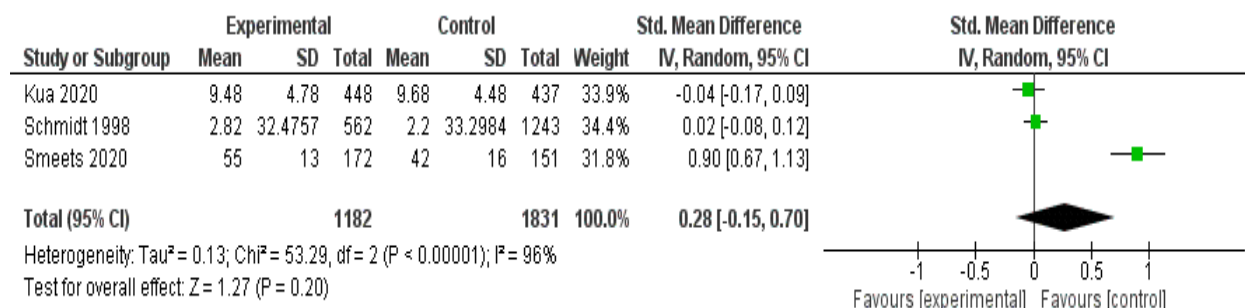
SD: Standard deviation; CI: Confidence interval.

Figure 2. 3 Forest plot displaying the effect of the intervention on the appropriateness of prescribing. Standard mean difference (SMD) measured at 12 months (fixed-effect model).

Four studies [265, 268, 272, 277] reported a statistically significant effect ( $p$ -value<0.001). However, one study [279] did not identify a significant change ( $p$ -value= 0.083) when measuring the number of potentially inappropriate medication (PIM) defined daily dose per resident (Appendix 2.5).

### Frequency of prescribing

Six studies [264, 266, 269, 270, 275, 276] measured the proportion of residents prescribed certain classes of medicines. Data from three studies [270, 275, 276] were pooled for effect estimates using a random effects model ( $I^2= 96\%$ ). There was no difference identified in the frequency of prescribing between study groups at 12 months follow-up (SMD= 0.28; 95% CI -0.15 to 0.70;  $p$ -value= 0.20, Figure 2.4).



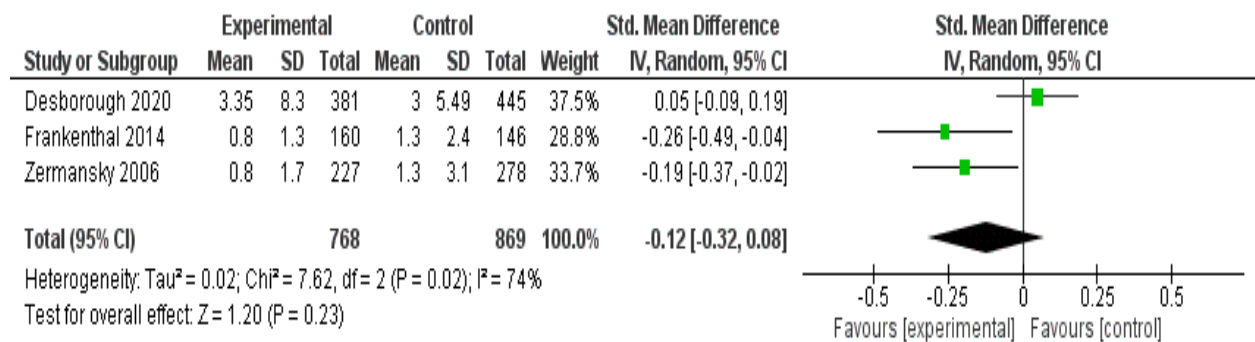
SD: Standard deviation; CI: Confidence interval

Figure 2. 4 Forest plot displaying the effect of the intervention on the frequency of prescribing. Standard mean difference (SMD) (random-effects model).

Two studies [264, 269] reported no statistically significant effect on the frequency of prescribing psychoactive and other unspecified classes of medications. Kennedy and colleagues [266] reported a successful increase in the proportion of residents prescribed vitamin D and calcium (Appendix 2.5).

Falls

Of the ten studies [1, 264, 265, 267, 268, 272-274, 278-280] measuring the number of falls at 12 months follow-up, three studies [265, 273, 274] were pooled and meta-analysed using random effects model ( $I^2 = 74\%$ ). No statistically significant association was identified between study groups (SMD= -0.12; 95% CI= -0.32 to 0.88;  $I^2 = 74\%$ ;  $p$ -value= 0.23, Figure 2.5).



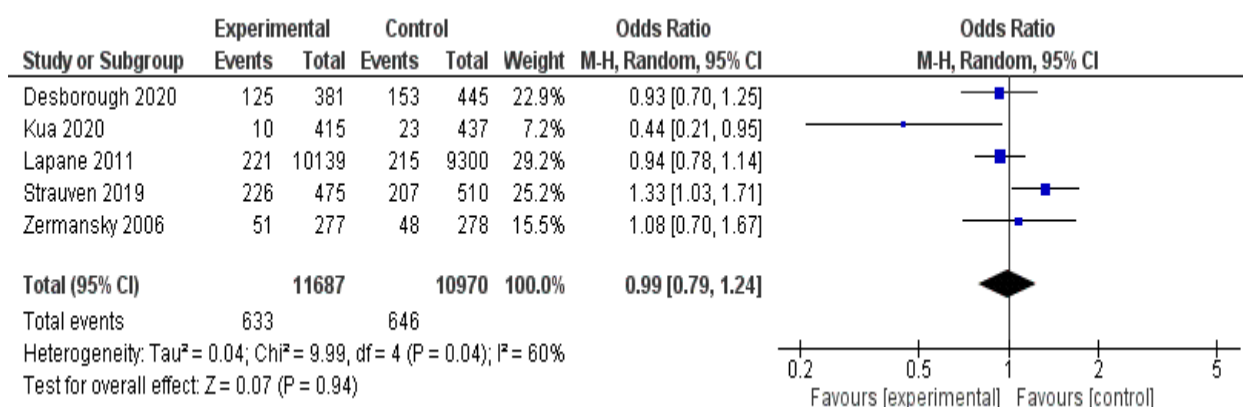
SD: Standard deviation; CI: Confidence interval

Figure 2. 5 Forest plot displaying the effect of the intervention on the fall rate. Standard mean difference (SMD) (random-effects model)

Seven studies (two educational [264, 278] and five MR [1, 267, 268, 272, 280]) reported no impact and one study reported a statistically significant reduction in the number of falls ( $p$ -value= 0.002) [1, 280] (Appendix 2.5).

Mortality

Eight RCTs investigated the mortality rate of NH residents at 12 months [1, 267, 269, 273-275, 277, 279, 280]. Five [267, 273-275, 277] were pooled for effect estimates using a random effects model ( $I^2 = 60\%$ ) and showed no statistically significant effect (OR= 0.99; 95% CI 0.79 to 1.24;  $I^2 = 60\%$ ;  $p$ -value= 0.94), figure 2.6).



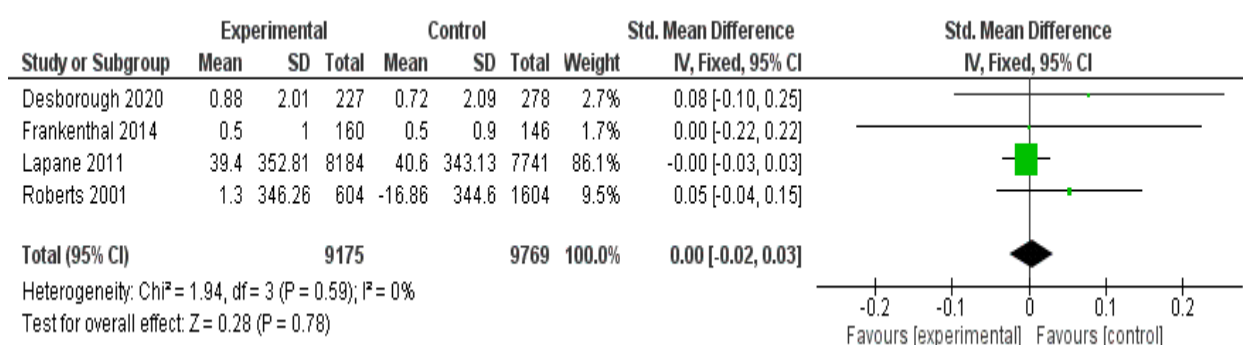
CI: Confidence interval

Figure 2. 6 Forest plot displaying the effect of the intervention on mortality rate. Odds Ratio (OR) (random-effects model)

One study [279] reported a statistically significant reduction in mortality rate at 12 months, while another two studies reporting single-component MR [1, 280] and one intervention comprising multiple-component MR and education [269] reported no significant effect on mortality (Appendix 2.5).

### Hospitalisation

The incidence of hospitalisation was measured in ten studies [1, 265, 267, 269, 273-275, 277-280]. Data from four studies [265, 267, 269, 274] were meta-analysed and did not show a statistically significant effect at 12 months' follow-up (SMD= 0; 95% CI= -0.02 to 0.03; I= 0%; p-value= 0.78, figure 2.7).



SD: Standard deviation; CI: Confidence interval

Figure 2. 7 Forest plot displaying the effect of the intervention on hospitalisation rate. Standard mean difference (SMD) fixed-effects model)

Five other studies reported no change in the number of hospitalisations between study groups [1, 273, 277-280]. One study [275] reported a statistically significant reduction in hospitalisation at 12-months'

follow-up, with that intervention targeting prescribing and monitoring ( $p$ -value  $<0.001$ ). (Appendix 2.5).

#### **2.4.8. Narrative summary of other outcomes investigated**

One study reported a statistically significant reduction in onset of delirium [267]. On the other hand, there was no considerable effect identified on quality of life including both physical and cognitive function assessments in five interventions [1, 265, 271, 273, 278]; behaviour assessment in two interventions, where, where Crotty *et al.*, used the Nursing Home Behaviours Problem Scale (NHBPS) and Tadrous *et al.*, used Aggressive Behaviour Scale (ABS) [263, 278]; neuropsychiatric symptoms assessed using two types of the Neuropsychiatric Inventory, questionnaire (NPI-Q) and NH version (NPI-NH) [272, 276]; and care-need and disability measured using the Resident Classification Instrument (RCI) [269] (Table 2.8). Studies reporting these outcomes had heterogeneity of outcomes measurements and insufficient pooled data, thus meta-analysis was precluded.

## **2.5. DISCUSSION**

The aim of this systematic review and meta-analysis was to systematically identify and describe interprofessional interventions involving pharmacists that target stages of the MMP for older people residing in NHs. Thus, 19 manuscripts were identified reporting on 18 interventions that targeted various stages of the MMP and measured several outcomes, published from 1998 to 2021. The included interventions varied in components and providers of the intervention, population characteristics, frequency of intervention provision, tools used to assess and measure outcomes, and stages of the MMP targeted. This review adds to the existing evidence base a systematic reporting of RCTs and meta-analysis of the impact of these interventions on outcomes. The key findings were: (1) MR was the most common intervention type described in 12 out of 18 included interventions, either MR alone ( $n=12$ ) or supported by education of HCPs ( $n=4$ ) and case conferences ( $n=2$ ); (2) the key contributors to the interventions in addition to pharmacists were GPs, nurses, residents and/or family members; (3) prescribing was the most frequently targeted stage of the MMP; (4) interprofessional interventions involving pharmacists reduced the prevalence of inappropriate prescribing NH older adults included; and (5) the use of theory in the development of interventions was not reported. Pharmacists contributed to various direct patient care roles, mainly through accessing medical records, appraising medication regimen and preparing recommendations for discussion with other key stakeholders and providing education to other HCPs. This contribution is recommended by guidance on the safe delivery of MMP approaches [281, 282].

Most of the included interventions targeted the prescribing stage of the MMP ( $n=16$ ) to improve the use of potentially inappropriate medications and to prevent potential prescribing omissions, which is

unsurprising given the body of evidence reporting the prevalence of PIP in the NH setting and the need for interventions to improve prescribing [283, 284]. All of these interventions resulted in successful reductions in PIP, using different prescribing tools and criteria such as: Beers [272, 275, 279]; NORGE-PH [279], STOPP/START [265, 272, 274, 275], and American Omnibus Budgetary Reconciliation Act [268].

Seven interventions targeted the monitoring stage of MMP; one used an electronic software that generates reports that monitor NH residents at risk of falls and delirium. These reports also assist pharmacists in conducting MRs, therefore potentially improving other stages of the MMP such as prescribing or administration [267]. Relatively fewer included studies examined the administration and dispensing stages of MMP, despite the body of evidence that reports on medication administration and dispensing problems in the NH setting and on the importance of improving administrative techniques [285-288]. According to Prasanna *et al.*, observational study including 100 NH older adult in Sri Lanka, up to ninety-five percent of residents had medications with at least one dispensing error [289]. Although Baqir and colleagues' retrospective analysis of interprofessional MR interventions suggests that targeting the monitoring stage of the MMP avoids undesirable MRPs [290], Spinewine *et al.*, highlighted the lack of evidence from RCTs targeting distinct stages of the MMP through interprofessional practice [151]. Therefore, it is necessary to strengthen the evidence about interventions that address different stages of the MMP in the NH setting.

Our meta-analysis findings suggest that the identified interprofessional interventions involving pharmacists significantly improve the appropriateness of prescribing for older NH residents. These findings are consistent with previous published systematic reviews investigating similar interventions in the NH setting [291-293]. However, the previous reviews differ from this review by including all study designs, having earlier search dates and/or not meta-analysing the data. Kaboli and colleague's systematic review of interprofessional interventions involving a pharmacist in the hospital setting have reported similar results to this systematic review and meta-analysis in the NH setting [235]. Our review findings suggest that interprofessional interventions have no effect on the frequency of prescribing of certain drug classes or medication to manage certain health conditions. This could be explained by the difficulty of stopping multiple chronic medications for older NH residents with multimorbidity [264]. In other words, when a medication for a chronic condition is stopped, another may be initiated to avoid the clinical decline of the condition, and this alternative medication may also be "inappropriate" albeit more suitable in the circumstance. Therefore, future interventions should prioritise the prescribing of the appropriate medication rather than reducing the number of chronic medications prescribed. This suggestion is in-line with Jessop and colleagues' suggestion of lowering doses of antipsychotic medicines rather than deprescribing them [294].



None of the included studies (including eight reported referenced protocols) reported a theory underpinning intervention development. Kolanowski *et al.*, suggests the direct relationship between theory-driven interventions and the impact of outcome measured [295, 296]. Similarly, Glasgow and colleagues suggest that the use of theory in intervention development '*results in more powerful interventions*' [297]. The absence of reporting of the theoretical underpinnings of the included interventions limited our commentary on its impact. Likewise, despite all included studies involving a pharmacist as a key HCP in delivering the intervention and the known benefit of the pharmacists' contribution to prescribing and monitoring practices on improving residents' outcomes [298], it is difficult to assess in non-theory driven reporting whether this involvement is the underlying reason for the benefits observed, such as the appropriateness of prescribing. Furthermore, reporting the effectiveness of theory-driven interventions in this area remains unknown. It has also been explained by Michie *et al.*, that even if the theory does not confer a positive effect on outcomes in favour of the intervention, it helps to clarify what does and does not work in an intervention [299]. On that account, this review encourages the use and reporting of theory in intervention development and evaluation to potentially better explain and strengthen the impact of interprofessional interventions involving pharmacists in the NH setting.

The involvement of resident/family members as contributors to interprofessional interventions is a key finding. Residents' or their family members' opinions were interpreted in recommendations for changes before the final action decision was made. Holden and colleagues argue on the importance of collaborative work between healthcare professionals and patients to improve patient safety using a person-centred approach [300].

### **2.5.1. Strength and limitation**

#### **Strengths**

The reporting of this systematic review followed PRISMA [255] guidelines. The protocol development adhered to PRISMA-P [301] guidance and was registered on PROSPERO. The use of the EPOC guidance to develop the data extraction templates enhances the quality of this review [258]. Meta-analysis followed recommendations from the Cochrane Handbook of systematic reviews of interventions [254]. Notably, data collection and combination of information from cRCTs and RCTs followed the Cochrane handbook process to avoid unit of analysis error and false-positive conclusions. These steps enhance the rigour of this review.

#### **Limitations**

There are some limitations. The study was limited to English language publications; this may have excluded relevant references published in other languages. Most of the included studies reported the mean age group, implying that the population sample could include residents less than 65 years. However, this study's population still falls under the category of older adults. The substantial heterogeneity in the frequency of prescribing, falls and mortality outcomes limit the validity of the results. Another limitation is the overall heterogeneity of included trials and the challenges to compare them. However, this limitation is expected in multi-component complex interventions. The term 'theory' and or 'model' were not included in the search for two reasons; (i) to avoid narrowing the search as not all RCTs would have used as a theoretical underpinning to intervention development. This could be explained by the fact that the CONSolidated Standards Of Reporting Trials (CONSORT) guidelines do not recommend describing intervention development [302]; (ii) This study ought to systematically report interprofessional RCTs intervention with the involvement of pharmacist, and aimed at improving the medicines management process in the NH cohort. Thus, narrowing the search using theory' or 'model' terms might have resulted in missing important studies.

Nineteen RCTs were searched for theory involvement in the full text publications and cited trial designs and/or protocols. Only eight trials cited the protocol, therefore, there is a chance that the other RCTs had a theoretical basis reported in their developmental publications that were not referenced, thus limiting the reporting of their theoretical underpinnings. Additionally, other behaviour change tools could have been used to assess the extent and components of theory underpinning intervention development. However, the lack of reporting of any theory use in included interventions explains the exclusion of these tools in this study.

The risk of bias assessment suggests that blinding of participants, allocation concealment and blinding of outcome assessment were of 'high' and 'unclear' bias across most studies. None of the included studies employed 'double blinding'. This result is expected when researchers study a unique population and assess the trial's effect on a specific outcome, making it unfeasible to blind themselves to selection and performance bias. Therefore, these potential limitations are unlikely to lower the certainty of evidence. Residual bias is a potential limitation of the included studies; where the same HCPs delivered interprofessional practices for both experimental and control groups, some behaviours for improving the MMP may have been inadvertently influenced. Nevertheless, this influence is anticipated in any controlled trial when participants in both groups share the same provider. Finally, some included studies examined the cost of medication outcomes, but the economic assessment was beyond the scope of this study.

### **2.5.2. Impact of the findings on research, practice and policy**

This systematic review suggests that future research should: (1) study the effect of pharmacist involvement in interprofessional interventions which address more stages of MMP in the NH setting; (2) priorities improving the appropriateness of prescribing rather than reducing the number of chronic medicines prescribed; (3) use or report on the theory used in interprofessional intervention development in the NH setting to help explain intervention effect on the outcomes measured; (4) further assess the health-economic benefits to help inform the commissioning of these services; and finally (5) explore how residents/carers can be meaningfully involved to help design, implement and improve the provision of MMP to NH older adults. Implementation in practice could be potentially improved; for instance, NH managers/persons in charge could consider opportunities to involve pharmacists and residents/their families within the care plan of their residents.

### **2.6. CONCLUSION**

To our knowledge, this is the first systematic review and meta-analysis to systematically report interprofessional interventions involving pharmacists that target the MMP provided in NHs, identify interprofessional team contributors, the roles of pharmacists within, and assess the effect of these interventions on the most reported outcomes. The review findings suggest that such interventions in this setting positively impact the appropriateness of prescribing and future research and/or practice should focus further on implementation. Included studies did not report any theoretical underpinning to their development; either signifying that they were not informed by theory or that their development was not reported in detail. Thus, this review recommends that future interventions should be developed using theory, and the reporting of their effect should report theory in intervention development, if used. Finally, our finding of residents'/family members' contribution highlights the importance of studying the extent and effects of patient and carer involvement in improving the MMP for NH residents and thus improving patient safety in a person-centred way. The findings of this review will support chapter 3 of this thesis in the exploration and identification of the MMP provided in the NH setting in the Republic of Ireland.

## **Chapter 3**

Work system analysis to explore the medicines management system in the nursing home setting in Ireland:

A qualitative study using the Systems Engineering Initiative for Patient Safety model

### 3.1. INTRODUCTION

As discussed in Chapter 1 (Section 1.7.1), The Medical Research Council (MRC) framework for ‘developing and evaluating complex interventions’ recommends that interventions should be developed based on relevant theory [209]. As highlighted in chapter 2, there is a lack of theory-driven interprofessional interventions that involve a pharmacist and target medicines management provided to older people residing in nursing homes (NHs). Therefore, theoretical insights about how medicines are managed for older NH residents in Ireland and the system in which this management occurs is critical to intervention development in this area. Throughout this chapter, the medicines management process is explored and analysed using a systems-based approach; thus, is referred to in this chapter as a medicines management **system** (MMS) and its component stages, referred to as **processes**, are explored using a systems-based theoretical approach.

#### 3.1.1. The nursing home setting in the Republic of Ireland

As described in Chapter 1 (Section 1.3), NHs in the Republic of Ireland (RoI) are residential homes that provide services to people who are unable to care and support themselves and their frailty levels [112]. The anticipated increase in the volume of people living into old age in the coming decades is associated with an expected rise in NH demand as they provide long-term care for older people, among others, who may not want or be able to live independently [112, 303-305]. More than 20 thousand older adults reside in more than 400 NHs in the RoI [105]. Approximately, 80% of these NHs are privately owned NHs and 20% are governmental NHs managed by the Health Services Executive (HSE)[305]. The HSE is the Irish government agency, established in 2005, responsible for managing, contracting or delivering healthcare services such as community (GP and pharmacy), hospital, mental health, nursing home and social care services in the RoI [306]. The HSE is also responsible for setting national clinical policies and running programmes for many areas, including acute medicine [307], critical care for adults [308], older people [309], and medicines management [310].

As described in chapter 2, older adults residing in this setting are typically older than 65 years. Females represent the majority of NH residents' (70% in females vs 30% in male) [253]. Dementia is also a reported syndrome in the older NH residents [253], with 80% of residents having a diagnosis of Alzheimer’s disease [50]. This cohort’s physical disabilities and lack of informal carers are also factors contributing to their NH admission, where these older adults would need 24-hours assistance, for example in eating, drinking and dressing [112-114].

It is also reported that NH residents are often unable to self-administer their medicines, hence, their need for assistance and dependency on others to administer their medication for them [115]. In light

of that, older adults have complex medication needs and those residing in this NH setting are reported to have greater medication complexity than those living in the community setting. Tatum and colleagues' study identified a significant association between age and polypharmacy in the RoI, where the percentage of people experiencing polypharmacy increases with advancing age [311]. Not only that but these people are also vulnerable to medication error and inappropriate prescribing [84, 85]. As discussed in Chapter 2, Section 2.5, potentially inappropriate prescribing remains a concern in NHs globally, despite the available resources and criteria to aid in detecting and improving prescribing [84, 253].

Older adults' services in the NH setting in the RoI are regulated by the Health Information and Quality Authority (HIQA)[113]. HIQA is an independent statutory body that sets standards for regulating NHs, outlined in the *National Standards for Residential Care Settings in Ireland*, in compliance with the Health Act 2007, and performs inspections to assess compliance with these standards [113, 312](Chapter 4 of this thesis provide further details about HIQA and its roles). The *National Standards for Residential Care Settings* aim to improve all services provided to older people in NHs in the RoI. There are a number of topics that are the focus of these standards, including safe and effective services, governance and management, the use of information and resources and staffing [113].

The main HCPs that provide services for older people residing in the NH setting are nurses, pharmacists and general practitioners (GPs) [144, 253]. These healthcare professionals can work individually, collaboratively or both to ensure that NH residents get the most appropriate medical, social, physical and emotional support to meet their needs [113, 114]. Nurses are typically the prime HCP group working on site in the NHs [144]. Nurses in the RoI have to be registered with the regulatory body for nursing, namely the Nursing and Midwifery Board of Ireland (NMBI), to be able to work in any healthcare setting in the country, including the NH setting [114, 313]. Nurses are generally responsible for managing chronic conditions, wound care, and communicating with HCPs and NH residents and/or family members. Nurses are also expected to be involved in the administering and monitoring processes of the MMS where they have to ensure adherence to the 10 rights of medication administration (i.e., right person, reason, medication, route, time, dose, form, action, documentation and response) [114].

Similar to nurses, pharmacists in the RoI must be registered with the national pharmacy regulator; the Pharmaceutical Society of Ireland (PSI), to provide pharmacy services for any patient including the older cohort that reside in NHs [312, 314, 315]. Pharmacists in the RoI are not typically located in the NH facility, but they are offsite in community/retail pharmacies or hospital pharmacies. A PSI report in 2011 identified that 33% of community pharmacies in the RoI supply and provide pharmaceutical

services to older people in NHs [316]. Another survey report by PSI in 2012 suggested that 11% of hospital discharge medicines were for NH residents [317]. These pharmacies often supply and deliver medicines to older NH residents on foot of a prescription generated in the nursing home, and often documented on a drug prescription and administration chart, commonly known as the Kardex [314]. Pharmacists are also required, by law (Medicinal Products, Statutory Instrument No. 540/2003), to review every prescription before dispensing and by HIQA standards to review older resident's medications every three months to ensure medicines are prescribed correctly and that NH residents are supplied with the correct dosage, dosage form *etc* [113, 314, 318]. Medication reviews performed by pharmacists seek to support optimisation of medication use, for example, detecting and addressing medication interactions and contraindications. The HIQA three-monthly medication review outlines that some medication classes require greater scrutiny, such as antipsychotics, sedatives, antidepressants, medications for cardiovascular problems, and non-steroidal anti-inflammatory drugs [113, 144, 314].

GPs in the RoI are typically the primary registered prescriber and care provider for older people in all (primary care) settings, including the NH setting [144]. In the RoI, GPs also typically work off-site in their GP practice and provide remote care for NH residents. Standard 4.1.7 of the National Standards for Residential Care Settings allows all NH residents access to a GP of their choice. Only medicines which have been prescribed and signed by the prescriber may be administered to older NH residents [113]. To ensure safe and appropriate care of NH residents, the NH Kardex (the prescription and administration record) must include the resident's name, list of medicine (including the name, dose, form, frequency, route, duration, PRN indication, details about whether the medications should be manipulated in any way, *e.g.*, crushing, and patients' information including their allergy status and date of birth. This must also be signed by the prescriber [144].

Other HCPs may also be involved in the care provision to older NH residents. Section 4.1.6 in the *National Standards for Residential Care Settings* in Ireland supports NH residents having access to other specialists in the community or hospital setting as needed during their stay in the NH. This may include clinical specialist physicians who can also prescribe and make medicines-related recommendations [113].

### **3.1.2. System Engineering Initiative for Patient Safety**

The Systems Engineering Initiative for Patient Safety (SEIPS) model was used as the theoretical framework for this thesis. As discussed in Chapter 1 (Section 1.7.2), using theory in research is a core element of the MRC framework for developing complex interventions as it helps in explaining components of an intervention, inter-relationships and effects on findings. Theory can be used in

various types of research including qualitative research to provide a comprehensive approach to multiple perspectives of topics or processes. In this thesis, the NH resident's MMS is investigated and is referred to throughout this chapter as the NH resident MMS journey. SEIPS can be used in many stages of qualitative research, for example, to guide study design, data collection, data analysis and intervention design [319]. The use of the theoretical framework (SEIPS 3.0) informed the interview guide and data analysis aspects of this chapter and parts of Chapter 4.

### Human factors

Human factors is an ergonomic discipline that explores issues that affect human performance. The study of human factors supports the exploration of work systems and their elements, and the understanding of the interrelationships between people (humans) and these work system elements and how that impacts on performance. Although initially applied to physical ergonomics, human factors has been recognised as a unique discipline in health research as it helps in improving patient and medication safety through the application of both physical and cognitive ergonomics [320]. Human factors has been widely used over the last decade in health research to understand how healthcare systems and their elements interact through complex processes to produce outcomes. For instance, the World Health Organization (WHO) employed a human factors approach to identify gaps in medical school's curriculum on patient safety [321]. The United States (US) Agency for Healthcare Research and Quality (AHRQ) explored the human factors of healthcare service provision and medical device relocation during transitions from hospital to home, with a goal to improve patient safety. [322, 323] The US Institute Of Medicine (IOM) employed a human factors approach to develop and design health information technology that can reduce medication error [324]. In the RoI, the NMBI Guidance for Registered Nurses and Midwives on Medication Administration states that nurses should understand the human factors of systems that can impact patient safety [114]. The use of human factors approaches to improve outcomes in complex systems is typically guided by theoretical work system models [325]. Dul et al., proposed that work system models usually involve three core principles [326]:

- 1- *The systems-orientation principle* where the performance of people is a result of interactions within the work system.
- 2- *The person-centeredness principle* where the people are supported by efforts taken through work system design that fits their characteristics.
- 3- *The design-driven improvement principle* where a person-centred design of work structures and processes improves the outcomes experienced by both patients and healthcare professionals.



## The Systems Engineering Initiative for Patient Safety (SEIPS) Model

The SEIPS model provides a framework to explore how different elements of the work system interact within processes to produce outcomes. SEIPS was introduced in 2006 by Carayon and colleagues and was developed for use in healthcare [325]. (Figure 3.1).

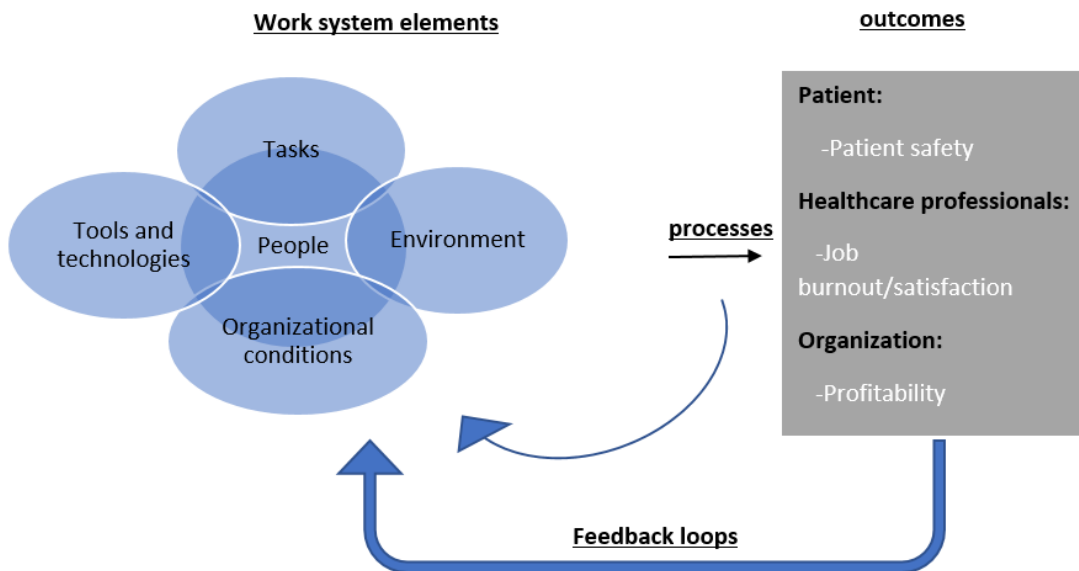


Figure 3. 1 Systems Engineering Initiative for Patient Safety 2006 [325]

A System is composed of several components:

- The work system and its elements;
- The processes;
- The interactions;
- The outcomes;
- The feedback loops.

The work system in the SEIPS framework consist of five **elements**:

1. **People** involved in the system, which can be healthcare professionals (HCPs) such as nurses, prescribers or pharmacists or any other stakeholder group.  
The people's characteristics can take two different forms:
  - a- Individual characteristics, such as frustration, attention, skills, education and knowledge.
  - b- Collective characteristics, such as team cohesiveness.
2. **Environment** surrounding the people where they perform their work, can include light, noise, distance, and layout.

3. **Organizational conditions** of the workplace/organization that the people work in, such as policies, management, training and staffing.
4. **Tasks** that the people perform within processes such as collecting and reading patient medical information or taking a medication package from the cupboard. These can be characterised by complexity, level of time-consumption and other dimensions.
5. **Tools and technologies** that these people use to aid in performing their daily/regular tasks. These can include devices (*i.e.*, computers, tablets or phone) or tools such as email, fax, telephone or evidence-based guidelines. The characteristics of these tools or technologies can include the accessibility, usability and portability.

Carayon and colleagues described **the work process** as a set of tasks, which is an element of the work system. The authors built on previous human factors models where the work process was described as the care process(es) that encompass 'how care is provided, delivered and managed'. Each process is composed of several related tasks. Examples of processes within the MMS include assessing, prescribing, administering, dispensing, review and monitoring of medications.

In the SEIPS model, the **process** was expanded to include both direct patient care and other processes which may have an impact on patient safety in healthcare organisations, such as housekeeping and management.

**Interactions** between the five work systems elements and processes can potentially influence the **outcomes** experienced by the people, who may be the patients (*e.g.*, patient safety), healthcare professionals (*e.g.*, workload) and organizations (*e.g.*, organizational performance). It has been proposed by researchers experienced in this area that any change in a work system element produces interactions and changes to other elements within the work system. These interactions can be weak with no apparent influence and with minimal impact on outcomes, or they may be significant and dynamic and significantly influence outcomes. This influence can act as barrier or a facilitator to the process.

The SEIPS 2006 model (version 1) also illustrated two **feedback loops**: one from the processes to the work system, and the second from the outcomes to the work system (Figure 3.1). These feedback loops are useful in (re)designing a work system where negative work system elements or 'barriers' are identified and tackled and positive work system elements or 'facilitators' are appreciated [325]. This is useful when healthcare processes are reported as being risky, or where work system processes are malfunctioning. This exploration and manipulation of feedback loops is suggested to potentially improve patient safety and quality of healthcare processes to achieving optimum outcomes experienced by care providers and care recipients [327].

SEIPS has been applied in various clinical settings to investigate and improve healthcare and care processes. For instance, Chui and colleagues applied SEIPS to identify the work system components of the cognitive pharmaceutical services (CPS) in community pharmacy and to understand how these components affect outcomes. They identified that the people (pharmacists' leadership skills) and organisational conditions (coordination) are the key facilitative elements [328]. Seibert *et al.*'s study used SEIPS to explore visitors' contact precautions, knowledge and adherence in a hospital infection ward setting. They identified that nurses are the primary source of information and provision of protective equipment for visitors. Achet *et al.*'s SEIPS work to understand the reasons for hospital readmission within 30 days of discharge after an abdominal surgery identified a deficit in knowledge and education of both patients and caregivers on discharge care materials [329].

### SEIPS 2.0

An expanded SEIPS 2.0 Model was introduced in 2015 by Holden and Colleagues: the next-generation healthcare human factors framework' (Figure 3.2). SEIPS 2.0 differs from and adds several crucial concepts to the previous model:

- 1- The people element expanded to include both the HCPs and non-HCPs such as the patient, family member or others as key people in the work system. Patient characteristics (*e.g.*, preference, education and knowledge) are proposed to have an effect on the work system as patients are involved in their own care process (*e.g.*, self-administration of medicines or symptom management). The people in this model can be individuals or a group of individuals (teams) where their involvement and their collective characteristics are proposed to influence the processes and outcomes. This addition aids in understanding the individual and collaborative influences of people in the process.
  - Characteristics of individual persons can include age, knowledge, and experience.
  - Characteristics of the team can include cohesiveness.
- 2- The environment element described in the original SEIPs was re-named 'internal environment' in SEIPS 2.0 representing the physical WS environment in which the system operates.
- 3- SEIPS 2.0 added an additional environment, the 'external environment', representing the environment outside the WS internal-physical environment and including the organizational conditions elements of the work system, such as policies, macro-society and economic or ecological factors.
- 4- The configuration concept of SEIPS 2.0 proposes that components of the work system interact 'simultaneously' at 'a moment of time'. In other words, components of the work system are

interlinked, forming a network of interactions (barriers and facilitators). These interactions can be single interactions or multiple interactions happening at the same time.

- 5- Processes in SEIPS 2.0 are sub-classified as behavioural, physical and cognitive performance processes. These performances are classified as
  1. *Individual performance*: e.g., professional work (i.e., HCP without patient participation, for example surgeons performing surgery on a sedated patient) or patient work (i.e., patients/family/non-HCP, example symptom monitoring; and
  2. *Collaborative performance*: e.g., Professional-Patient work where both HCPs and non-HCPs are the primary contributors to the collaborative work, for example medication review and decision-making meetings with the involvement of HCPs and patients/family members.
- 6- Outcomes: Similar to the original SEIPS model, interactions between work system components and the work processes yield outcomes experienced by patients, HCPs and organizations. In SEIPS 2.0, these outcomes are described more specifically as desirable and undesirable, to patients, HCPs and organizations. They were also described as being proximal or distal. Proximal outcomes are those that result immediately from the work processes, whereas distal are those that may be delayed and / or that are less directly related to the work process or are further down the causal chain. For example, the risk of medication errors can be a proximal-undesirable outcome for patients; job satisfaction can be a distal-desirable outcome for HCPs; and shortage of staff can be a distal-undesirable outcome for organizations.
- 7- Feedback loops are adaptations between outcomes, processes and work system components. In addition to the two feedback loops in the original SEIPS, SEIPS 2.0 adds a third loop between outcomes and processes. Adaptations can be categorised as:
  - a- Anticipated or unanticipated
  - b- Long or short-lasting
  - c- Regular or intermittent

SEIPS 2.0 has been applied in various studies and has demonstrated its value in improving patient safety and healthcare processes in different contexts. For instance, Holden and colleagues' work system analysis applied SEIPS 2.0 in the development of the study's interview guide, observational protocols and data analysis to investigate barriers to self-care among older adults' who are admitted to the hospital emergency department [330].

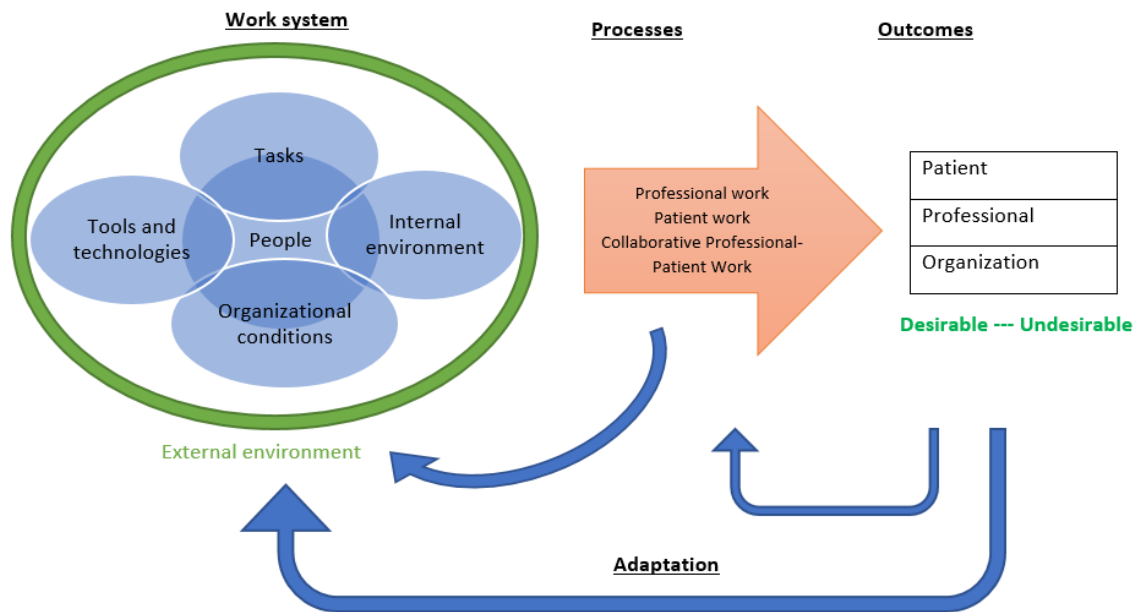


Figure 3. 2 System Engineering Initiative for Patient Safety 2.0, 2015 [330].

### SEIPS 3.0

SEIPS 3.0 (Figure 3.3) was introduced in 2020 to further improve patient safety through focusing on expanding the work process of the previous models to the ‘patient journey’ concept within and between various healthcare settings through space and time. The patient journey is defined as ‘the spatial-temporal distribution of patients’ interactions with multiple care settings over time’. The patient journey is proposed to describe the patient’s emotions and experiences as a central element in addition to their physical journey. The suggestion is that the patient presumably interacts with multiple work systems and their elements. It is also suggested that across different healthcare settings, these interactions are influenced by the external environment in which these work system elements are embedded. Thus, the patient journey in this version of the SEIPS family of models incorporates both work system components and work processes. Similar to SEIPS 2.0, this version includes the feedback loops from the outcomes to the patient journey. These feedback loops may be used in the (re)design and modelling through adaptation and learning. Simultaneously, improvement can be both identified and updated throughout [331].

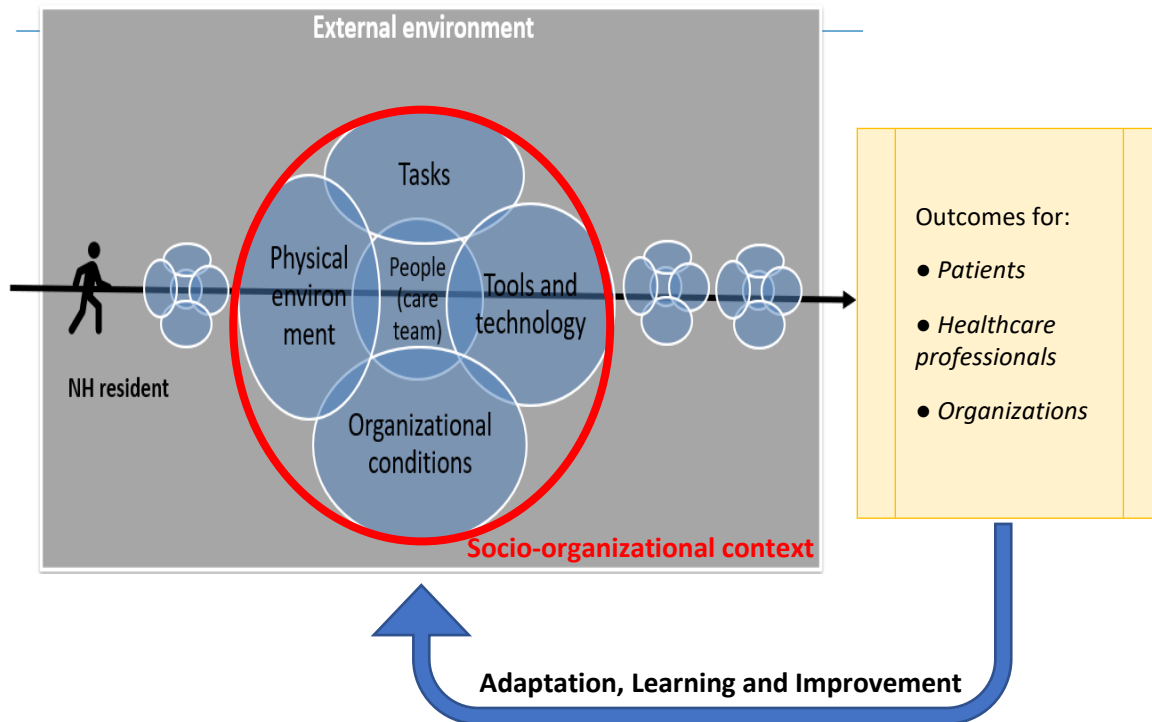


Figure 3. 3 System Engineering Initiative for Patient Safety 3.0,

The use of SEIPS 3.0 can aid the understanding of complex work systems such as the MMS and support the identification of barriers and enablers (described as interactions between work systems and their components) to produce safer outcomes [332, 333].

The MMS is composed of multiple processes such as assessing, prescribing, dispensing, administration, review and monitoring. Each process has a set of tasks within. Previous studies have applied SEIPS to explore the MMS in various clinical settings. For instance, Strauven and colleagues used SEIPS to explore medication safety in the NH setting [334]. Hysong *et al.*, used SEIPS to improve electronic communication in the hospital setting [335]. Carayon and colleagues used SEIPS to develop an intervention that improves patient safety in ambulatory care setting [336]. Faye *et al.*, and Gurses *et al.*, used SEIPS to improve patient safety in intensive care settings [337-339]. To our knowledge, the literature lacks studies about work system exploration of the MMS or related processes (*i.e.*, assessing, prescribing, administering, dispensing, review and monitoring) using a system-based approach and/or any of the SEIPS versions in the Irish NH context. To the best of our knowledge, the NH resident's MMS journey (patient journey concept that is introduced in SEIPS 3.0) has not been described to date. This approach, allows the identification of work systems existing in the NH resident MMS journey, and identify work system elements which interact. These interactions are expressed in terms of barriers and facilitators to outcomes experiences by stakeholders in the journey, including the NH residents.

This identification can be utilised in future interventions where researchers can develop an intervention, with a theoretical basis, to overcome barriers and suggest a system redesign [331]. The MMS in the NH setting is a complex system as it involves multiple stakeholders from multiple organisations, and work systems, thus SEIPS 3.0 and its patient journey concept were utilised in this chapter.

### **3.2. AIMS AND OBJECTIVES**

The aim of this qualitative study was to explore the MMS in the Irish NH setting.

The objectives were to:

- Gather medicines-related information by interviewing key stakeholders involved in the MMS.
- Apply the SEIPS 3.0 [331] model to identify work systems, elements within the work system, external environment elements, interactions, feedback loops and outcomes.
- Explore the impact of the COVID-19 pandemic on the MMS in Irish NHs.
- Map the MMS in the Irish NH setting.

### **3.3. RESEARCH DESIGN AND METHODOLOGY**

#### **3.3.1. Rationale for choice of research design**

In order to gain insight and to explore and describe the MMS in the Irish NH setting in detail, a qualitative study was undertaken involving relevant key stakeholders. The key stakeholders identified in chapter 2 of this thesis were considered. These were pharmacists, general practitioners (GPs), nurses, residents and/or their family members. A work system exploration of the MMS through perceptions of HCPs and non-HCPs in the Irish NH setting has not yet been undertaken. Previous work system analysis and process improvements have been applied in the transition of care from hospitals to home in the US and in Belgium NH settings through interviews of stakeholders [340, 341]. Thus, this study used qualitative research design to explore the MMS, map the resident journey and identify the perceived barriers and facilitators to MMS provision using SEIPS 3.0 [331]. An overview of qualitative research methodology is detailed in section 3.3.2.

#### **3.3.2. Qualitative research methodology**

Qualitative health research has been widely used to gain an in-depth understanding of experiences and opinions, to explore processes and needs and to aid in intervention and policy development and refinement [342, 343]. Qualitative research allows answering 'why' and 'how' systems generate the

outcomes that they do. This is significant to people in real practice. The interest in and significance of qualitative approaches has encouraged their thorough use by health researchers in various settings after the publication of the MRC framework 'development and evaluating complex intervention', which recommends the use of qualitative approaches and elaborates on the importance of peoples' opinions in developing interventions [209, 344]. *Muntell et al.*, further explain that when people are in their 'natural environment', it is efficient to obtain true descriptive data [345]. Various types of qualitative research methods include interviews, focus groups, and participant observation. The focus group and participant observation methods are briefly described below. The interview methods are described in detail as it is the method chosen for the qualitative study conducted in this chapter.

### Focus groups

A focus group is a group-based method where multiple participants get together simultaneously for a group discussion. This discussion is facilitated by a moderator to keep the discussion within the time and research topic track. The moderator often uses a topic guide to steer the conversation but need not be structured or limited to a set of questions. It is suggested that data saturation may occur after three focus groups of 6-10 participants. Below this group size and frequency, rich enough information might not be achievable. Beyond this group size and frequency, participants might not be able to contribute any new insights to the discussion. Focus groups encourage interaction between participants within the group and thus allow different data and opinions to generate during the discussion than those which might transpire in individual one-to-one interviews. On the other hand, group dynamics might also introduce bias and discourage participants from being truthful or complete in disclosing experiences, beliefs or opinions [346].

### Participant observation

The observational approach is also called field research. The researcher usually observes people in their own natural environment to collect data in two ways: 1. passively by observing behaviours and listening to a conversation, and/or 2. actively by involving in activities and asking questions [346]. The researcher may observe without becoming in any way involved with or in the subject being observed (non-participant observation) or may engage and interact with the subject (participant observation).

### One to one interview methods

An interview is the most common data collection method used in qualitative study research. Interviews are useful when exploring participants' experiences, feelings and ideas [346, 347]. There are three types of interviews differing in the degree of structure:



- 1- Structured interviews, also called standardised interviews; where the interviewer presents the same standard, pre-defined and structured sequence of questions from an 'interview schedule' to all interviewees. Additionally, the answers to these questions are commonly guided by an interviewer in a set of responses such as 'Yes'/'No' or multiple choices. The most common examples can be when conducting surveys or questionnaires. This method is not appropriate when in-depth exploration is required [346].
- 2- Semi-structured interviews, also called in-depth interviews; the method of choice by most researchers where the interviewer asks the interviewees few questions to allow the participant the freedom to narrate their opinions, experiences and feelings. Semi-structured interviews are usually guided by a list of questions or topics to be covered with all interviewees during the interview. This is known as the interview 'topic guide' and is described in detail in the next section. These questions are typically open ended [346]. Thus, semi-structured interviews allow the exploration of a particular area in detail which is useful when the research has a definite focus [342, 346].
- 3- Unstructured interviews: this is the most complex type of interviews where there is no 'interview schedule' or 'topic guide' and questions asked are not in a structured sequence and order. But rather, questions and interviews are shaped by allowing the interviewer to select and prompt questions from the participant's verbal and non-verbal responses during the interview. Unstructured interviews will have more prompts rather than a set of questions covering a specific area [344].

### Topic guide

Topic guides (also termed interview schedules) are used to ensure a degree of information/question consistency during interviews. Before starting the data collection stage, topic guides are often prepared and piloted with research team members/ Public and Patient Involvement (PPI) contributors (Chapter 1, section 1.7.3). Topic guide questions can be close-ended (*e.g.*, prompting yes or no answers) or open-ended (*e.g.*, what is your opinion on x? or what do you think of x). Open-ended questions are preferred in interviews as they allow in-depth information to be obtained. The semi-structured interview topic guide allows consistent conversation content where the interviewer asks specific topics and prompts participants to explore particular areas in more detail [346]. Topic guides can be theory-based, for example based on the Theory Domain Framework (TDF) or the SEIPS Model [344, 346]. Prompt questions may be used to encourage answers from interviewees and to reassure them that the interviewer is listening and interested. Piloting the topic guide is important before interviewing participants as it allows for testing the appropriate characteristics of questions and answers [342]. Not only that, but also piloting develops the interviewer's confidence before the

commencement of the interview [344]. The language used in the topic guide should be clear and unambiguous to ensure the questions are understood by interviewees [344].

### Sampling and sample size

In qualitative studies, sampling techniques are chosen depending on the nature and need of the research study [344, 346]:

- 1- Purposive sampling; *also called purposeful sampling*, is where the researcher purposively identifies and selects an 'information rich' group based on established pre-defined eligibility criteria [348].
- 2- Snowball sampling, *also called chain referral sampling*; is a subset of purposive sampling where the researcher initially identifies participants and these participants share information about the study and invite other potentially eligible participants [348].
- 3- Convenience sampling; *also called accidental sampling*, is where a sample of participants is selected based on their accessibility and availability to the researcher [346, 348].

The ideal sample size for a qualitative interview study depends on the aim of the study, heterogeneity of population, and the feasibility and logistics of conducting the interviews [344, 347]. There is no definite number for a sample size. Instead, the sample size is determined by the quality of information obtained from research participants. Data is often collected from participants until data saturation is attained. Data saturation is the point at which no new relevant themes emerge and no further information is captured [346]. At this point, data collection and recruitment can be stopped. However, during the planning of research, researchers often estimate the number of interviews that will be conducted based on previous similar studies, expertise and experiences in the research area, and the timeframe and funding available to undertake the research [342]. Researchers have proposed that data saturation can be attained after between 6-15 and 3-4 conducted individual interviews and focus groups, respectively [346, 349, 350].

### Data collection and management

Interviews can be taken face-to-face or virtually, for example over the phone or using video calls. Because this PhD project was undertaken during the COVID-19 pandemic, virtual interviews on MS Teams were conducted in compliance with guidance from the Trinity College Dublin (TCD) Information Technology (IT) department on undertaking qualitative research during COVID-19 (Section 3.3.4). Data may be collected by observation, audio or video recording and/or note taking during the interview. Interviews are generally audio-recorded, video-recorded and/or taking notes during interviews to ensure accurate information is recorded for use in the analysis stage [346]. The most common method

of recording in qualitative research is audio-recording, which allows the researcher to analyse ‘what’ and ‘how’ participants responded. Additionally, audio-recording is reported to be less intrusive for participants than video-recording [344]. Interview audio-recordings are then transcribed verbatim, and all identifiable, personal and sensitive data are removed to ensure participant confidentiality [346]. Computer software such as (NVivo<sup>®</sup>) can assist with managing and organising qualitative data.

#### Data coding and analysis

Data analysis for qualitative research studies begins with ‘coding’ where useful information are collected and extracted from transcript to answer the research question. Then extracted data were assigned a descriptive label [346]. There are various types of data analysis [344, 346]:

- 1- Grounded theory: is the first approach in qualitative data analysis. It uses an inductive approach or inductive generating of theories from data. On the other hand, due to the timeframe, it is known to be a timely and difficult process in health research.
- 2- Content analysis: It analyses data inductively by generating themes (inductive content analysis) or categorising data using pre-established themes (deductive content analysis). It can be used in both qualitative and quantitative data.
- 3- Thematic analysis: the most common type in health research. It identifies common themes within qualitative data. Similar to content analysis, thematic analysis can be inductive and deductive. Unlike content analysis, thematic analysis is exclusive to qualitative data.
- 4- Framework analysis: is a method commonly used by healthcare research that help in conducting a thematic analysis using a structured approach. It involves stages such as a. data familiarisation of data; b. thematic analysis and coding; c. indexing or applying codes to data, and d. charting a summary of findings [344, 346].

#### Reflexivity in qualitative research

Reflexivity is a term where data collected can be impacted by the researchers and the research design where skills, backgrounds and experiences of the researcher in the studied topic may potentially have an impact of the process of research. The PhD candidate (AS) is a pharmacist who conducted training in types of research methods including qualitative methodology. Additionally, the PhD candidate is closely supervised by the supervisors (CR and TG) who are pharmacists and experts in research methods in pharmacy. Transparent reflexivity in this qualitative research chapter is supported by using a reporting guideline for qualitative research studies, Consolidated Criteria for Reporting Qualitative Research (COREQ) [351]. COREQ is a 32-item checklist that allows transparent and structured

reporting of the important aspects of the study [351]. The qualitative studies reported in this thesis have been reported according to the COREQ checklist (Appendix 3.1).

### **3.3.3. Study design**

A qualitative study applying semi-structured interviews was chosen as the most appropriate method for the current study as it allows in-depth exploration of the MMS in the Irish NH settings from the natural environments. Qualitative methods were critical to gain an in-depth understanding of how the MMS works in the natural environment. These interviews were conducted with two groups: A) HCPs working in or providing care to the NH setting in RoI, and B) non-HCPs who are recipients of care provisions such as residents and their family members. Interviews were the most appropriate data collection type for these groups several reasons: focus groups would have been difficult to organize and gather participants at once due to their workload and difficult times during the COVID-19 pandemic; participants might have been hesitant to talk about MMS service provision or receipt with other participants in the room; and they may have felt more comfortable talking individually and provide honest opinion.

### **3.3.4. COVID-19**

This project was proposed at the beginning of the PhD in 2019, prior to the COVID-19 pandemic. Interviews were initially planned to be face-to-face with participants in environment of their choosing. At the time of seeking ethical approval for this study in 2020, face-to-face interviews were not feasible during the pandemic, and the study described in this chapter was conducted virtually between June 2021 and November 2022 on the Microsoft Teams® platform in compliance with guidance from TCD IT department in undertaking qualitative research during COVID-19 (Appendix 3.2).

### **3.3.5. Public and Patient Involvement**

As discussed in Chapter 1 of this thesis (section 1.7.3), the UK MRC describes the significance of PPI in health research to enhance the rigour of comprehensible and unbiased analysis. The PPI contributors recruited for this PhD project were engaged in this study. These contributors include one nurse with an administrative role, a nurse working in clinical practice, a former person in charge (PIC) of a NH, a general practitioner (GP), a consultant geriatrician, a director of a representative body in the RoI and a family member of an older NH resident.

The PPI panel contributed to the following study elements:

- a. Inclusion and exclusion criteria (section 3.3.6).
- b. Sampling methods (section 3.3.7);

- c. Designing topic guides (section 3.3.8); and
- d. Assisting in the recruitment of participants eligible for participation (section 3.3.7).

### 3.3.6. Study setting

This study was undertaken in the RoI, targeting stakeholders who are involved in and/or with the NH setting. These stakeholders were of two groups: 1) HCPs (*i.e.*, GPs, nurses and pharmacists); and 2) non-HCPs (*i.e.*, NH residents and family members of NH residents).

The eligibility criteria for these the two stakeholder groups are presented below.

- Inclusion and exclusion criteria for HCPs

<u>Inclusion criteria</u>	<u>Exclusion Criteria</u>
I. The person in charge (PIC) in a NH who is currently involved in MMS or	I. HCPs not currently or previously involved in the MMS in Irish NHs
II. HCPs including GPs, pharmacists, and nurses who are currently or previously involved in the Irish NH MMS	II. HCPs not currently registered with their professional regulator
III. Access to Microsoft teams® platform.	III. Less than one year’s experience in the MMS in Irish NH setting from the study start date
	IV. Involvement in another medicines management/similar study
	V. No access to Microsoft teams® platform.

The PIC of a NH in the RoI is also referred to as *director of nursing*. The Health Services (HSE) under Section 22 of the Health Act 2007 requires that every NH in the country has a PIC. The PIC must have the following characteristics [352]:

- a- Registered nurse with the Nursing and Midwifery Board of Ireland (NMBI)
- b- Have 10 years of nursing experience (nursing experience with older people in the last 3 years)
- c- Have management, administrative, leadership and clinical skills.

The eligibility to the study was self-assessed by the prospective participant through an eligibility checklist available in the participant information sheet (Appendix 3.3).

- Inclusion and exclusion criteria for NH residents and their family members

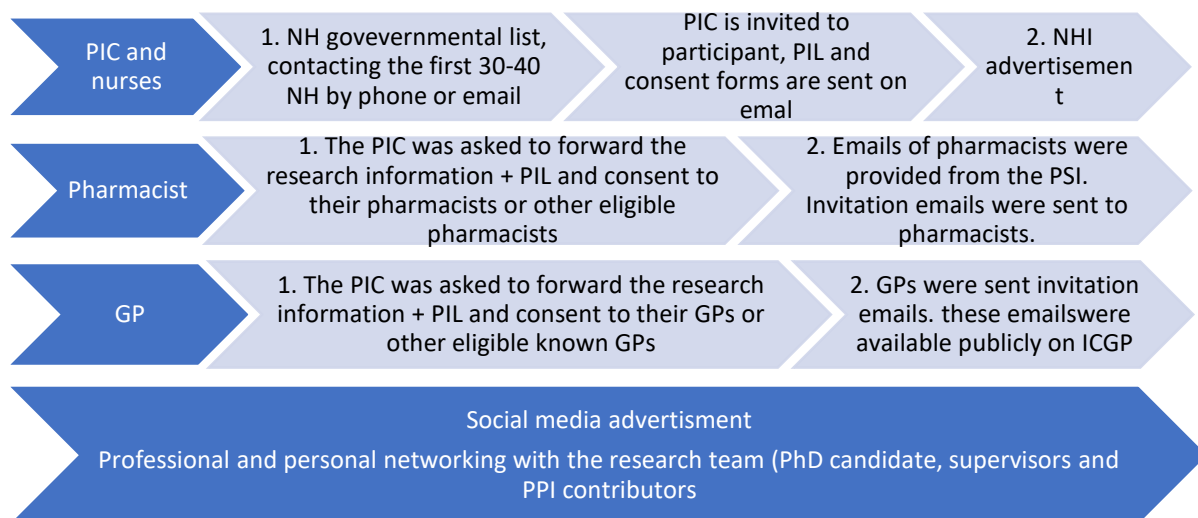
<u>Inclusion criteria</u>	<u>Exclusion Criteria</u>
I. NH resident, aged $\geq 65$ years and residing in a NH for at least 2 years.	I. NH residents aged less than 65 years.
II. Family members of age $>18$ years.	II. Family members of NH residents aged $< 65$ years.
III. Family members of NH residents aged $\geq 65$ years.	

### 3.3.7. Sampling and recruitment

The approach taken to recruit HCPs and residents/ family members are reported separately below in sections A and B, respectively.

#### A. HCPs

To choose NHs for participation from all regions in the RoI, a list of all NHs in the republic was obtained from the Government of Ireland's website (data.gov.org). Each NH in the list was assigned a number from 1-x and assigned a random number, generated on Microsoft Excel. The PIC from the first 30-40 NHs was contacted initially via telephone or e-mail if there was no response on the telephone, or so advised by the reception/nurse on duty (Appendix 3.4). Both the PhD student and the research nurse (Ms. Connie Brennan) performed this step. The researchers provided an overview of the study and invited the PIC to participate. If interested, the researcher sent an electronic copy of the participant information sheet (Appendix 3.3) along with a consent form (Appendix 3.5) via e-mail. The researcher followed up with the PIC after 14 days from when this e-mail was sent to determine their interest in participation. If adequate recruitment from the first batch of 30-40 NHs was not achieved, the next 30-40 NHs on the random list were contacted and informed about the study and invited to take part (Figure 3.4). This process continued until the end of the study period (Section 3.3.2).



**Figure 3. 4 Healthcare professionals' recruitment**

*PIC: Person in charge; NH: nursing home; PIL: Participants information leaflet; NHI: Nursing Home Ireland; PSI: Pharmaceutical Society of Ireland; GP: General Practitioners; ICGP: Irish College of General Practitioners.*

The Public and Patient Involvement (PPI) contributors (section 3.3.5) and research team (The PhD student and two supervisors: Prof. Cristin Ryan and Assoc. Prof. Tamasine Grimes) facilitated the recruitment of eligible participants through personal and professional networking, where an invitation e-mail (Appendix 3.6) was sent to potential participants. The study was also advertised via social media, facilitated through the research teams' and the TCD School of Pharmacy and Pharmaceutical Sciences' social media platforms (Appendix 3.7) (Figure 3.4).

An agreement was reached with Nursing Home Ireland (NHI), the national representative body for the private and voluntary nursing home sector and one of our PPI partners, to support the recruitment of PICs and nurses by advertising the study in their weekly membership e-mails (Appendix 3.8). Our study was advertised three times during a 12-month period from October 2021 to October 2022 (Figure 3.4)

The Pharmacy Society of Ireland (PSI) (Appendix 3.9) provided the PhD student and the supervisor with e-mail addresses of registered pharmacists. An invitation e-mail (Appendix 3.10) with a participant information sheet and consent form was sent to this list (Figure 3.4).

The Irish College of General Practitioners (ICGP) were contacted to facilitate the recruitment of general practitioners (GPs), but the request was refused due to their policy to only support ICGP surveys (Box

1). However, some GPs' e-mail addresses were publicly available on the ICGP website, and the researcher sent invitation e-mails to all e-mails found [Find a GP - ICGP Web Site](#) (Figure 3.4).

***Box 1: ICGP Refusal as per personal communication between the ICGP and PhD candidate***

“Our policy is that we do not provide access to our membership database or distribute surveys on behalf of any external organisation/individual for research purposes. The college only sends out ICGP surveys or those we are in collaboration with to our members”

The PhD candidate also asked the PIC in any NHs contacted, as described above, to pass the information (the e-mail with the participants information sheet and electronic consent attached) to any relevant stakeholder in their network, thereby supporting snowball sampling. All potential participants and interviewees were asked to nominate/invite other potential participants whom they thought would add value to the study (Figure 3.4). This method of recruitment helped to ensure information-rich participants were involved.

**B. Non-HCPs**

The research team members engaged with personal and professional networks through email (Appendix 3.11) to recruit NH residents and family members eligible for inclusion in the study (Figure 3.5).





*HCPs: Healthcare professionals; NHI: Nursing Home Ireland; PPI: Public and Patient Involvement)*  
**Figure 3. 5 Non-healthcare professionals’ recruitment**

The invitation poster (Appendix 3.12) was advertised via social media, facilitated by the research team’s and the TCD School of Pharmacy and Pharmaceutical Sciences’ social media platforms (Figure 3.5).

An e-mail was sent to the interviewed HCPs (Appendix 3.13) to invite them to advertise the study information and display the invitation poster to NH residents and/or family members (Figure 3.5).

PPI contributors facilitated the recruitment of NH residents and family members by advertising and inviting potential participants considered eligible for inclusion (Figure 3.5).

Nursing Home Ireland shared the advertisement poster with their members in the weekly e-mail sent to their members, where the PIC was invited to inform potential participants about the study or display the study’s poster in NHs to invite eligible potential participants to participate in the study (Appendix 3.14).

PPI contributors have engaged with personal and professional networking to invite family members to participate in the study via email (Appendix 3.15).

**Both A and B**

Table 3. 1 Sampling, recruitment and ethical approval process of A and B

	<u>HCPs</u>	<u>Non-HCPs</u>
<b>Contact method</b>	Email and/or phone	Email and/or phone
<b>Transfer of consent documents</b>	Electronically via email	Electronically via email Printed copy via post
<b>Follow-up</b>	14 days following issuing of consent form	14 days following issuing of consent form
<b>Sample size estimate</b>	10 PIC 10 nurses 10 Pharmacists 10 General practitioners	5 NH residents 5 Family members
<b>Ethical consideration</b>	Level I ethics (see section 1.3.10)	Level II ethics (see section 1,3.10)

*HCP: Healthcare professionals; PIC: Person in charge; NH: Nursing home; I and II: Italic numbering for 1 and 2.*

As presented in Table 3.1, prospective HCP participants were invited to contact the research team by *e-mail* or *phone* (depending upon their preference). The prospective participants were asked to email the electronically signed consent form to the researcher before scheduling the interview. Similarly, potential non-HCP participants were contacted by the PhD candidate by *e-mail* or *phone* (depending on their preference) for further information if required. The PhD student provided an **electronic** (via e-mail) or **printed copy** (via the postal service) of the participant information leaflet (Appendix 3.17) and consent form (Appendix 3.18) to the potential participant.

Both NHs and potential participants were contacted after 14 days after sending the participant information leaflet and consent form to follow-up on participation. Potential participants sent the signed consent form back by e-mail or post (addressed to the School of Pharmacy and Pharmaceutical Sciences, Panoz institute, Trinity College Dublin). Once consent forms were received, participants were contacted to arrange an interview time at their convenience.

All participants were invited to share the study advertisement with other potential participants whom they thought would add value to the study at the end of the interview (snowballing).

Data coding and analysis were conducted in parallel to recruitment which continued until the majority data saturation was attained in some topic and due to the end of the study (section 3.3.2, Sampling and sample size). The research team estimated a sample size of A) ten participants per HCP group (*i.e.*, 10 PIC, 10 nurses, 10 pharmacists and 10 GPs); and B) five participants per non-HCP group (*i.e.*, 5 NH

residents and 5 family members). This sample size was estimated by the research team to achieve data saturation (*i.e.*, when no new themes emerge and/or) based on the previous experience in other similar studies and knowledge of previous qualitative studies and in undertaking qualitative research.

### 3.3.8. Interview topic guide

Four semi-structured interview topic guides (Appendix 3.19) were developed for this qualitative study: the PhD candidate drafted the interview guides, these were reviewed and piloted by the supervisory team and the relevant PPI contributors (Figure 3.6)

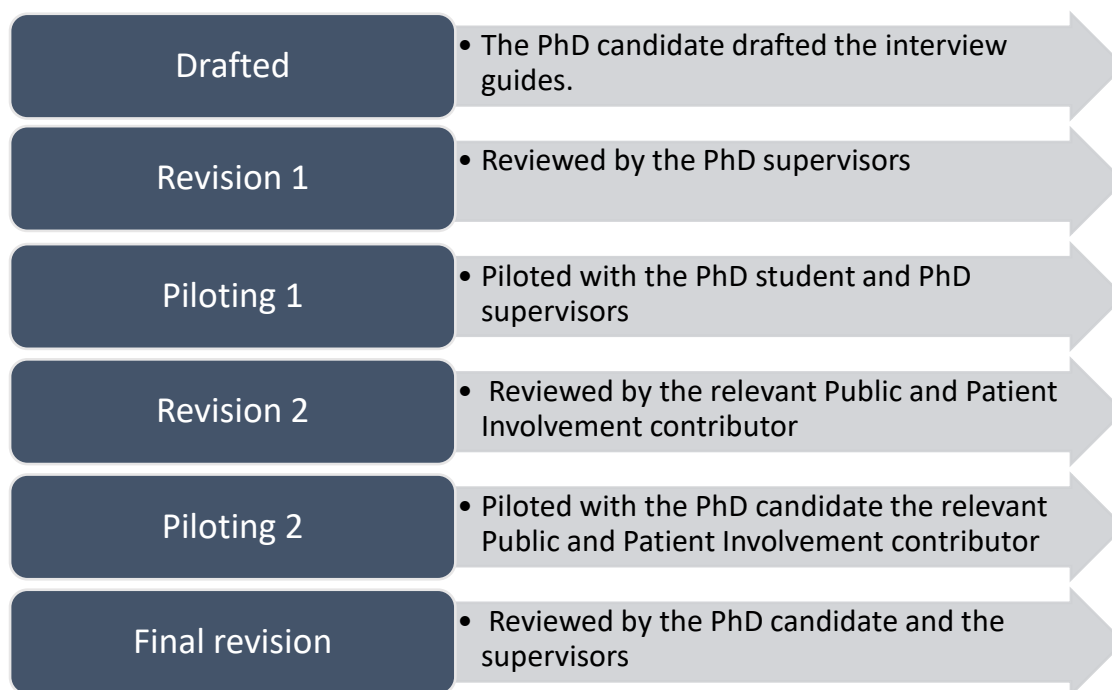


Figure 3. 6 Interview topic guide steps

Topic guide 1: For the PIC of the NH; targeting questions to describe the overall MMS in the NH and the involvement of the PIC and other stakeholders in the MMS;

Topic guide 2: for the HCPs exploring their involvement, roles, and perceived barriers and facilitators to safe and effective MMS provision;

Topic guide 3: for NH residents, exploring their involvement in managing their own medications; and

Topic guide 4: for family members, exploring their involvement in managing medications for their loved ones in NHs.

Interview questions were developed using the SEIPS 3.0 model [331]: the five work system elements: *people, tasks, tools and technologies, physical environment, and organisational conditions*, socio-organisational context and external environments.

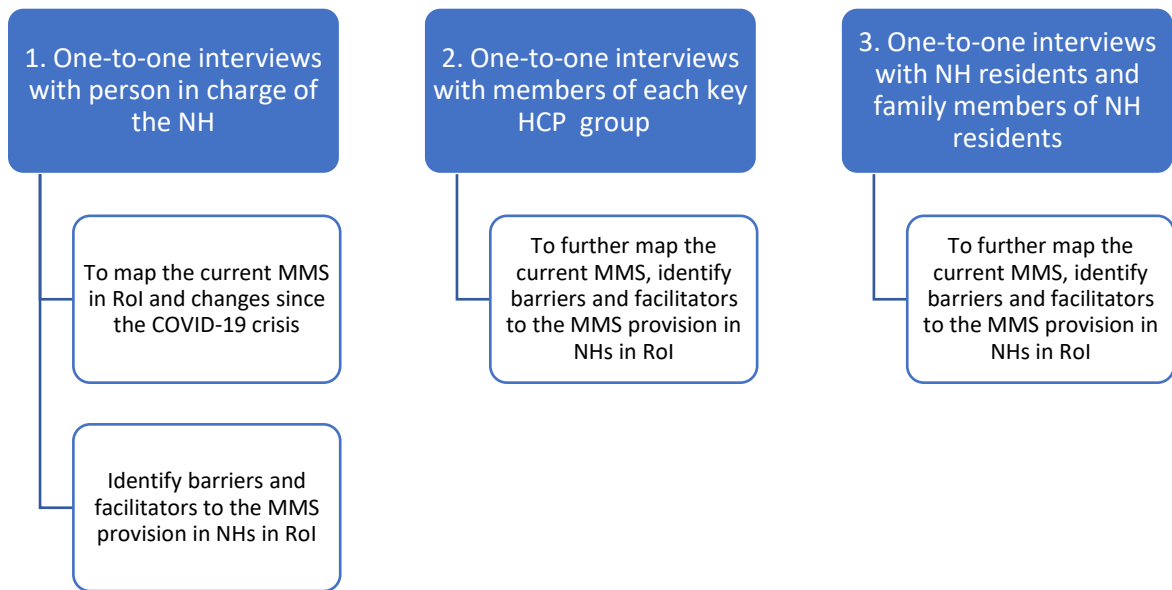
Prompts were included in the topic guide to elicit additional information, where necessary and to seek information about interactions, feedback and outcomes as they emerged during the interviews. The interview topic guide was piloted and discussed with PPI contributors (PIC, nurse, pharmacist, geriatrician, advanced nurse practitioner, and family member). Refinements were made after discussion with the research team, for example, the wording used to improve clarity and type of questions. Interview guides 3 and 4 were prepared using lay language to optimise accessibility to lay participants.

Each interview began with the PhD candidate asking demographic questions (*e.g.*, job titles, qualifications, number of years working/involved in the NH setting in Ireland, location by city/county) to ease the participant into the interview. An illustrative image of the proposed MMS (Appendix 3.20) was provided through the 'share screen' option in Microsoft Teams® throughout the interview and the proposed MMS definition was read out loud during the interviews- with HCPs only. Questions were asked and prompted on each MMS process, *e.g.*, prescribing, ... based on the SEIPS 3.0 model components. Questions were also asked to identify perceived barriers and facilitators (feedback loops) to safe and effective MMS provision and to explore the impact of the COVID-19 pandemic.

### **3.3.9. Data collection**

As explained in section 3.3.4, interviews were conducted by the PhD candidate virtually via the Microsoft teams® platform. Audio data were collected and recorded using the recording option on Microsoft Teams® platform (section 3.3.10). Recording began after obtaining the participants' consent (prior to interview) and verbal permission (during the interview). Verbatim transcription was undertaken using the "video text tracks. vtt" option on TCD Microsoft team ® platforms, followed by proofing by the PhD student. This process was compliant with guidance from TCD IT department on undertaking qualitative research during COVID-19.

Data collection for each target group is summarised in Figure 3.7.



NH: Nursing home; MMS: Medicines management process; Rol: Republic of Ireland

Figure 3. 7 Data collection

Interviews were undertaken between December 2021 and November 2022. Interviews were organised and conducted at a time convenient to the participant.

To ensure confidentiality, each participant’s recording and transcript was pseudonymised by assigning a unique identifier (*e.g.*, PIC/nurse\_01 for the person in charge/nurse, GP\_02 for the general practitioner, PH\_03 for the pharmacist etc.) for the purpose of applying matching codes across data sets (see section 3.3.10. for further information on data management and ethics). In addition, the researcher listened and double-checked the audio recording and transcription to ensure accuracy. Once transcripts were fully de-identified and validated as verbatim, all personal identifiers were removed, rendering full anonymisation (*e.g.*, names, location). Anonymised transcripts were then imported into a software package (NVivo<sup>®</sup> 12 Plus) for managing and organising interview data which are described in section 3.3.10.

### 3.3.10. Data management

Data storage and backup complied with the data protection rules in health research, *i.e.*, the General Data Protection Regulations (GDPR) 2016 [353], the Health Research Regulations 2018 and TCD Policy on Good Research Practice (version 4.8) [354]. Any processing of data/records was supported using MS Excel and was stored in a one drive folder through TCD staff facility and an encrypted password-protected computer (Table 3.2). Access to the one drive folder was limited to the PhD student (Asil Sadeq), the supervisors (Cristin Ryan and Tamasine Grimes) and the research nurse (Ms. Connie

Brennan). All mentioned processes were the responsibility of the PhD student under the supervision of her supervisors.

Table 3. 2 Data processing submitted for level I and level II Research Ethics Committees

<b>Data collected and form in which utilised</b>	<b>Format of data</b>	<b>Process activity</b>	<b>Retention time</b>
<i>Personal data: Contact details; name; e-mail address. (Electronic document).</i>	<i>Original (.xlsx)</i>	<i>The electronic excel sheet was stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD. Any participants' identifiable information was removed after validation of interview transcription.</i>	<i>7 years on TCD encrypted server beyond study completion.</i>
<i>Consent (electronic document).</i>	<i>Original (.pdf)</i>	<i>The electronic consent document was stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD.</i>	<i>7 years on TCD encrypted server beyond study completion.</i>
<i>Code keys of personal data (electronic).</i>	<i>Pseudonymised.</i>	<i>The electronic excel sheet was stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD. Identifiable code keys will be removed and decoupled after validation of interview transcription.</i>	<i>Identifiable code keys were deleted at point of interview transcription validation.</i>
<i>Research data: Audio recording (on MS teams) and transcribed (electronic document)</i>	<i>-Interview audio: MS teams audio recording (.vtt)</i>	<i>- The original audio record was saved on TCD Microsoft Steams platform for up to 28 days via TCD server and was irreversibly deleted after interview full data anonymisation and data transcription validation.</i>	<i>-Audio recording: 28 days on Microsoft Teams stream.</i>

	<i>-Transcription (.docx) or (xlsx)</i>	<i>-The anonymised electronic document was stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD.</i>	<i>-Transcribed: 7 years on TCD encrypted server beyond study completion.</i>
<i>Research data: Demographic data- sector of employment (pharmacy, hospital, NH), years of providing services to NH older residents, location by city. (Electronic document)</i>	<i>Original (.xlsx).</i>	<i>The electronic excel sheet was stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD. Any participants' identifiable information was removed after validation of interview transcription.</i>	<i>7 years on TCD encrypted server beyond study completion.</i>

*TCD: Trinity College Dublin; NH: Nursing home*

### **3.3.11. Ethical considerations**

Two applications for ethics approval were submitted and were granted for this qualitative study:

1- The School of Pharmacy and Pharmaceutical Sciences' Research Ethics committee for level I research. An application was submitted for recruiting and interviewing healthcare professionals such as the PIC of NH, nurses, pharmacists and general practitioners. This study was granted approval: [REF: 2021-01-01], Table 3.2, Appendix 3.21.

2- The Faculty of Sciences Research Ethics committee for level II research. An application was submitted for recruiting and interviewing NH residents and family members of NH residents. This study was granted approval: [REF: 220501], Table 3.2, Appendix 3.21.

➤ Data protection Risk Assessment was conducted and approved by the Data Protection Officer in TCD (Appendix 3.22)

All participant information leaflets, consent forms and interview topic guides developed were submitted to research ethics committees and the data protection office. Data management, potential risks and the associated management plan were also submitted to the research ethics committees. All participants' rights were exercised under GDPR, 2018. (Appendix 3.21)

All research team members had undertaken the required data protection training with TCD. The PhD student studied two TCD modules:

- 1- Data protection, IT security and Management.
- 2- Research Integrity and Impact in an open scholarship era

### **3.3.12. Funding**

This study did not receive any financial support or funding.

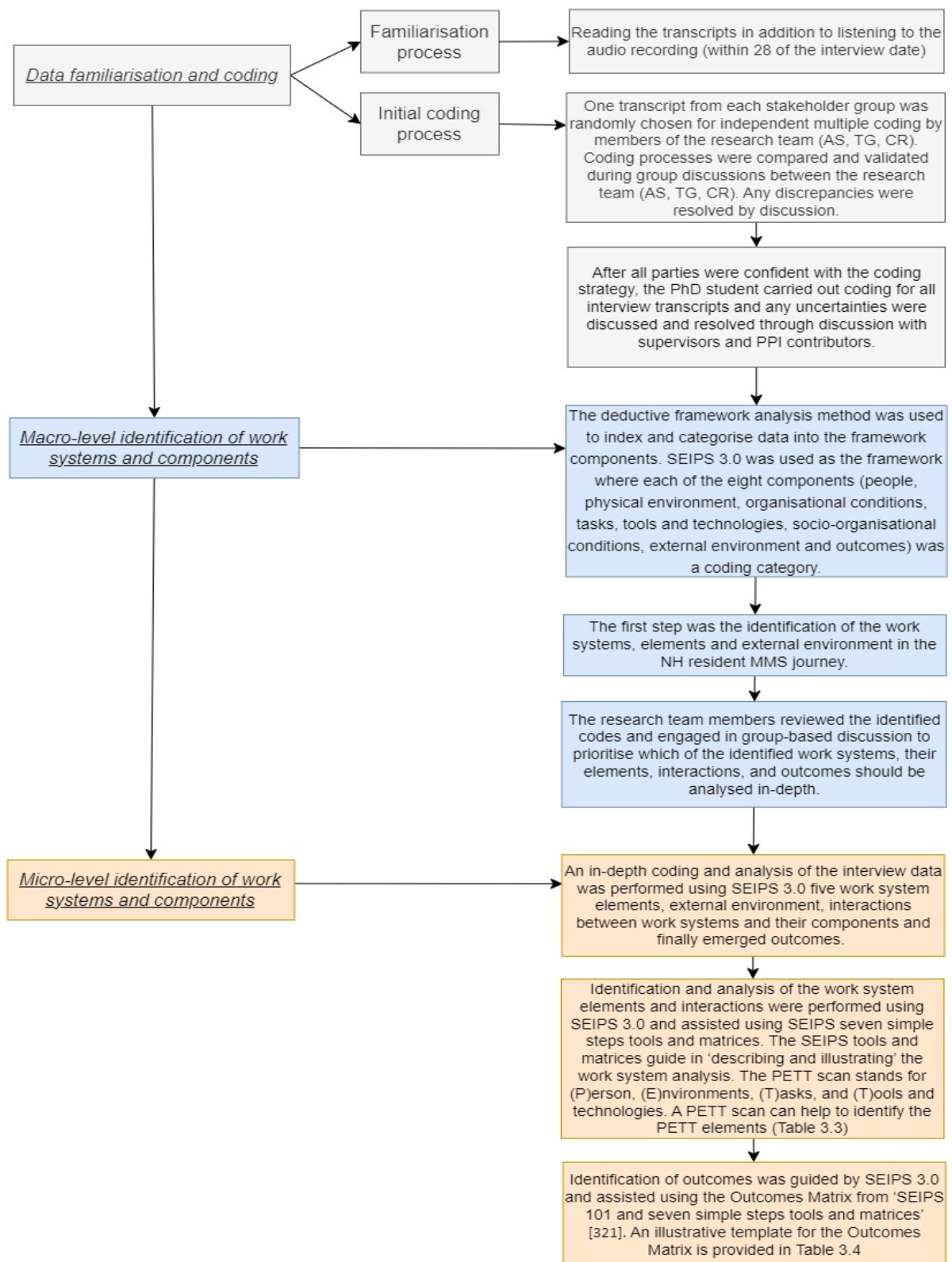
### **3.3.13. Data analysis**

Data analysis consisted of three stages to explore and identify work systems and external environment (Macro-level analysis); and an in-depth exploration of the work system elements, interactions and outcomes (Micro-level analysis). These analyses preceded a familiarisation and coding processes of the data transcripts. The stages are illustrated in Figure 3.8. Data were then synthesised to map the MMS.

Results of the macro-level are described in section 3.4.2. Within this section, results of the identified work systems and their components are presented. Identified work systems are categorised into three categories: (i) main work systems, (ii) related work systems, (iii) other distal work systems. Elements identified from interviews of the first two categories are described in the same section.

Results of the work systems that are relevant to this PhD project are further described (micro-level analysis) in sections 3.4.3 and 3.4.4. The in-depth analysis of these work systems included identifications of interactions between work systems and their elements, these are described in section 3.4.5. The SEIPS 3.0 model suggests that work systems and their elements are embedded in an external environment component, this is presented with relevant interactions with the work systems in section 3.4.6. Furthermore, outcomes experienced by NH residents and HCPs were also identified and described in section 3.4.7. Finally, using the findings generated from the macro and micro-level analysis, the NH resident MMS journey map was developed to summarise interview findings of work systems, elements and their interactions. The map was designed by the PhD candidate using a graphics application called draw.io, then it was discussed and validated by the supervisors.





AS: Asil Sadeq; TG: Tamasine Grimes; CR: Cristin Ryan; PPI: Public and Patient Involvement; NH: Nursing home; MMS: Medicines Management System; SEIPS: Systems Engineering Initiative for Patient Safety.

Figure 3. 8 Data analysis

Table 3. 3 PETT scan

<b>Element</b>	<b>Details</b>
People (Patients, healthcare professionals, others)	Individuals or groups of people and their physical ( <i>e.g.</i> , physical strength or reach), cognitive ( <i>e.g.</i> , knowledge), and psychosocial ( <i>e.g.</i> , motivation) characteristics
Environments (Physical, socio-organisational, external)	Settings of activity internal to the unit of analysis or the surrounding external context, and the characteristics and influences of these environments
Tools and technologies	Objects of varying technical advancement used to transform an input into an output and the characteristics of these tools, technologies, devices, or artifacts ( <i>e.g.</i> , usability)
Tasks	Specific activities assigned or performed within a broader work process and the sequence and characteristics ( <i>e.g.</i> , complexity, difficulty) of those tasks

Table 3. 4 Outcomes matrix

	Outcomes for			Notes and rating		
	Patients	HCPs	Organization	Priority/importance	Outcome likelihood	Measure(s) used
Desirable						
Undesirable						

HCPs: Healthcare professionals

### 3.4. RESULTS

#### 3.4.1. Participant characteristics

A total of 90 NHs were contacted from the government list of operating NHs (section 3.3.7) and 400 NHs received the invitation e-mail from NHI. More than 250 pharmacists and 50 GPs were invited by e-mail to participate in the study. The number of participants contacted using other recruitment strategies cannot be definitively stated.

In total, 17 participants were recruited and interviewed: PICs who were also practising nurses (n=7), pharmacists (n=5), GPs (n=3), and family members (n=2). Data saturation in the majority of the topics was met after these 17 interviews, and recruitment timeframe ended for the overall PhD project. The duration of the interviews ranged from 40-60 minutes. Participants' demographics are provided in Table 3.5.

Table 3. 5 Participant demographics

Participant characteristics	Participant group			
	PIC/nurses (n=7)	GPs (n=3)	Pharmacist (n=5)	Family members (n=2)
Number of residents to whom the participant provided care (range)	35-140 residents	35-70 residents	50-1000 residents	1 Resident for each family member
Years of experience/ involvement within Irish NH setting (range)	4-26 years	7 months- 30 years	6 months- 20 years	NR
Work setting (nursing home, community, and hospital)	Nursing home (n=7)	General practice (n=3)	Community pharmacy (n=3) Hospital pharmacy(n=2)	NR
Geographic (county)	Waterford Limerick Wexford Tipperary Dublin Westmeath Clare	Dublin Cork Kildare	Mayo Dublin Sligo Kerry Kildare	NR

PIC: person in charge; GP: general practitioner; NR: Not reported.

### 3.4.2. Macro-level work system analysis

Applying the SEIPS 3.0 model, our work system analysis of the NH resident MMS identified one predominant work system: the internal NH work system, and three related work systems: 1) community pharmacy work system; 2) hospital work system; 3) GP practice work system. It also identified other more distal work systems: out of hours GP practice work system; clinical experts work system; family members work system; and previous setting work system (Figure 3.9). Table 3.6 summarizes the identified work system elements presented in this chapter. All identified work systems were embedded in an external environment. The analysis of the interview data identified three primary external environments, namely: 1) Professional regulation; 2) Clinical guidance; and 3) the COVID-19 pandemic (Figure 3.9).

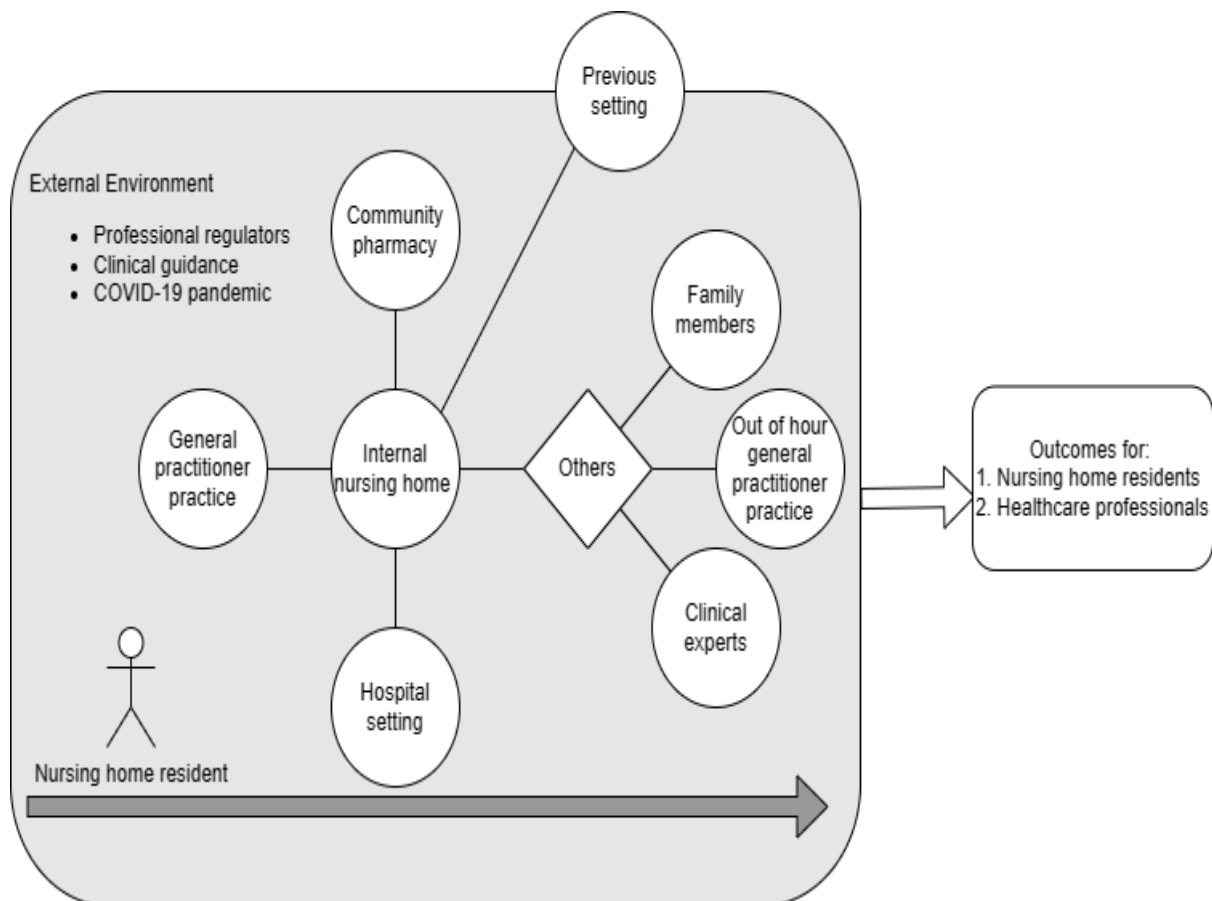


Figure 3. 9 nursing home resident medicines management system journey (Macro-level)

The in-depth exploration of two work systems was conducted as they met the scope of this PhD. The internal NH work system was chosen as it is the central work system and the permanent work system for NH residents. The community pharmacy work system was also chosen for an in-depth micro analysis to identify pharmacist involvement and within an interprofessional medicines management practice and to identify interactions between the predominant work system and the one related work system with its elements. These are described in detail in the following sections: the internal NH work system (Section 3.4.3) and the community pharmacy work system (Section 3.4.4). In addition, interactions (Section 3.4.5), the external environment (Section 3.4.6) and outcomes (Section 3.4.7) are presented. All of these are depicted as the MMS journey (Figure 3.9).

The in-depth exploration of work system elements of the remaining work systems was outside the scope of this PhD thesis, as per the discussion of the research team. However, some elements of the hospital and GP practice work systems were identified along the way and have been used to navigate and support the in-depth analysis of work systems interactions and synthesis the MMS process map.

Table 3. 6 Studied work systems and their elements.

Work systems	Elements				
	People	Physical environment	Organizational conditions	Tasks	Tools and technologies
<b>Internal NH</b>	Nurses, healthcare assistants, GPs, pharmacists, residents and family members	-Geographical proximity between NH and workplace of offsite HCPs. -Availability onsite/ offsite to the nursing home -Noise and interruptions	-Employment conditions between NH facility and GP -Shortage of staff -Staff turnover	-Level of complexity and time-consuming tasks	-NH Kardex, medical notes, clinical guidelines, reference sources, transfer letters -Clinical decision support software -Communication tools
<b>Community pharmacy</b>	Pharmacist and pharmacy technicians	-Separated dispensing area for NHs -Busy workplace	-Working hours	-Time consuming tasks -Task duplication	-Reference sources -Clinical decision support software -Communication tools -Automatic pill dispenser
<b>Hospital</b>	Nurses, GPs, pharmacist, clinical specialists.	-Noise and interruptions -Level of business of the hospital setting	-Interdisciplinary people working onsite	Tasks of hospital pharmacists identified were within the dispensing, review and monitoring of NH residents	-NH Kardex -Laboratory results -Hospital Kardex -Reference tools
<b>GP practice</b>	GPs	-Level of business -Distance to the NH	-Working days/hours of GPs in the GP practice and the NH -Directness of communication with pharmacists	Tasks identified were writing and signing prescriptions, checking if a medication is licensed, reviewing guidelines on prescribing.	-NH Kardex -Communication tools -Clinical guidance -Reference sources -Clinical decision support software - Prescribing system

NH: Nursing home; GP: General practitioner; HCP: Healthcare professionals

#### **3.4.2.1. Internal NH work system**

The internal NH setting work system is the core work system that connects all other identified work systems together, being the home and permanent location of the older NH resident (Table 3.6 and figure 3.9). Three groups of people were identified: (1) *internal HCPs, i.e.,* nurses, nursing assistance (2) *external HCPs, i.e.,* GPs and pharmacists and (3) *residents and their family members*. The processes identified were assessing medication on admission, prescribing, transcribing, ordering, dispensing and delivery, administration, review and monitoring. Within each process, multiple tasks were identified (described in Table 3.7).

The physical environment identified include the *geographical proximity, onsite and/or off-site, and interruptions*. *Level of staffing and employment conditions* were identified as the organisational context component.

Tools and technologies used were:

- *Reference tools* that aid in medicine related decision making (e.g., Screening Tool to Alert Doctors to Right/ Screening Tool of Older People's Potentially Inappropriate Prescriptions (STOPP/START), National Institute for Health and Clinical Excellence (NICE) guidelines, national guidelines on prescribing or detecting drug-drug interactions during the prescribing and monitoring stages:
- NH residents' medical *records (Kardex)* and *hospital transfer letters* (paper and/or electronic);
- *Communication tools* such as phone, secure email and virtual meeting platforms.
- *Clinical decision support software*

The socio-organization context was identified as the *NH facility* context.

The Internal NH setting work system is explored in depth in section 3.4.3.

Table 3. 7 Tasks description (internal NH setting work system) as identified from the interview data

	Processes in the MMS							
	Assessing on admission/transfer	Prescribing	Transcribing	Ordering	Dispensing	Delivery	Administration	Review and monitoring
Nurse	-Collecting resident medical notes -Communicating with the care team from previous setting	Receiving the prescription from the GP	Transcribing the prescription into the medication chart (Kardex)	Communicating with pharmacist to order the medicine from the pharmacy	Transferring pharmacists' interventions /concerns to GPs	Manage delivery time with the pharmacy	Making medication administration rounds -Administering the medication to the NH resident -Signing the administration Kardex	-Daily monitoring of resident's symptoms and medication concerns -Reporting to resident's GP if there is any MMS-related concern or risk -Documenting of all medicines-related information as required by HIQA -Participating in regular review and monitoring with GP during drug rounds. -Participating in three monthly medication review required by HIQA with other HCPs
GP	-Reading and reviewing the old and transfer medical notes -Meeting the resident to confirm diagnoses.	Writing the prescription Signing the prescription Travel back to the GP practice to print the prescription. Send the prescription to the NH (physically or electronically) Sign the Kardex						-Regular review and monitoring of resident's medicines during visits and phone calls (remote monitoring). -Regular review and monitoring with nurses during drug rounds. -Three monthly medication review requirement by HIQA
Pharmacist		Receiving the prescription from the GP			-Reviewing, checking and dispensing of prescribed medicines -Communicating with GP through nurses if there are any interventions or concerns about the prescription	Manage delivery time with the NH		Three monthly medication review, as required by HIQA -Available to answer any medicines-related questions from nurses during visits or on the phone (remotely).
Resident/family member	Providing medicines-related information							Monitoring of resident's symptoms and/or reactions to medicines during visit -Can participate in recommending an appropriate medicine for their loved ones.

MMS: medicines management system; GP: general practitioner; NH: nursing home; HIQA: Health Information and Quality Authority

### 3.4.2.2. Community Pharmacy work system

The people/care team in this work system were the *pharmacists* and the *pharmacy technicians*. Pharmacists in the community pharmacy had several tasks in the reviewing, supplying, and dispensing processes of the MMS. Pharmacy technicians were involved in the dispensing and delivery processes. Within these processes, multiple tasks were identified (Table 3.8). The physical environment identified include *separate area in the pharmacy for NH dispensing* and the *busy workplace*. Organisational context described were the *working hours of the pharmacy*.

Table 3. 8 Tasks description (community pharmacy work system) as identified from the interview data

	Processes		
	Reviewing	Dispensing and supplying	Delivery
<b>Pharmacist</b>	<ul style="list-style-type: none"> <li>-Reviewing prescriptions</li> <li>-Checking medication history</li> <li>-Checking for drug-drug interactions</li> <li>-Making deprescribing recommendations</li> <li>-Communicating with nurses or GP</li> </ul>	<ul style="list-style-type: none"> <li>-Entering the prescription into an electronic system.</li> <li>-Reviewing and checking interactions.</li> <li>-Communicating with nurses if required</li> <li>-Ordering the medication from the wholesaler</li> <li>-Applying for hardship scheme for the unlicensed medications</li> </ul>	<ul style="list-style-type: none"> <li>-Making sure all the medicines are packaged</li> <li>-Manage delivery times with the NH</li> <li>-Making sure the pharmacy technician went to make the medicines delivery to the NH</li> </ul>
<b>Pharmacy technician</b>		<ul style="list-style-type: none"> <li>-Preparing the medicines</li> <li>-Dispensing tasks (not specified)</li> </ul>	<ul style="list-style-type: none"> <li>-Delivering the medicine from the pharmacy to the NH</li> <li>-Making sure the nurse receives the medications and signs the delivery form</li> </ul>

NH: nursing home; GP: general practitioner

Tools and technologies attributes identified were:

- *Reference sources* such as the British National Formulary (BNF) and drug interaction tools.
- *Communication tools* such as phone and secure mail.
- *Automatic pill dispenser machines*.
- *Clinical decision support software*, e.g., an electronic system that can detect medication related problems (MRPs) such as interactions and contra-indications.

The socio-organizational context identified was the *community pharmacy context*.

The community pharmacy work system is explored in further depth in section (3.3.4)



### 3.4.2.3. Hospital work system

People identified in the hospital work system were nurses, pharmacists, GPs, and other specialists.

The identified attributes of these people were:

- *staff level of knowledge and familiarity* with the NH resident admitted,
- *skills level* of staff in medicine-related concerns, and
- *interest levels of staff* in providing medical information to the care team in different work systems,
- NH residents were characterised as *complex* due to polypharmacy and NH residents' acute conditions.

Physical environment characteristics identified were *noise and interruptions* from visitors and the *level of busyness* of the hospital setting. One organization condition was identified which include the interdisciplinary people *working onsite*.

Tasks relevant to the NH MMS were identified for hospital pharmacists were identified in the dispensing, review and monitoring processes.

Tools and technologies characteristics identified include healthcare notes such as *laboratory results*, hospital's and NH's Kardex, *reference tools* such as STOPP/START criteria, the *BNF*, *drug interaction tools* and *national prescribing guidelines*.

The socio-organization context was *the hospital setting*.

### 3.4.2.4. GP practice

The people identified were GPs. People characteristics identified were:

- *the directness of communication with pharmacists* and
- *knowledge and skills in clinical therapeutics*.

The physical environment was described as

- *the level of busyness* in the GP practice (*i.e.*, GPs in the practice have a lot of community patients to look after and
- *Distance from the GP practice to the NH* (*i.e.*, when NHs are near the GP practice, it is easier for the GP to visit and provide medicines-related care).

Identified organizational conditions were characterised as *working days/hours* of GPs in the GP practice and the NH. Some GPs described that they only work three days a week in the GP practice

and if nurses were to phone the GP practice on a non-working day, another GP could get the call and do the work.

Tasks identified were writing and signing prescriptions and reviewing guidelines on prescribing. These tasks were characterised as *time consuming* and *complex*.

Tools and technologies characteristics were the *NH residents' Kardexes*, *communication tools* (such as phone, video conferences and Healthmail), *clinical guidance*, *reference sources* (i.e., STOPP/START) and *clinical decision support software*. Some GPs reported they do not have access to the NH resident's Kardex for prescribing and blood results for monitoring in their GP practice, they have access to it when they visit the resident in the NH facility. Other GPs reported that with the electronic transmission of information, they can access NH resident's Kardexes remotely.

The socio-organizational context was identified as the *GP practice/surgery*.

### **3.4.3. Micro-level analysis of the internal NH setting work system**

As described in macro-level (Section 3.4.2) analysis, five work system elements were identified with their characteristics and work processes in the internal NH setting work system. Throughout this section, the characteristics of the internal NH work system elements (Section 3.4.3.1) and the interactions (Section 3.4.3.2) are further explored and discussed. All illustrative quotes from study participants were related to medicines-related questions (Section 3.3.8 and Appendix 3.19)

#### **3.4.3.1. Characteristics of the internal NH work system elements**

##### *Healthcare professionals' Knowledge and familiarity*

HCPs' knowledge and familiarity of residents and their medication needs was the most emerging attribute of the people element. For nurses, being onsite with residents, they know their residents very well and often can become their representative.

*"If resident has been with us for a long period of time, we would know the resident almost as well as their relative will know them"* [PIC/nurse\_03].

*"They (nurses) are a valuable source of information on the patient on more than one occasion"* [GP\_03].

One GP reported that nurses are familiar with the GP's prescribing attitude.

*“The nurses have a very clear understanding of how I manage things. And so they're familiar with my antibiotic prescribing, they're familiar with my attitude to say for instance, Vitamin D and sedatives and tranquilizers” [GP\_03].*

### Resident behaviour

NH residents were reported to display some challenging behaviours that impacted on the MMS. For example, a resident’s refusal to take their medications can impact the ease of medication administration.

*“Our residents over the years again sometimes. They might hide the medication in their mouths and then spit it out afterwards” [PIC/nurse\_04].*

*“She has missed a few doses last week and that's when she has elected not to take the dosages” [Family member\_01].*

### Resident cognitive abilities

The NH resident’s cognitive ability was reported to limit their involvement in their own care, including their medication. For example, one family member said:

*“Because it is the dementia, there wasn't really huge involvement from her” [Family member\_01].*

*Other HCPs also reported:*

*“There isn't actually any need of any significance when it comes to a resident wanting to be involved, they've no interest” [PIC/nurse\_04].*

*“Their cognitive ability is not allowing them to understand their medication. We would generally tell them when we're starting or stopping a new medication and why. Unfortunately, I suppose 75% of the patients we take care of do not have the ability to understand and make decisions about their medication” [GP\_03].*

### Family members’ level of interest in being involved

Some family members of NH residents are interested to be involved or to monitor side effects of medicines, this has been reported by several HCPs, for example:

*“Family may express and say: we feel this medication made him way more drowsy”* [PIC/nurse\_02].

*“And families are actually very good at monitoring as well for when they're coming in for their visits, they'll say I don't like the look of Mummy. I don't like the look of Daddy, or you know she's very sleepy today”* [PIC/nurse\_05].

On the other hand, some family members' involvement in the medicines management is limited. For example, one family member said:

*“The amount of family involvement in their medication and their kind of clinical care is limited enough”* [Ph\_03].

### Care team trust culture

HCPs and non-HCPs described trust in the HCP's work behaviours. For instance, family members trust in nurses' administration and/or GP prescribing behaviour for NH residents.

*“ I could ring the GP myself and I trust what they're doing is correct because the standard of care where she is so good, I have a lot of trust in them”... “I've been at different times of day and I see them (nurses) going around with the trolley, I've seen her (nurses) getting it plenty of times with the medication, so I presume she (the resident) gets the medication all the time when she needs it”* [Family member\_02].

Nurses trust in pharmacists' expertise with medicines pharmacology and pharmacotherapeutics was described.

*“He's (the pharmacist) very good in medication interactions regard as well”* [PIC/nurse\_04].

*“I personally find that our local pharmacists are great so any concerns (regarding medicines) we ever have, even if it is a basic query they have no problem what so ever they are always available to us”* [PIC/nurse\_07].

### Geographic proximity between care team and the NH

The choice of the GP who cares for the NH resident may be based on the geographic proximity between the NH and the GP. Some older NH residents retained their former local GP from their previous setting (home or hospital) who is familiar with their medication history and what

works/doesn't work for them. During the transition of care to the NH, the NH could be in a different city or distant from their former GP. This distance sometimes necessitated a change to a new GP that is located closer to the NH. This had been noted by both HCPs and family members.

*"They always use a local GP because they sometimes have to be called in at short notice. And so that's why you transfer to a GP that's closer to the nursing home"* [Family member\_01].

*"When she moved into the nursing home, they asked if we could change GP. Which is local to the nursing home and to be honest, I thought it would be more sensible. Because the GP is actually literally 1 1/2 kilometers away from the nursing home. So I said that makes way more sense to use that one"* [Family member\_02].

*"Instead of being you know living 500 yards up the road. They're (NH residents) now living 10 miles away in a nursing home and where their (NH residents) care needs will always be relatively high"* [GP\_02].

#### Availability of GP services onsite/offsite to the NH

One PIC reported that their NH have a GP working on site in the NH.

*"Our medical officers (GPs) are here Monday to Friday, so you know that it's very. It's very frequent that the prescription would be looked at"* [PIC/nurse\_05].

Other HCPs reported that GPs are offsite to the NH facility, in which they come to visit their NH residents regularly during the week (i.e., three times a week) or as needed. These GPs can be contracted by the NH to provide MMS services, or they can be NH residents' own GP from community that continue to provide MMS services during their residency.

*"I have a I have a defined commitment to the nursing home, which means I'm there. Let's say three times a week. No matter what's happening, even if it's only for you know 30 minutes or 40 minutes"* [GP\_02].

Another PIC/nurse reported that each resident should have their own GP, who is naturally offsite to the NH.

*"Everybody who lives with us has their own GP from the community, and it's not. It was, and nor should it be to any facility that one doctor should be a person's GP. I feel strongly about that"* [PIC/nurse\_04].

### Noise and interruptions

Noise and interruptions from NH residents, visitors and other HCPs were identified to impact on HCPs concentration and focus during medication rounds, these include complaints from NH residents about medication trollies blocking the corridors, interruptions from visitors, phone calls to the NH and NH residents knocking on the door asking for cigarettes.

*“Some residents would complain about medication trollies that are blocking the corridors which are not wide enough so sometimes the nurses are getting distracted” [PIC/nurse\_07].*

*“You certainly have patients coming up kind of knocking on the way they’re interrupting looking for a cigarettes and stuff like that. So there is a lot of interruptions and phone calls and things like that on ward rounds and I’m not sure if it is in any way possible to really eliminate that when it’s their home. At the same time, you can’t do too much about that. But I think there is much really a lot of interruptions during drug rounds and things like that” [GP\_01].*

*“There’s more people coming into the nursing home, so the into the nurse’s office or into visit. So that’s maybe more opportunity for more interruption” [PH\_05].*

### Employment conditions between the NH and GPs

Some GP participants reported that when they are contracted by the NH, they dedicate time and commitment to the NH residents, which they get paid for. For example, on GP said:

*“I have a defined commitment to the nursing home, which means I’m there. Let’s say three times a week. No matter what’s happening. You know, even if it’s only for you know 30 minutes or 40 minutes. You know it, it oversees everything so we, it’s an opportunity, then to catch up on any record that was slow to get into place. So from my perspective, it probably is reasonably efficient.... I think where in order to make a commitment to a nursing home, you need to be able to give dedicated time to the nursing home and I suppose that dedicated time needs to be structured and I suppose rewarded financially in terms of the contract and commitment that you make to these places” [GP\_02].*

Other GPs reported their contract is not directly with a NH setting but is from the General Medicine Service (GMS) scheme (described in Section 3.4.6: The external environment).

### Staff shortage and turnover

Participants reported the shortage of NH staff, especially nurses.

*“it was the challenges that staffing levels were very low if you went in at the weekend and you may see two healthcare assistants and one nurse for the entire facility of seventy patients with severe acquired brain injury” [Family member\_01].*

*“there is a shortage of staffing everywhere” [GP\_01].*

Participants reported that there were high levels of nurse turnover within the NH setting.

*“I find that the turnover of staff is high and you just get used to dealing with the nurses who are good but then they move. And then you are dealing with another person who’s just getting to know everybody again” [PH\_04].*

#### Level of complexity and time-consuming tasks

Nurses and family members reported that the task of collecting all required old medical notes is often complex and time-consuming where nurses find it challenging to reach and communicate with the newly admitted NH residents’ former care team(s) in the community, hospital, and GP settings (Table 3.7). This complexity can be further increased where other organisations (such as hospitals) archive medical notes, making it almost unfeasible to obtain old notes.

*“We (nurses) are struggling to get any information and we could ring and say oh the doctor is due to do around at a specific time, the doctors would see then the patients but no decisions in regarding to care would have been made. So they is no major communication once transferring, they would be contacting the next of kin who is also struggling to get information as well and then they ring us and we don’t always have the information cause we couldn’t get through” [PIC/nurse\_07].*

*“It took five months to get her medical records fully from the x hospital to x hospital and even then we didn't get all of the medical records and then between the two x hospital visits the medical records went to archives and then they lost them in archives, so they lost all her first visit records to the hospital so between hospitals. We found major issues with transfer of records. So there's no history, there in there in terms of the pharmacological history gets lost” [Family member\_01].*

GPs reported that their tasks of reviewing and reading the collected medical notes is time-consuming, where they have to go through packs of papers about the NH resident's medical conditions and medications (Table 3.7).

*"Old GP notes can take quite a long time to read through and to really clarify if there are errors and stuff" [GP\_02].*

Pharmacist and GP participants also described the services they provide for NHs as complex and time-consuming due to the NH residents' complex medication regimens (*i.e.*, polypharmacy).

*"There's a considerable amount of work involved in providing meds for a nursing home, it really takes up a significant part of your daily routine every day. So it's challenging" [PH\_04].*

*"I suppose they (the residents) are quite complex and there is a lot of polypharmacy, there is a lot of behavioural issues and stuff like that as well. There can be things like have a prescription for years that we really need to actively deprescribe" [GP\_03].*

#### Tools and technologies

Tools identified were medical notes, Kardexes, pictures of residents on the Kardex, transfer letters, drug-drug interaction tools, and guidelines directing the use of medicines. These can be in paper form.

*"We would have pictures of the resident on the Kardex.. So obviously we can verify then the person and that they're going to administer the medication too" [PIC/nurse\_05].*

*"Medical notes that we have with regards to anything that's discussed with the doctor. So it can be about medication, it could be about addressing, it could be about symptom, it could be about psychological, it could be anything.... it's kept in the nurse's office and the nurses, pharmacists and GPs have access to it" [PIC/nurse\_04].*

These tools can also be electronic. Some nurses reported that decision support functions can be embedded in the software. For example: administration times and doses.

*"So what I find particularly useful is the availability of electronic patient Kardexes" [PH\_02].*

*"It's all electronic, so it's there when you order a medication that's recorded on the on the electronic system, and then when the medication is delivered, the nurse has to click on received on the electronic system. Once she has verified is the correct medication" [PIC/nurse\_05].*



*“The software we have, you know if someone got paracetamol and I went in to give it to them at 11:30 it won't allow me, it says, I'm sorry this resident has had paracetamol more less than four hours ago” [PIC/nurse\_01].*

Communication tools were also reported to be commonly used between the care team (HCPs and non-HCPs), these included phone, secure email (namely, Healthmail) and virtual meetings (*i.e.*, through Zoom).

*“We do often contact the GPs and pharmacies. Through the Healthmail or on the phone” [PIC/nurse\_01].*

*“I know that some nursing homes did set up zoom consultations and things like that, I think it has done a great way to practice medicine, they're tele consultations” [GP\_02].*

#### NH size

The five elements of the internal NH work system were encircled by the socio-organizational context identified as the NH facility. The size of NH (*i.e.*, number of residents in the NH) was an important characteristic to support resident centred care. For example, the care team opined:

*“They're (small NHs) making a very small profit, but the patient is the centre of the care so it works very well” [Family member\_01]*

*“We're very small.. I can see how the ordering and the delivery of you know where things could go wrong, but I've never known it to go wrong with us” [PIC/nurse\_04].*

#### **3.4.3.2. Interaction within internal nursing home setting work system**

Within the internal NH work system, interactions were identified between elements that influenced one another (Figure 3.10). The people element of the work system was identified in all interactions.

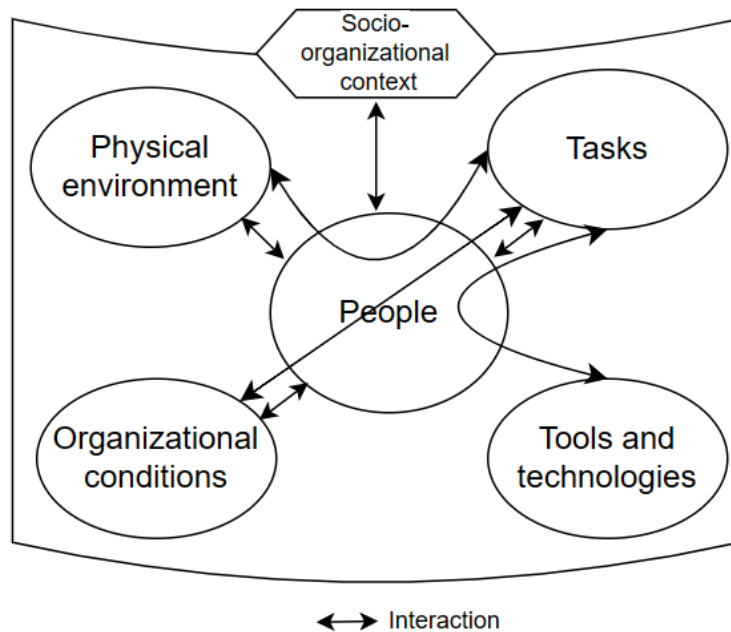


Figure 3. 10 Internal interactions within the nursing home setting work system elements

➤ People x physical environment

The choice of the HCPs to care for NH residents depends on the geographical proximity between HCPs and the NH. For example, as described in section 3.4.3.1, a NH resident’s former GP from the previous setting is more familiar and knowledgeable with their medical conditions and medicines. However, the GP often gets changed in the transition of care due to the physical distance between the GP and the new NH. At the same time, the change of GP to one that is closer (in the physical distance) to the NH was identified as being related to high levels of care.

*“Keeping or changing the NH resident’s own GP would have been discussed pre-admission, because we have residents here from another county and so obviously their GP is not going to follow them from there, so they change their GP” [PIC/nurse\_03].*

One family member also reported that because of the physical distance and traffic, it can take them a while to arrive to the NH to be involved in care for their loved ones.

*“You’re like last Friday. I got a call. I had to urgently get to the nursing home, but because the peak traffic. It takes a while” [Family member\_01].*

➤ People x organizational conditions

Pharmacists reported that staff turnover influences HCP's knowledge and familiarity of each other and of NH residents.

*"You just get used to dealing with some of the nurses who are very good. And then they moved on. And then you're dealing with another person who's just getting to know everybody (NH residents and HCPs) again. You can imagine that's challenging in any environment"* [PH\_04].

➤ People x task

GPs reported that nurse's familiarity and knowledge of the GP's prescribing practices influenced the prescribing tasks.

*"It has brought much more uniformity to the prescribing in the practice"* [GP\_03].

It was also identified that the resident's cognitive ability influenced the medication administration tasks for nurses.

*"Some residents with dementia can believe that they are being poisoned during every single administration time"* [PIC/nurse\_04].

➤ People x Tools and technologies x Tasks

Participants reported that the care team often use reference tools to support their medicines related tasks. For example, one PIC/nurse said:

*"They [GPs and pharmacist] would look at the (START/STOPP) and you know when they're reviewing medication here they would use that and I'm sure they're following their BNF and their medication guidelines"* [PIC/nurse\_01].

Another pharmacist also said:

*"I would refer to STOPP/START and STOPP frail and just for if I have a question mark over certain medication in a certain patient, I would have a look"* [PH\_05].

➤ Tasks x physical environment x people

The NH's interruptive environment influences how tasks are undertaken and can jeopardise the resident's medication safety outcomes. For example, as explained in section 3.4.3.1, interruption from phone calls or NH residents during drug rounds can influence the MMS-related tasks. For example, one GP said:

*"I think there is really a lot of interruptions during drug rounds. There have been times at the rounds where we say "oh we forgot to prescribe those three things we were talking about earlier and we have to go back and play catch up on it" [GP\_01].*

➤ Tasks x organisational conditions x people

One family member reported that the shortage of nursing staff during the weekend influences task complexity for them and may impact the resident's medical care. Staffing levels and contractual terms and conditions can influence task complexity, by impacting on the time available for HCPs to provide the appropriate MMS practices.

*"If two patients had had serious illnesses simultaneously, staff (nurses) at the weekends would have struggled" [Family member\_01].*

A GP reported that because they have a contract in place with the NH, it facilitated them having more structured and dedicated time for medicines-related task provision.

*"NH facilities like the one I have a definite commitment from a from a GP to the nursing homes, which means that they're structured and dedicated time so that gives you a lot of time then to catch up on let's say the administration side of things, I'm around prescribing as well. Of course, and around, you know the communication and letters, so that it's in place so from my point of view, probably works out" [GP\_02].*

➤ Tasks x tools and technologies x people x external environment

Task complexity and time taken to perform tasks were largely influenced by the use of tools and technologies. The use of resources and communication tools have simplified the complexity of tasks, for example by reducing the time taken to perform the tasks, improving the quality and frequency of communication between HCPs, and overcoming the need for off-site HCPs to travel to the NH because many tasks can be completed remotely. For example, GPs formerly needed to be physically onsite to prescribe and sign any medication order, then nurses had to physically send it to the pharmacy for

dispensing. More recently, since the Covid-19 pandemic, the use of electronic transmission of prescriptions means that GPs can now prescribe while they are at their practice and email the prescription directly to the NH or the pharmacist (This is further described in Section 3.4.6 as COVID-19 pandemic as an external environment).

*“I can actually do work from here, off site, if they need something urgently, I can get that prescription done” [GP\_01].*

*“If there's you know, some issue about something that's prescribed or something that's wrong dose or the medication left out or you know, these things get corrected quite quickly” [GP\_02].*

*“Now the prescription goes directly to the pharmacist via their Healthmail link” [PIC/nurse\_04].*

*“It has made things a lot easier as well because you know you can request a prescription and if the if the GP practice is responsive if you get what you're looking for quickly” [Ph\_04].*

#### **3.4.4. Micro-level analysis of the community pharmacy work system**

As described in the macro-level analysis (Section 3.4.2), five work system elements were identified with their characteristics and work processes in the community pharmacy work system. Throughout this section, we further describe the characteristics of the community pharmacy work system elements (Section 3.4.4.1), and the interactions identified between them (Section 3.4.4.1).

##### **3.4.4.1. Characteristics of community pharmacy work system elements**

###### Pharmacological skills and knowledge

Pharmacists' skills and knowledge of medicines (*i.e.*, pharmacology and pharmacotherapeutics of medicine) and their interactions with other medicines or diseases were often described.

*“We have a very good pharmacist at this. You know, keep the close eye on the medications that the resident is on and we very much try to reduce the amount of medications around where possible” [PIC/nurse\_04].*

*“There is a huge benefit there for having pharmacists involved in that space and to alleviate the problem of polypharmacy. So, I think the more opportunities there are for pharmacist involvement on various stages of the patient journey, the better” [PH\_02].*

### Interprofessional working

Community pharmacists and GPs providing medicine-related services to NH residents do not typically know each other or have any established relationship. They deal with each other through a third party, *i.e.*, the NH staff.

*"I don't think I've ever spoken to the pharmacist at all actually that deals with the NH" [GP\_02].*

*"They (pharmacist) will alert the nursing home and then we have selected GPs because there's the pharmacist will not get will not be able to get in touch with GP" [PIC/nurse\_04].*

### Separate dispensing area for NH

One participant reported having separate areas in the community pharmacy for distinct dispensing functions, *i.e.*, one area for dispensing to community dwelling people and one area for dispensing to NH residents.

*"Contained and dedicated to nursing home function only, it decreased the liability or the chances of getting error" [PH\_01].*

### Busy environment

The community pharmacy work environment was described as busy. Pharmacists have their own community patients coming and going in their workplace all the time.

*"It is a very busy dispensary or busy home dispensary" [PH\_01].*

*"In the community setting there is a continuous flow of work that has to be addressed, so you can't really spend too much time again in one particular patient case" [PH\_02].*

### Time-consuming tasks and workload

Tasks described included review, dispensing, supply, and delivery processes (Table 3.8). These tasks were characterised as time consuming, challenging, and high workload.

*"The only difficulty with that is just purely the time involved to do it because there's a lot of chart review that goes into procedure" [PH\_03].*

*"There's a considerable amount of work involved in providing meds for a nursing home, it's really takes up a significant part of your daily routine every day. So it's challenging" [PH\_04].*

One pharmacist reported that the process of ordering a prescription with an unlicensed medication can be time consuming.

*“There's a lot of time and effort involved in ordering and dispensing unlicensed medications”*  
[PH\_04].

### Task duplication

Pharmacists said they sometimes have to do the same task more than once. For example, they can identify a medicine-related concern in a prescription and recommend a change, then during the 3 monthly medication reviews, they find themselves making the same recommendations again’

*“There's often a duplication and then a lag time between the two (regular review on dispensing and the three-monthly medication review)”* [PH\_05].

### Working hours

Community pharmacists normally operate at scheduled working hours. Medicines are being reviewed, dispensed, supplied, and delivered during these working hours. Outside these working hours or if the order is received late in the afternoon, medicines are dealt with the next day.

*“There can be a gap in delivering of the medicines that they may order from us too late in the day to be sent to the next day, so it might be just a delay in treatment”* [PH\_05].

*“Then the resident, arriving here at 7:00 o'clock in the evening when there is no access to pharmacy and we have to wait until the next morning thinking to obtain the medications”* [PIC/nurse\_03]

### Tools and technologies

Similarly to the internal NH work system, pharmacists in the community pharmacy work system are using communication tools such as phone, secure mail (*i.e.*, Healthmail) and virtual conferencing software such as zoom to communicate medicine-related information with other HCPs.

*“We do often contact the GPs and pharmacies. Through the Healthmail or on the phone”*  
[PIC/nurse\_01].

*“Electronic with zoom meetings like we're having now conferences, clinical team meetings can all be held so you don't have to physically. I think that that has the potential So you know, if you*

*could set aside an hour every three months for the pharmacist or GP with the director of nursing to have the zoom call I think you know you could achieve quite a lot” [PH\_04].*

Some pharmacists are using an automatic pill dispenser in their community pharmacy. This technology can dispense hundreds of pills into blister packs in a short amount of time.

*“It has an automated method of dispensing medications into plastic blister packs. So there is for that volume of patients, there’s huge throughput of medications every day and these medications are typically packed down into monthly strips. So instead of that process being manual it is all automated with robotic technology and with automatic photo recognition technology so that the medications that are dispensed are checked electronically and any discrepancies then are manually checked by a pharmacist” [PH\_02].*

Pharmacists are also using clinical decision support software in their community pharmacy to support dispensing and medication review processes for NH residents, for example, drug-drug interaction detector function that can automatically detect an interaction when a prescription is entered into the system.

*“We set the patient up on the computer system... this software makes it very easy to check prescriptions now that are dispensed in” [PH\_01].*

*“My software will tell me that if patient is getting a SSRI like sertraline and they're also prescribed mirtazapine at night, which would have the danger of serotonin syndrome. So every time we do a review, all the potential interactions that could occur are flagged” [PH\_04].*

Reference sources are used by pharmacists; these include the use of British National Formulary (BNF), and other prescribing criteria/guidelines.

*“Using a deprescribing system, the (the pharmacist) stopped quite a lot of the medications” [PIC/nurse\_04].*

*“There’s a lot of guidance online that I would use. Obviously the NICE guidelines you’d use, you’d use up-To-Date” [PH\_03].*

*“ Obviously the BNF is key for all medication related recommendations” [PH\_01].*

On the other hand, community pharmacist participants reported not having access to NH residents’ healthcare records, medication charts (Kardex) or blood results unless they are physically in the NH.

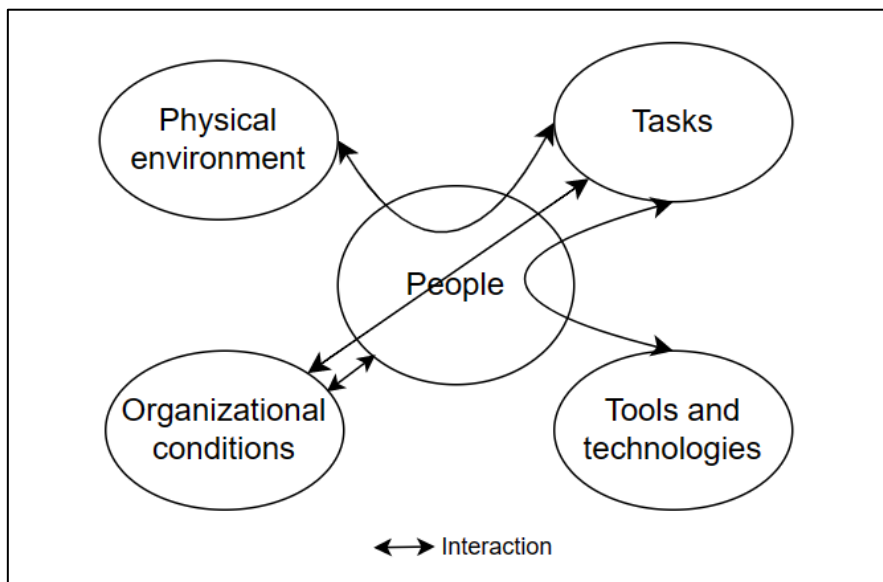


*“Medication folders (Kardex)- We have three medication folders (Kardex) for different areas of the nursing home, so each resident has their own separate prescription record within that folder and that is accessible only by the nursing staff” [PIC/nurse\_03].*

*“The monitoring section will be hard, especially if there's no access to all of those recent results from the nursing home” [PH\_05].*

#### **3.4.4.2. Interaction within community pharmacy work system**

Internal interactions are interactions within and between elements of the community pharmacy work system (Figure 3.11). The people element of work system was identified in all interactions.



*Figure 3. 11 Internal interactions within the community pharmacy work system elements*

#### ➤ Tasks x physical environment x people

The physical structure of the dispensary in the pharmacy where the NH dispensing area is separated from the community pharmacy influenced structured dispensing tasks, as reported by one community pharmacist.

*“if you have crossover between everyday dispensing and NH dispensing, there is the potential for greater risk of error. Whereas contained and dedicated to nursing home function only, it decreased the liability or the chances of getting error” [PH\_01].*

➤ Tasks x tools and technology x people

The use of drug interaction checking tools and communication tools influenced the efficiency of the pharmacists' medication review and the dispensing tasks for NH residents.

*“So instead of that process being manual it is all automated with robotic technology and with automatic photo recognition technology so that the medications that are dispensed are checked electronically and any discrepancies then are manually checked by a pharmacist. So having that mostly automated process, it really increases the throughput and it increases the efficiency of the dispensing and checking process” [PH\_01].*

The use of Healthmail that was initiated since the COVID-19 pandemic, was reported by participants to influence the degree of interaction and communication with other HCPs through electronic transmission of medicines-related information such as prescriptions (This is further described in Section 3.4.6).

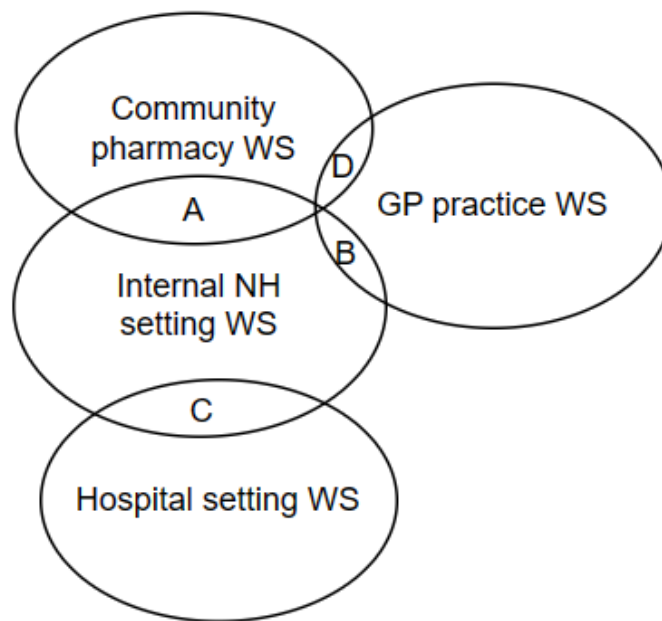
➤ Task x organizational conditions x people

Participants reported that the working hours of the pharmacy can influence the time until the NH resident receives their medications and the nurses' medication administration process tasks,

*“There can be a gap in delivering of the medicines that they may order from us too late in the day to be sent to the next day, so it might be just a delay in treatment” [PH\_05].*

### **3.4.5. Interactions between work systems**

Several interactions between work systems within the resident MMS journey were identified (Figure 3.12). The predominant work system with the most dynamic interactions with all other work systems was the internal NH work system.



NH: Nursing home; GP: General Practitioner; WS: work system  
 Figure 3. 12 External interactions between work systems

➤ **Interaction A: Internal NH setting and Community Pharmacy work systems**

Direct interactions were identified between pharmacists (people) in the community pharmacy work system and nurses (people) in the internal NH work system during the dispensing and ordering, delivery, medication review and monitoring processes (tasks) using phone, virtual meetings and Healthmail (tools and technologies).

*“I suppose, between the nursing home and the pharmacist. We have very good open communication system” [PIC/nurse\_02].*

*“We do often contact the GPS and pharmacies through the Healthmail or on the phone” [PIC/nurse\_01].*

*“Electronic with zoom meetings like we’re having now conferences, clinical team meetings can all be held so you don’t have to physically. I think that that has the potential So you know, if you could set aside an hour every three months for the pharmacist to GP in the nursing director of nursing to have the zoom call I think you know you’d have a You could achieve quite a lot” [PH\_04].*

➤ **Interaction B: Internal NH setting and GP practice work systems**

Interactions between the GP practice and the internal NH work system were identified. GPs contractual terms and conditions (organisational conditions) for service provision to the NH can influence the time taken (or given) for the GP (people) to perform medicines-related tasks (Tasks). One GP reported that GPs can make a definite commitment to providing medicines-related care when there is a contract in place between them and the NH.

*“NH facilities like the one I have a definite commitment from a from a GP to the nursing homes, which means that they're structured and dedicated time so that gives you a lot of time then to catch up on let's say the administration side of things, I'm around prescribing as well. Of course, and around. you know the communication and letters. so that it's in place so from my point of view, probably works out” [GP\_02].*

Another GP reported that the working hours/days of the GPs (organizational conditions) and the level of business (physical environment) in the GP practice can influence the GP's time and availability to provide medicine-related service (tasks) for NH residents.

*“I'm in there (NH) every month and I do their repeat prescriptions for the most part. But if there is any issues kind of outside the days that I'm working cause I'm only here 3 days a week. It'll be one of the other GP in the practice that would deal with the more acute issues like if someone had fallen or if someone had a chest infection. Or Friday they get out of hours service and they do attend them frequently enough because there is 168 hours a week and I'm only around for 30 of them, so they often get out of hours GP” [GP\_01].*

The same GP continued:

*“I suppose, look where we are is very busy and often if there was a phone call coming in from the NH, it gets tagged on the end of our morning call list. So, if there is an issue in the nursing home 9:30 or 10 in the morning they may not get a phone call back from us until 1 in the afternoon sometimes. So that's the only thing like we're not really that readily available, or I suppose as available as you would be to anyone else in the community” [GP\_01].*

➤ **Interaction C: Internal NH setting and hospital work system**

Interactions between the internal NH and the hospital work systems were identified as influencing the residents' MMS journey. Poor communication was identified between people in the two work systems which influenced their medication-related tasks during various processes:

- *On transfer of resident from hospital to NH (on admission and after hospitalisation):*

During this stage, obtaining medical notes can be time-consuming and complex (tasks) due to the level of busyness in the hospital setting (physical environment) and files management system (organizational conditions). This negatively influenced HCP's knowledge and familiarity with NH residents (people) and the prescribing, dispensing, and administering processes and the tasks within. For example, one family member said:

*"It took five months to get her medical records fully. We did not get all of the medical records and then between the hospital visits, so the medical records went to archives and then they lost them in archives, so they lost all her first visit records to the hospital and between hospitals. We found major issues with transfer of records. So, there's no history, there in there in terms of the pharmacological also history got lost"* [Family member\_01].

And another GP said:

*"particularly for new admissions to the nursing home, that is an area where there is a lot of clinical risk because they're not only moving to a new prescriber, but also a new pharmacy. So, if there is any you know significant errors of omission coming from the hospital, we don't have old notes to go to judge that and we don't have an old record to go off.. It sometimes gets us quite a while to get through old GP notes then which can take quite a long time to read through and to really clarify if there are errors and stuff. So that has led to poor prescribing"* [GP\_01].

- *Acute hospitalisation*

If a resident is acutely hospitalised (organizational conditions) and this coincides with the three-monthly review (tasks for pharmacists and GPs), this review may be missed, which can contribute to increasing the level of task complexity that is linked with managing polypharmacy.

*"Like have a prescription for years that we really need to actively deprescribe. And sometimes when you are coming to the 3 monthly review they may not be there, they maybe in hospital and suddenly the 3 months review gets skipped and you find things that are being repeat prescribed for much longer periods than you'd like them to be. So, I think there is some logistical issues there as well just with the polypharmacy and the need of the patients always changing and that as well"* [GP\_01].

The care team in the internal NH work system reported that for the duration of the NH resident's hospitalization, they do not know anything about the NH residents' medical condition or medicines because they are never contacted by the hospital staff. Communicating with the hospital staff (nurses or GPs tasks) is complex and time consuming; hospital staff either are not familiar with the NH residents (people) to provide relevant medical information (task) and/or the relevant hospital staff (people) required are almost impossible to reach due to working hours or level of business in the hospital work system (physical environment).

*"Once the patient leaves the building and they're gone until they come back and they're just no communication with tertiary care or secondary care between nursing homes and hospital. I would use the nurses follow through on some question, but the problem is when you ring hospitals the time is limited and you don't get through to the person you're looking for. And so you could be spending half an hour trying to track down somebody in a hospital"* [GP\_02].

*"We'd never be contacted by the hospital"* [PIC/nurse\_03].

*"We are struggling to get an information and we could ring and say oh the doctor is due to a around at a specific time, the doctors would see then the patients but no decisions in regarding to care would have been made. So they is no major communication once transferring, they would be contacting the next of kin who is also struggling to get information as well and then they ring us and we don't always have the information cause we couldn't get through and people do not know"* [PIC/nurse\_07].

➤ **Interaction D (Community pharmacy and GP practice work system)**

The level of business in the GP workplace (physical environment) influenced the GP's choice/preference (people) to communicate indirectly with the pharmacist through the nursing staff (task). For example, one GP noted:

*"Where a pharmacist identifies that there is an interaction that I have not seen. I have encouraged them to come through the nursing home because I have such volume of e-mails in the practice and if they e-mail me, it might not necessarily come to me in a timely manner. So, I will say (Contact nursing home) and then the nursing home, depending on the urgency and the situation, they (nurses) can contact me"* [GP\_03].

Another PIC/nurse also reported:

*“They (pharmacist) will alert the nursing home and then we have selected GPs because the pharmacist will not be able to get in touch with GP” [PIC/nurse\_04].*

One pharmacist reported that this indirect communication with GPs (people) influenced their medication review process (task) where there is a lack of clarity about whether their recommendations have reached the GP and been declined or whether the nurse did not inform the GP about the recommendations (task).

*“In the reviews of medicines, we go in every three months. We go through all the different recommendations and speak with nurses. They (nurses) pass that on to the GP. But sometimes, more times, these changes just get ignored” [PH\_05].*

### **3.4.6. The external environment**

All work systems were identified as being embedded within three primary external environments: professional regulation (section 3.4.6.1); clinical guidance (section 3.4.6.2); and the Covid-19 pandemic (Section 3.4.6.3). These are described below.

#### **3.4.6.1. Professional regulators**

##### ➤ HIQA

As described in section 3.1.1, HIQA is the regulatory body in the RoI that sets standards and regulates services for older adults in all clinical settings. HIQA reported by participants to influence the NH resident’s MMS journey.

*“If HIQA would visit, so if they would do an inspection, let’s say medications so a day inspection would be very much kind of observing when nurses administer medication or what’s the full process, how we administer. And then they would look through Kardex as well, how well they are being kept” [PIC/nurse\_02].*

*“Everything has to be compliant and you know with HIQA you know, so you need to have signed off and these things as well. You know within the appropriate place. This in the patients’ Kardex files so all of that needs to be done in a timely fashion, let’s say, and it’s not left undone” [GP\_02].*

*“The nursing home are very aware of the regulations that they work within and so they would often remind me. You know something needs to be done so for instance, HIQA require you to have a three-monthly review of my all medication, so we do” [GP\_03].*

HIQA are also responsible for inspecting the appropriateness of medication-related processes provided to NH residents according to their regulations and standards.

*“The HIQA inspectors would carry out a drug round for one of our nurses. They would follow the nurses around, making sure that they're doing everything right there, washing their hands between each resident. They're making sure for medication is to be crushed. You know it's document that has to be crushed. And then be checking the maximum doses of PRN medication to be making sure that the medications are locked, that the drug trolleys are locked so you know they are the audit processes” [PIC/nurse\_01].*

*“From the medication management, HIQA will look all through this same thing, prescribing ordering how we store medication and stuff like that” [PIC/nurse\_06].*

GP participants reported that HIQA (external environment) positively influences HCP's adherence (people) to the practice (task).

*“HIQA guidelines kind of encourage us to do, the 3 monthly review, kind of keep us a little bit on top of that medication review and stuff as well” [GP\_01].*

On the other hand, HCPs reported HIQA and their inspection requirements as being:

(a) Paper-work oriented rather than patient-oriented, making tasks more time consuming

*“I think the biggest issue with either HIQA or the PSI you know, is there big dependence and this regulation around paperwork you know that the professionalism and the judgment after pharmacists and doctors and nurses is kind of compromised” [PH\_02].*

*“HIQA aren't focused I suppose on clinical guidance from our perspective I don't feel, they're very much just feel like more of a checkbox on a practical kind of initiative” [GP\_01].*

*“HIQA spend all their time criticizing the physical infrastructure and very little time looking at the actual patient outcomes.. there would be just they'd be just box ticking exercises, you know, you just run a report and send it in and somebody from HIQA will come along and they'll have a look at it and they won't understand what's in it anyway. And they'll say Oh yeah, you've done a review every month. Well done” [PH\_04].*

(b) Not clear, influencing the medication review process tasks

*“I find the HIQA guidelines difficult to get hold of from our perspective. In terms of medication reviews and stuff like that. There isn't a huge degree of clarity on it” [Ph\_01].*



And (c) Time consuming work

*“Because if a GP ends up having a half a day of extra work a day just to facilitate the HIQA requirements, the reality is that they’re going to have to hire another doctor to see the patients in their practice while they’re doing that” [GP\_01].*

One GP reported that HIQA regulate the internal NH work system, although the medication-related processes are often undertaken by people situated in multiple work systems but not employed by the NH.

*“If I'm asked to see a patient who's got abdominal pain or chest pain or is vomiting and they (HIQA) have no jurisdiction over that they have no right to look at my notes in the context of clinical they (HIQA) might. So, if I make a note on something or if I didn't make a note. It's the nurse gets hammered not me” [GP\_01].*

However, another GP reported that the nurses influence GPs to fulfil HIQA requirements and to be compliant with regulations.

*“But they (HIQA) do impact me because the nurses have get the nurses have got to get me to do things in a certain way In order for them to be compliant with HIQA and that's fair enough and I buy into that because I know the nurses have a difficult job and the staff have a difficult job so, so if they want me to do things in a certain way in order to be, honestly, compliant and I'll do that to facilitate their requests. But it's basically a request from the nurse that is, we have to do with this, you have to sign that you have and we have to be able to show HIQA, but that's not HIQA to me. That's HIQA, telling the nurses that this is what they want in order for them to make sure that to the patient is getting the correct care” [GP\_02].*

➤ Pharmaceutical Society of Ireland

One pharmacist opined that the PSI influence the burden of work and reduce the integrity of a pharmacist’s professional practice, partly due to over regulation and administrative requirements.

*“The problem is that I would see a lot of pharmacists coming out now who are more worried about the paperwork than they are about the patient-That's a big, big problem... the patient is suffering because of the paperwork” [PH\_01].*

*“Get the PSI who make up these things that they stand (regulations) to just come and work with*

*the pharmacist in a busy thing, you know, get a working group together” [PH\_01].*

➤ Nursing and Midwifery Board of Ireland

The NMBI is the regulatory body for nurses in Ireland and therefore nurses follow their guidelines and standards for medication management. One interview with the PIC/nurse talked about the medication safety aspect where nurses monitor for MRPs. Another PIC/nurse reported the use of the 10 rights of medication administration from the NMBI.

*“We're following the medication management guidelines from NMBI. The Nursing Board always were monitoring for adverse side effects” [PIC/nurse\_01].*

**3.4.6.2. Clinical guidance**

➤ Health Services Executive and/or Department of Health

HCPs (people) in the NH resident’s MMS journey identified that they follow the national guidelines (tools and technologies) set by the HSE or the Department of Health (external environment) in their medicines-processes’ (tasks). These include the National Standards for Falls, National guidelines on antipsychotics and sedatives, and the HSE antimicrobial stewardship guidance.

GPs reported that there is no clear guidance for medication review set by the HSE for them or pharmacists to follow.

*“In terms of medication review, there isn’t any clear guidelines on it” [GP\_01].*

One pharmacist reported that their task in ordering an unlicensed prescribed medication under the Hardship Scheme from the HSE is time-consuming. Another GP reported that they are hesitant to prescribe unlicensed medications because of the legislation.

*“There's a lot of time and effort involved in ordering and dispensing unlicensed medications” [PH\_04].*

*“If a medication is unlicensed, I think I’d be hesitant to prescribe, certainly the melatonin, the one thing that comes up most frequently everywhere, melatonin is unlicensed in Ireland. So I would not routinely prescribe it because I think our licensing and the legislation would have a little issue with us using unlicensed medications” [GP\_01].*

### General Medical Services

As mentioned in Section 3.4.3, GPs reported two types of types of contractor agreements to provide care for NH residents; one is a direct contract between the NH and the GP and the other type is the *General Medical Services (GMS) contract* where the GPs are contracted by the HSE to deliver services to patients in possession of a GMS card. This contractual arrangement is commonly referred to as “*The GMS contract*” and it stipulates the contractual arrangements and the time that GPs should dedicate to GMS NH residents. GPs reported that some time-consuming tasks such as the three-monthly medication review (task for GP), are not included in the GMS contract for GPs and this therefore created a tension about how the GP expended time and effort on their NH resident patients in return for remuneration from the funder. A GP also reported that they are doing the three-monthly medication review required by HIQA because the nurses want them to and not because they believe it is for the benefit of the NH resident.

*“You’re contracted the GMS doctors to NHs. But then HIQA has guidance on NH and they’re criteria to meet that actually OUR contract doesn’t cover. Like technically the 3 months reviews are not covered in the under the GMS scheme. I think the contract in relation to the GMS and the NH need to reflect a little bit what HIQA is asking as well. Like I do know like our practices are very positive, we got a fairly good relationship with our NH, so we’re certainly not going to leave them in a difficult position. But like if you have a GP practice elsewhere that is very busy from practice day-to-day perspective, the GP is entirely within their right to go and not do the 3 months review and not doing anything more than the GMS script, I’m not doing your Kardex, I’m not doing any of that because all of that is time consuming and not covered in the contract”*  
[GP\_01].

#### **3.4.6.3. The COVID-19 pandemic**

##### ➤ Positive influence

(i) The COVID-19 pandemic was identified as an external environment. It supported the government to introduce legislation to facilitate the electronic transmission of prescriptions and other communications between healthcare providers and organisations through secure mail, called Healthmail. This is an identified interaction between two external environments (COVID-19 pandemic and legislation).

*“You know that’s how Healthmail was introduced during COVID as a means of prescribing and getting prescriptions down so that brought an awful lot of efficient. In fact, COVID made some*

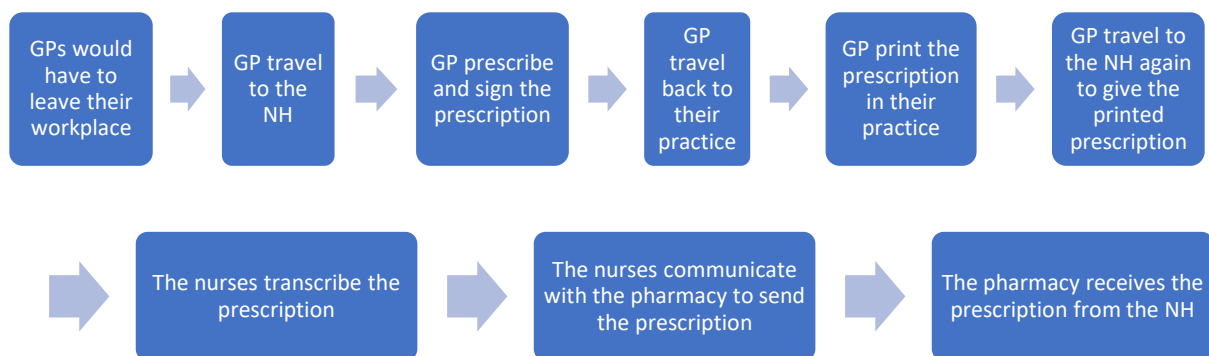
things increased efficiency, and I would say it brought an awful lot of efficiency around prescribing, particularly in nursing homes where obviously needs that they need their regular prescriptions. They need repeat prescriptions. So it did away with all the paperwork around that by the by the you know the setting up of Healthmail, which has made the prescribing element of it very efficient" [GP\_02].

"COVID has brought about some benefits. One example would be making more use of electronic transfer of documentation" [PH\_02].

Healthmail has changed the way prescribing and medication or medical information flow between HCPs in different organizations, overcoming the level of task complexity and time consumption identified in section 3.4.3. For instance, the process prior to COVID if a NH resident needed a prescription is described in Figure 3.13. For instance, participants reported:

"I remember one of the other GPs from the practice was working in the nursing home for COVID and would have had to go down to sign one prescription then come back here in the practice to print them and then bring them back down the nursing home again" [GP\_01].

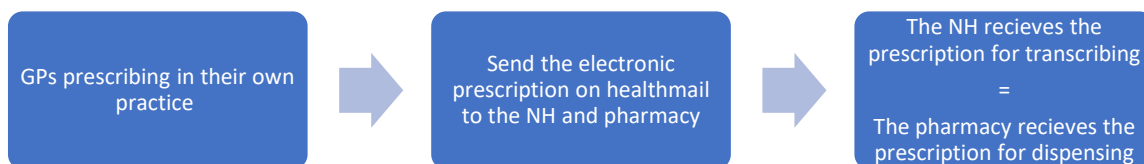
"The positive things that has arisen that I suppose distance is no longer a problem" [PH\_02].



GP: general practitioners; NH: nursing home

Figure 3. 13 prescribing process tasks prior to COVID-19 pandemic

Since the introduction of Healthmail during the COVID-19 pandemic, this scenario changed to that depicted in Figure 3.14:



GP: general practitioner; NH: nursing home

Figure 3. 14 prescribing process tasks during and after COVID-19 pandemic

This change has influenced the time taken for task completion and the ease of communication between the care team situated in different organisations.

*"I think e-prescribing has been something that was really needed because it means that at least I can actually do that from here, I can do that if I am off site, if they need something urgently I can get that prescribed" [GP\_01].*

*"In addition, there is no longer the need to sign paper prescriptions, which has been fantastic and I now communicate. I now e-mail my scripts directly to the pharmacy So that that is that is fantastic because previously we were signing You know stacks of paper and it had to be delivered or delivered then to the pharmacy. So I use Both Healthmail to send prescriptions to the pharmacy and I also use their management system their meds management system to e-mail, the regular prescriptions" [GP\_03].*

*"I suppose the big change for us since COVID pandemic is electronic prescribing. It's really quick to get a prescription, so if we bring the GP and we say someone complained of a headache, they don't have paracetamol tomorrow. Can we get Paracetamol more PRN please? And the GP just electronically prescribes that to the pharmacy and we get it immediately, so it it's saved huge amount of time for us" [PIC/nurse\_01].*

Healthmail has influenced better communication between GPs and pharmacist in the prescribing process.

*"There has been an improvement in communication with the as far as the access for Healthmail for nursing homes and we can get prescriptions directly from the file system. There's no real requirement now for natural paper prescription and we can get a prescription directed directly from the GP and pharmacists. It will accept them as well and so that that is a vast improvement" [PIC/nurse\_04].*

(ii) HCPs also reported the frequent use of phones and video conferencing using zoom during the COVID-19 pandemic for communication and to perform medication review and monitoring tasks.

*“Medication reviews done over the phone, yeah” [PIC/nurse\_01].*

*“We use zoom or teams for direct issues related to medications that will be even more so done over the phone” [PH\_02].*

➤ Negative influence

On the other hand, participants reported the COVID-19 pandemic as having a negative influence on the MMS:

(i) GPs and pharmacists reported that the level of busyness in their workplaces was influenced by the COVID-19 pandemic.

(ii) The PIC/nurses reported that the COVID-19 pandemic influenced staff shortages and staff turnover.

(iii) During the pandemic, new staff were hired to compensate for shortage of staff. One PIC/nurse reported that the new staff had different practice habits than those more established in the NH, therefore increasing work difficulty for other HCPs and creating opportunities for medication errors.

*“Yeah, it was very stressful 'cause I lost the time we were running very tight with staff or we are relying on external from agency or staff from other services coming in to help. So yeah, it's that was very difficult... And we also had a number of medication errors at that stage as well because staff from other agencies had their own way of doing things which was not really our way of doing things” [PIC/nurse\_05].*

PIC/nurses participants reported strategies that were used during the COVID-19 pandemic to overcome these challenges, such as double checking and forward task planning, which added further work.

*“Strategies we came up with to make things actually work with less issues were Double check triple check, quadruple check” [PIC/nurse\_03].*

*“Probably an awful lot more of forward planning” [PIC/nurse\_04].*

### 3.4.7. Outcomes

The identified outcomes are categorised into desirable and undesirable and are presented in Table 3.9.

Table 3. 9 Work system outcomes with associated processes and components

Outcome type	Outcomes for residents	MMS- related process(es)	Details of SEIPS component
Desirable	Reduced medication error	Prescribing	NH size ( <i>socio-organizational context</i> ) Familiarity with and knowledge about NH residents ( <i>people</i> )
		Dispensing	Separate section for NH resident's medication ( <i>physical environment</i> )
		Administration, review, and monitoring	Double checking and early detection of error ( <i>Tasks</i> )
		Prescribing, dispensing, administration, review, and monitoring	Familiarity with and knowledge about NH resident ( <i>people</i> ) HCPs' skills and knowledge ( <i>people</i> ) Provision or availability of old medical notes ( <i>tasks</i> ) Having the picture of the NH resident in the Kardex ( <i>tools and technologies</i> ) Use and access to clinical support decision electronic software ( <i>tools and technologies</i> )
		Prescribing and monitoring	Access to another specialist ( <i>external environment</i> ) Quick electronic transmission of prescription ( <i>external environment and tools and technologies</i> )
Undesirable	Increase medication error	Administration	Shortage of staff ( <i>organizational conditions</i> ) High staff turnover ( <i>organizational conditions</i> )
		Administration	Residents' behaviour ( <i>people</i> )
		Prescribing, dispensing, administration, review, and monitoring	Hospital transfer of care issues ( <i>organizational</i> ) ( <i>tasks</i> ) Over-prescribing in community setting ( <i>tasks</i> ) Lack of interprofessional communication ( <i>organisational</i> ) ( <i>people</i> ) ( <i>socio-organisational</i> )
Outcome type	Outcomes for family members	MMS- related process(es)	Details of SEIPS component

Desirable	Satisfaction and trust with care provided by HCPs	Administration Prescribing	Familiarity and knowledge ( <i>people</i> ) Skills and knowledge of medicines ( <i>people</i> )
Outcome type	Outcomes for HCPs	MMS- related process(es)	Details of SEIPS component
Desirable	Simplified task complexity -Improved communication	Prescribing, dispensing, administration, review, and monitoring	The use of secure mail, phone, and reference resources ( <i>tools and technologies and external environment</i> )
	Reduced time-taken to perform tasks: -Faster prescribing -Quicker access to prescriptions -Quicker change of prescriptions -Quicker dispensing -Easier spotting of medication error -Reduced paperwork burden	Prescribing, dispensing, administration, review, and monitoring	Accessing electronic software ( <i>tools and technologies</i> ) Using secure mail ( <i>tools and technologies</i> ) Introduction of secure mail and electronic transmission of prescriptions ( <i>external environment</i> ) Automatic pill dispenser ( <i>tools and technologies</i> )
	Reduced the issue of physical distance between the NH facility the workplace of HCPs.	Prescribing, review, and monitoring	Use of secure mail and phone ( <i>tools and technologies</i> )
	Psychological safety on the HCPs	Prescribing	Employment and contractual conditions ( <i>Organizational conditions</i> )
Undesirable	Discomfort in performing their tasks -Stress and stretched -Lack of resources -Compelled to do work for reasons that are not person-centred but to satisfy regulations	Prescribing, dispensing, review, and monitoring	Employment and contractual conditions ( <i>Organizational conditions</i> ) Unclear clinical guidance and regulatory requirements ( <i>external environment</i> ) Lack of affiliation between the GMS contract and the HIQA requirement ( <i>external environment</i> ) The workload associated with ordering and dispensing unlicensed medications ( <i>task</i> )( <i>external environment</i> )



	-Hesitation to prescribe unlicensed medication		
	Increased workload	Prescribing, administration, dispensing review, and monitoring	Shortage of staff ( <i>organizational conditions</i> ) Level of busyness in the workplace ( <i>organizational conditions</i> ) Staff turnover ( <i>organizational conditions</i> ) Paperwork requirement ( <i>external environment</i> ) Unlicensed medications ( <i>external environment</i> )
	Increase task complexity -poor communication between HCPs -Limited time to review all Kardexes	Prescribing, administration, dispensing, review, and monitoring	Polypharmacy ( <i>tasks</i> ) Employment and contractual conditions ( <i>organizational conditions</i> ) Multiple carers and HCPs in different organizations ( <i>people</i> ) GPs channelling communication with pharmacists through NH staff ( <i>people</i> )
	Lack of task clarity	Prescribing, review, and monitoring	Unclear guidelines on medication review ( <i>external environment</i> )
	Task duplication	Prescribing, assessing, review and monitoring	GPs channelling communication with pharmacists through NH staff ( <i>people</i> ) Level of busyness in workplace ( <i>physical environment and organisational conditions</i> ) Noise and interruptions ( <i>physical environment</i> )
	Hesitation to prescribe	Prescribing	Unlicensed medication ( <i>external environment</i> )

NH: Nursing home; GP: General practitioners; HCPs: Healthcare professionals

#### **3.4.8. The NH resident MMS journey map**

The findings from the above sections were synthesised to create the NH residents MMS journey map.

The groundwork of the map projects the flow of processes within the MMS, tasks of the care team

(i.e., PIC/nurse, GP, pharmacist, pharmacy technician, family member and others) within and

interactions that were reported from the interview data to act as barriers or facilitators to the process.

(Figure 3.15. The figure can be also accessed electronically via this link ([Click here](#)).

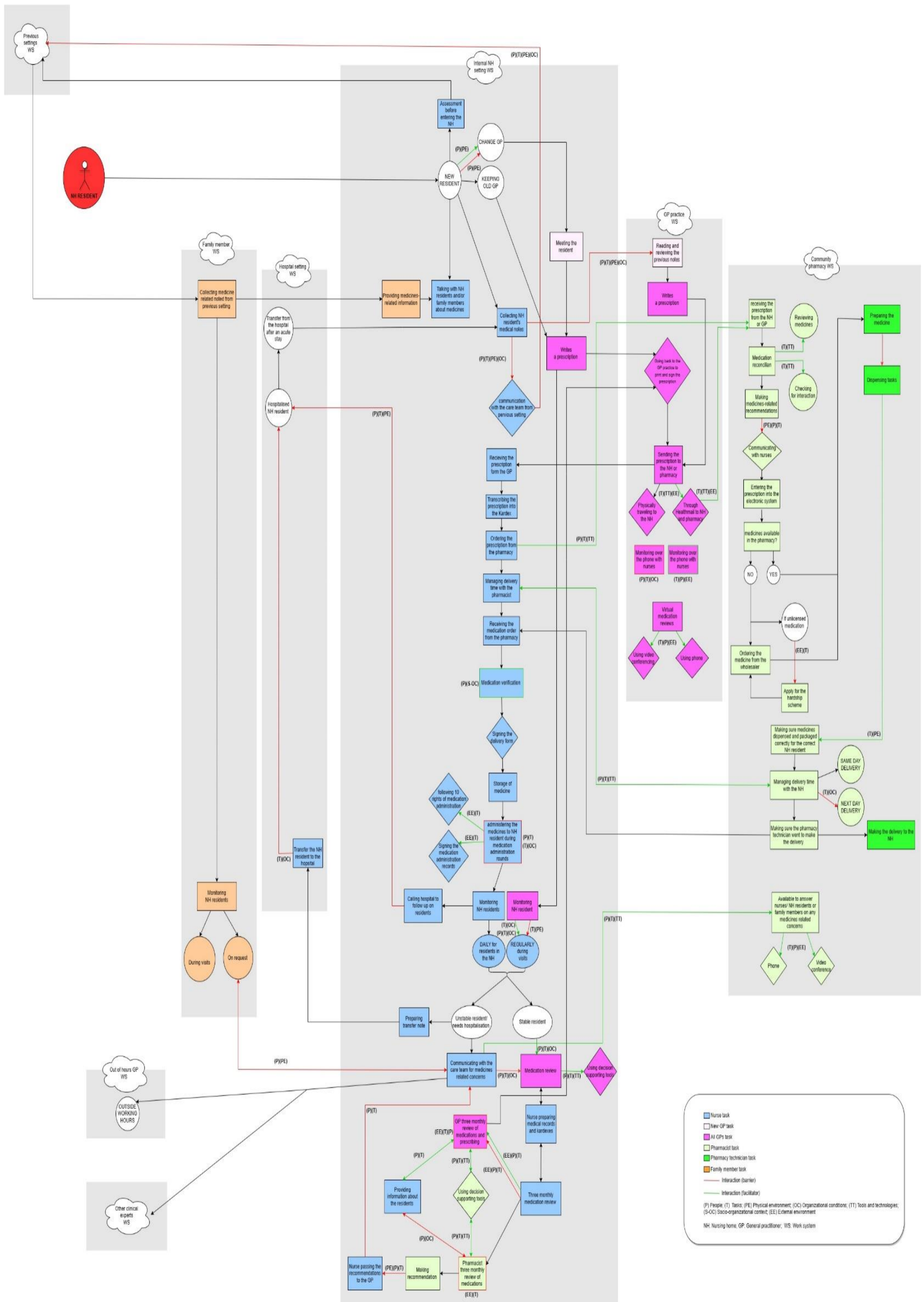


Figure 3. 15 The nursing home resident's medicines management system- processes journey map

### 3.5. DISCUSSION

The aim of this qualitative study was to explore the MMS in the Irish NH setting. To achieve that, we conducted 17 interviews with members of the care team who are involved in providing MMS-related services to older NH residents (Section 3.4.1). In our study, we identified multiple work systems that were categorised: (i) one predominant; internal NH, (ii) three related work systems; community pharmacy, GP practice and hospital work system, and (iii) four other linked work systems that contribute to some stages of the MMS; previous setting, family members, out of hours GP practice, and other clinical experts (Section 3.4.2). Multiple and rich work system elements were identified, and multiplex interactions were uncovered within and between work systems in the NH resident MMS journey (Sections 3.4.3, 3.4.4, 3.4.5). The external environment of the work system, including 'statutory regulators', 'clinical guidance' and 'COVID-19 pandemic' (Section 3.4.6) were identified to significantly impact the characteristics of the work system elements and the dynamics of interactions, contributing to the outcomes experienced, for example, the frequency of medication errors reported as being experienced by NH residents and the complexity of HCPs tasks (3.4.7).

This study uses a system-level analysis as the MMS studied consists of multiple associated processes and systems. Hettinger and colleagues suggest that a system-level analysis of complex systems facilitates the identification of performance outcomes, referred to as *emergent properties* [355]. In this study, four key emergent properties were reported in this work: complex MMS (section 3.5.1); communication and interprofessional practice (section 3.5.2); technologies triggered by the COVID-19 pandemic (3.5.3); and ambiguity of service provision (3.5.4).

#### 3.5.1. Complex medicines management system

The identification of several work systems and the richness of elements illustrates the '*complexity*' of the MMS in the NH setting in the RoI. This has been previously proposed in the literature and the WHO where the NH system was defined as being '*complex*', '*adaptive*' and '*non-linear*' [356, 357]. In the same way, Strauven and colleagues' findings of one work system using SEIPS (the internal NH setting work system) in the Norwegian NHs have described the MMS- provided in NHs as a complex system [340]. Our study findings go beyond the internal NH setting work system and add to Strauven and colleagues' work that the complexity of the MMS is related to the existence of the multiple other work systems and the dynamic network of interactions. This identification provides evidence of critical appraisal, in which it adds to the evidence base a systems-based explanation of the MMS complexity, strengthening the evidence of MMS complexity in the Irish NH setting and provides new insights of informing future strategies to address this complexity.

Researchers have also described the MMS in settings other than the NH setting as *'complex'* [358, 359]. The literature offers evidence to explain the reasons behind this complexity, for instance, Phipps *et al.*'s interviews with HCPs providing MMS-process services to patients with renal failure in community and hospital settings reported that *'characteristics of the disease'* and *'organisational conditions'* were identified as concerns to the complex MMS [360]. Likewise in our study, the *'people'* element of SEIPS such as a NH residents' challenging behaviour and the burden of a NH resident's polypharmacy, and *'organisational conditions'* such as staffing levels, all contributed to undesirable outcomes in NH residents. Lee's systematic review demonstrates a potential association between the ownership type of a NH and the nurse's staffing level in the NH setting, which can be linked with NH residents' health-related outcomes, the well-being of nurses and the NH organisation's spending [361]. Similarly, McGregor and Harrington explain the evidence of the association between the ownership type of NHs (*i.e.*, private/public) during the Covid-19 pandemic [362]. Studies previous to COVID-19 reported similar results, for instance, Harrington and colleagues' study reported that private NHs had fewer staff than publicly owned NHs [363]. Interviews conducted in this study did not identify reasons for the shortage of staff. However, it may be argued that the COVID-19 pandemic can be one of the reasons. This is supported by interviews that were undertaken during the COVID-19 pandemic where the number of people infected with the disease was high, strict quarantine measures (described in Chapter 1, section 1. 6) and studies reporting the low prevalence of NH staff during the COVID-19 period [364, 365]. Maintaining a sufficient number of nursing staff to provide care for NH residents is reported to exert a positive influence on older people's clinical outcomes and the task's attributes experienced by NH staff [366-369]. Thus, this study suggests maintaining an appropriate staffing level and urges researchers and policy makers in this area to develop a strategy to overcome the undesirable consequences, in this case specifically related to medication management, for both residents and carers.

Another considerable contributor to the complexity of the MMS is the physical environment of the NH. For example, interruptions have been shown to be related to an increase in the risk of medication error and a reduction in the level of patient safety in all clinical settings [370-374]. Westbrook *et al.*'s study in the hospital setting reported similar results and noted that approximately 20% of interrupted tasks remained incomplete [375]. Odberg and colleagues' identified similar results in the Norwegian NH setting and reported that nurses can be interrupted up to 14 times per hour while performing their MMS-process related roles [376]. There have been some strategies published to inform how to reduce interruptions in various clinical settings including the NH setting [376, 377], however, the literature about how to manage the direct impact of this on patient safety is sparse [378]. Odberg and colleagues suggested that adaptation and *'normalising'* unavoidable characteristics of work system elements was

one approach that could potentially improve outcomes experienced by HCPs. However, the long-term impact of this approach is not evident. Thus, this study suggests that more research is needed to understand the components of interruptions during medication management tasks and approaches that can be adapted to address this and therefore to improve NH residents' outcomes.

### **3.5.2. Communication and interprofessional practice**

As described in this chapter, the care team consists of multiple people from different disciplines or professional groups, situated in different settings and caring for one/multiple NH residents. Each of those carers provides distinctive MMS-process roles. With the exception of nurses in the internal NH setting work system, the people in all other work systems were identified to have inconsistent or indirect communication with each other. These people were opportunistically working together with a shared interest of a NH resident rather than as a formal team. Edgar and Harvey link the existence of care team members in different organisations to the deficient coordination between them [165]. There is evidence presented in the literature about the positive impact of interprofessional practice on enhancing the quality and safety of the MMS and reducing MRPs (Chapter 2, Section 2.4.7) [253]. Interprofessional practice is recognised internationally by many organisations such as the WHO and nationally in the RoI by HIQA as being person-centred. HIQA refer to the interprofessional team working as a "*collaborative multidisciplinary partnership*" and define it as "*an approach to the planning of treatment and the delivery of care for a resident by a team of health and social care professionals who work together to provide integrated care*" [113, 144]. HIQA require an interprofessional MMS practice for older people residing in the NHs and report this in their *National Standards for Residential Care Settings for Older People in Ireland* and the *Medicines Management Guidance*. Areas relevant to interprofessional MMS practice in these documents include: developing and reviewing NH residents' care plans, nutritional concerns, end-of-life care, assessments on admission, and medication review [113, 144].

HIQA also recommends pharmacists' involvement as part of the interprofessional team [144]. Nevertheless, this study did not identify any evidence of direct collaborative work as a team between the HCPs providing care to NH residents (*i.e.*, nurses, GPs, pharmacists), but rather suggest that interprofessional working is 'a networking coordination'. This is referred to by Reeves and colleagues' systematic review as a *pseudo team* that describes how members of the team may be "*labelled as a 'team' but, in reality, have little shared responsibility or coordination of their teamwork*" [379]. The lack of truly collaborative working identified in this study suggests a definite gap in interprofessional practice and its definition within the NH resident MMS-process journey in the RoI. This may be explained by the fact that many HCPs are offsite to NHs and irregularly visit on-site, often without forward planning or without any co-ordination with other HCPs when they do. This therefore limits the opportunity to meet

colleagues and communicate or interact. Similar results have also been reported by Jenkins *et al.*, in the primary care setting, suggesting that the co-location HCPs in one place allows better communication between different HCPs [380]. Such *pseudo team* working has been associated with MRPs, for example, Abraham *et al.*, reported the communication barrier between pharmacists and other HCPs in the hospital outpatient and inpatient wards to increase the possibility of undesirable outcomes [381]. This study identified better collaborative teamworking through the use of Healthmail, this is described in detail in Section 4.1.3.

Nurses in the internal NH work system were identified as the route of communication between the different people within and between all work systems for the majority of MMS processes. Nurses were the only HCP involved and performing tasks in all internal MMS processes. This finding is consistent with Odberg and colleagues' results where nurses' tasks were present during all examined processes of the MMS [382]. Such distribution of nursing work across all MMS tasks in the internal NH work system may be expected because nurses are working with the NH residents in their current permanent homes where other HCPs visit for MMS service provision, if needed. Furthermore, all of these roles form part of their obligations from the NMBI and HIQA towards NH residents and communicating well with other HCPs [114, 144, 383]. HIQA also mandates the PIC/nurse to facilitate MMS-related services provided by the external HCPs in meeting their obligations, for instance, one of the criteria within *Regulation 29: Medicines and Pharmaceutical services* states "the provider must facilitate the pharmacist concerns in meeting his or her obligation to a resident under any relevant legislation or guidance issued by the Pharmaceutical Society of Ireland" [312]. However, this distribution of nursing effort may also contribute to a challenging work environment as described by White *et al.*'s cross-sectional study reporting that the NH environment plays a significant role in outcomes for NH residents such as reducing the consequences of MRPs (*e.g.*, hospitalisations) [384]. Coupled with the shortage of nursing staff described in Section 3.5.1, this identifies that the interaction between environments and task is a potent interaction that can be targeted for improvements.

Furthermore, it was identified in our study that important medicines-related recommendations by pharmacists can be lost through the *channelling* of these messages by nurses to GPs. Participants interviewed explained that GPs' preference is one factor contributing to this. Pojskic and colleagues identified similar results and reported that this is an important barrier to interprofessional collaboration [385]. This indirect communication resulted in increasing the burden of tasks for pharmacists and risks of inappropriate MMS-process service provision. In this study, it appeared to increase workload burden for both pharmacists and nurses. Henneman and colleagues describe the desire to collaborate as an important principle to successful interprofessional practice [386]. In like manner, Nancarrow and colleagues' literature review suggested 10 characteristics of good interprofessional practice, which

include the 'climate' characteristic which they describe as "valuing contribution" and creating an "interprofessional environment" [387]. Furthermore, O'Donnell and colleagues developed a framework of the "core competencies for interprofessional collaboration" to guide care team members into effective interprofessional working. This framework consists of three linked domains (i) knowledge; (ii) communication; and (iii) decision-making [388]. In light of that, this study identifies knowledge about key characteristics of the MMS and evidence on factors contributing to better communication between interprofessional team members.

Factors that possibly influenced GPs' decision to bypass direct communication with the pharmacist could be explained by the organisational context; a busy GP practice environment. Bollen and colleagues reviewed the results of GPs' limited time to support medicines-related services by pharmacists [389]. Although this qualitative study did not explore reasons for the busy workplace, other studies have quantitatively explored the prevalence of GP practice visits within a similar timeframe (during the COVID-19 pandemic) to our study and identified contradictory results. For example, Homenuik and Collins in the RoI reported face-to-face GP visits were significantly reduced during the COVID-19 outbreak ( $p < 0.001$ ) [390]; a large-scale cross-sectional study conducted by Michalowsky *et al.*, in Germany reported fewer visits and consultations in community and hospital during COVID-19 [391]; the National Health Services in the UK reported a 30% reduction in the number of GP appointments during the pandemic [392].

Furthermore, Bollen and colleagues also identified GPs' level of trust in pharmaceutical knowledge and skills to have an influence on interprofessional collaboration [389]. Our study findings identified data on HCPs' acknowledgement of pharmaceutical skills. At the same time, there was no evidence from the interview data that the medicines-related recommendations made by the pharmacist were directly communicated to the GP via tools and technologies. In contrast, Gleeson and colleagues interviewed Irish pharmacist and reported evidence on pharmacists communicating Healthmail information to relevant GP in the primary care setting [393]. This study highlights that the communication between pharmacists and GPs during dispensing, medication review and monitoring processes remains a gap in the care of Irish NH residents despite national guidance recommending interprofessional medication reviews [113, 196]. Thus, this study recommends a further in-depth analysis of the GP practice work system and within MMS interprofessional teamworking is needed.

NH residents and/or family members were identified as part of the people element in the internal NH setting work system. NH resident's involvement is recommended in the *Medicines Management Guidance* which states "Good practice suggests the review of medicines should involve the resident, his or her representative as appropriate" [144]. However, this study identified that the extent of their



involvement was limited due to their cognitive characteristics and dependency on their carers. Thus, it remains unclear how resident's or family's involvement, or lack of, in the MMP has an impact on outcomes. Similar results were reported by Damiaens and colleagues' qualitative study in Belgium NHs [394]. More research is needed to explore any influence of NH residents' or family's involvement on their journey map.

### **3.5.3. Technologies triggered by the COVID-19 pandemic**

The use of technologies, such as Healthmail, to aid the electronic transmission of information (*e.g.*, prescriptions) was triggered by the COVID-19 pandemic (*external environment*). As described in Chapter 1 (Section 1.6), Healthmail was established in 2014 but its use for transmitting prescriptions did not become legal practice until 2020 when COVID-19 pressured the government bodies (*i.e.*, HSE) to enact legislation to accommodate the use of 'electronic' transmission of information (such as prescriptions, Kardexes, therapeutic plans, and reviews/audits) through Healthmail [195, 205]. The interaction is therefore a multi-component interaction identified within (i) two external environments (in this case COVID-19 and legislation); (ii) tools and technologies (in this case Healthmail); and (iii) people in multiple work systems. This finding is consistent with the Irish data describing the impact of COVID pandemic on MMS practices but is described from a systems-based analysis. Thus, these system-based findings provides valuable evidence about the impact of the external environment of the NH residents MMS journey on the way healthcare systems and their components are operating.

Moreover, the reported HCPs' opinions about the benefit of technology to enhance communication and interprofessional working within the prescribing process in this study is similar to Gleeson and colleague's interview findings in the Irish primacy care setting [206, 393]. This is consistent with the Australian NHs where Elliott *et al.*'s, similar findings discuss the direct relationship between the electronic transmission of medicine-related information and increased medication safety [395]. Similar results were also reported in different healthcare settings targeting the prescribing and administration processes and other MRPs were significantly reduced through the use of digital health technology [396-399]. This finding strengthens the evidence for the use of technologies that can improve interprofessional MMS team working in the NH setting. Equally important, future research should explore the benefits of enhanced use of technologies to improve interprofessional working between GPs and pharmacists around medication management for NH residents, such as operating a mutually accessible electronic system between nurses, GPs, and pharmacists; where pharmacist's recommendations can be entered into the electronic system and viewed or actioned by GPs. Irish GPs have expressed a desire for such shared access to resident information with pharmacy and the NH [400]. Additionally, the need for governance support to implement a secure electronic healthcare systems has

also been recommended by HIQA in their reported recommendation to improve health information systems in the RoI [401].

#### **3.5.4. Ambiguity in service provision and role clarity**

Healthcare services provided to NH residents in the RoI are regulated by HIQA which aims to promote person-centred practices in their *National Standards for Residential Care Settings for Older People in Ireland* [113] (described in Chapter 4 of this thesis). HIQA also regulates NHs and assesses compliance with various regulations, including those relevant to medicines management [144, 312]. Although HIQA is only responsible for regulating NHs and the responsibilities of the PIC, HIQA mandates that NH residents should have access to other HCPs (i.e., GPs and pharmacists) who should provide a three-monthly medication review [144]. Findings from this study describe the challenges for GPs to provide care, including medication management, for NH residents for various reasons, including 1) lack of time; 2) lack of clarity on the job description; and 3) lack of a funding structure for the work required by HIQA. In other words, HIQA's medication review requirements are not accounted for in the GMS contract for GPs who provide care for NH residents both privately and under the GMS scheme, as reported by interviewed GPs in this study. On the other hand, this was not reported as a challenge to the pharmacists and may be explained by the clarity of their job description from the PSI and the Memorandum between HIQA and the PSI regarding medication management [316, 402]. GPs also reported that as a result of this ambiguity in roles, they were providing NH services because the PIC/nurse in the NH wants them to do that rather than the GP considering that there was a genuine need to perform the task or for patient-centred purposes. This finding highlights the gap in person-centred practice provided to older people in the Irish NH setting. GPs who had a contract with the NH did not identify these challenges. Thus, regulators and contractors in the RoI should consider these issues to balance regulatory requirements and contractual terms and conditions to enhance person-centred practice. In addition, this PhD did not identify an association between the ownership of NHs (i.e., private NHs or publicly owned) compliance with HIQA inspection standards (Described in Chapter 4), and there is limited evidence available about the interaction between model of ownership and the MMS outcomes. However, this area could be qualitatively explored in future studies. Furthermore, it remains unclear whether the three-monthly medication review requirements for HCPs are integrated or recommended to support interprofessional collaboration. Thus, more research is needed in this area.

#### **3.5.5. Nursing home residents journey map**

The concept of process modelling or *mapping* is essential to understand the complex NH setting, which encompasses multiple processes that are connected across and within work systems. Carayon and colleagues defined a care process as *"a series of tasks performed by individuals using various tools and*

*technologies in a specific environment*”[327]. Each process consists of a set of task-related activities performed by people using tools and technologies in certain environments. For example, the processes of monitoring medicines-related reactions can be performed by nurses and GPs in the NH, or by GPs remotely during the COVID-19 pandemic using phones and remote access to medicines-related information in their own GP practice.

We sought to map the ‘systems’ of processes or ‘workflow’ fashion. Jun and colleagues reported that a workflow is a comprehensive approach in process mapping [332] and Wooldridge *et al.*, added this approach in their processing mapping and reported it to be beneficial in identifying challenges and facilitators in complex healthcare systems [403], such as the MMS in this study. Our NH resident MMS journey map, presented in Section 3.4.8, incorporates these concepts with the latest concept of the patient journey proposed by Carayon *et al.*, using the SEIPS 3.0 model [331].

The advantages of process mapping were previously described in the literature in different healthcare settings. For instance, Asan and colleagues identified that the inconsistent prescribers use of electronic healthcare records influences their regular tasks in the primary care setting [404]. Likewise in the NH setting, Odberg *et al.*, used the SEIPS model and highlighted three work system elements (tasks, organizational conditions and tools and technologies) that largely contributed to positive and negative interactions in the medication administration process [382]. It is important to note that Odberg *et al.*, described the ordering, transcribing, dispensing, and administering stages under the medication administration process while our study describes these as processes in addition to the assessment, prescribing, monitoring and medication review processes under the MMS.

This study established for the first time the NH resident MMS-process journey in the Irish NH setting, which adds to the current evidence on this topic by conceptualising the systems and component processes and highlighting targets to enhance outcomes. Future work could deepen and extend this exploration by building on the findings of this study, for example (i) mapping the workflow and interactions of/with other work systems such as hospital setting, previous setting, out of hours GP and other clinical experts work systems; (ii) integrating outcomes. In addition, both the process mapping methods and the complexity of the MMS identified in this study can be useful to researchers as a means of process remodelling and learning from feedback loops as described by SEIPS; where learning about poor processes can help redesign better healthcare systems. This recommendation is in line with the WHO recommendations that aim at improving medication safety by targeting the care team, human factors and high-risk circumstances [357, 405].

### 3.5.6. Strengths and limitations

The reporting of this qualitative study was in line with the COREQ checklist (Appendix 3.1). The involvement of a multidisciplinary PPI contributors of HCPs and non-HCPs in this study to develop and refine the methods conducted has enhanced the rigour of the study and robustness of findings; and to our knowledge, this is the first multi-faceted PPI panel created in the area of medicines management provided to older people residing in NHs in the RoI. This study also followed the recommendations in the MRC framework by using theory in the developmental stage of designing complex interventions. The topic guides for this study were based on the SEIPS 3.0 model and were piloted with the research team members (supervisors and PPI contributors) to ensure the clarity and validity of questions. The use of the SEIPS 3.0 model in the analysis allowed the constructive mapping of the work systems, their components, and outcomes. This has facilitated the creation of the first NH resident MMS-process journey map in the RoI. Finally, the use of virtual interviews on MS Teams<sup>®</sup> facilitated (i) conducting this qualitative study during the pandemic which may otherwise not have been possible; and (ii) facilitated the recruitment of participants from different geographic locations which allowed a better representation of the Irish context.

There are some limitations to this study. Firstly, the target recruitment of a minimum of 10 participants from each HCP group and 5 from each non-HCP group was not achieved. This was due to a variety of reasons including HCPs' workload and their limited time, which is supported from interviews findings; the COVID-19 pandemic challenges; and the lack of financial motivation to participation, Kelly et al., reported that financial rewards can improve participants recruitment [406]. Secondly, no NH residents were recruited as we were not contacted by any NH residents or any of their carers regarding any interest in participating, which may explain the lack findings on NH residents' involvement in their own MMS journey. The time pressure on the PhD candidate limited the flexibility in time to continue with participant recruitment, this might have reflected on data saturation in some reported topics. Thirdly, some participants had less than two years of involvement in the MMS services provided to older NH settings. This was not in line with the eligibility criteria for this study (Section 3.3.6). However, due to the challenges described in recruiting participants the research team decided to include any HCP who is involved in the MMS services provided to older NH residents. Finally, other facilitators of the NH resident MMS journey could exist but were not identified from interviews. Hollnagel explains that the healthy outcomes are often hard to recognise as they are an integral part of the normal functioning workday [407].

### **3.6. CONCLUSION**

To our knowledge, this is the first systems-based exploration and mapping of the NH resident MMS journey in the Irish NH setting. The identified work systems, their components, interactions, and outcomes strengthen the available evidence and highlight factors contributing to the complexity of the MMS provided to this cohort and opportunities for future research and improvement. The findings of this study provide a solid basis for further in-depth exploration of other work systems and their impact. This study identified that deficient interprofessional collaboration, ambiguity in service provision and role clarity, and the disconnect in regulation across professional groups and settings were the main barriers to positive outcomes. Thus, this study suggests further research and focus on the area of interprofessional MMS practice for researchers and policymakers. Additionally, exploring the system from the statutory NH regulators' perspective is needed. A key facilitator of positive outcomes was the use of technologies triggered by the pandemic, which simplified prescribing tasks for HCPs and reduced medication errors for NH residents. The knowledge and learning from these findings can help redesign and improve the MMS in the RoI.

## **Chapter 4**

An exploration of the medicines  
management process in the Irish nursing  
home setting:

A secondary mixed methods analysis of the  
National Inspection Reports

## **4.1. BACKGROUND**

As described in chapter 3 of this thesis, the national statutory regulators in the Republic of Ireland (RoI) were identified in the Systems Engineering Initiative for Patient Safety (SEIPS 3.0) analysis as being part of the work system component involved in the medicines management process (MMP), namely the external environment. This external environment was identified as interacting with several elements of the work systems, and to influence the nursing home (NH) resident's MMP journey and the resulting outcomes for residents and healthcare professionals (HCPs).

### **4.1.1. The nursing home context in the Republic of Ireland**

The Irish NH context has been described in detail in Chapter 3, section 3.1.1. In short, more than 20,000 older adults in the RoI live in NHs [105]. This cohort can be admitted to the NH setting from any care setting, such as a hospital or even from their own home. Factors that influence NH admission include age-related cognitive and physical impairments, multimorbidity, polypharmacy, frailty, and most commonly a high level of dependency and inability to care for one-self at home [112].

There are more than 400 NHs in the RoI [105]. The majority of these are privately owned (approximately 80%), while others are voluntary NHs (*i.e.*, non-profit or charity) or publicly owned (*i.e.*, by the Health Services Executive (HSE); described in Chapter 3, Section 3.1.1) [305]. Regardless of the ownership type, all NHs are regulated by the Health Information and Quality Information (HIQA). HIQA is an independent statutory body with the responsibility for setting standards and monitoring Irish healthcare services to promote best practices in the delivery of care. HIQA was established under the Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People [303] and Registration of Designated Centres for Older People [112])[113]. Prior to 2007, all NHs were regulated by the HSE.

### **4.1.2. The Health Information and Quality Information's remit**

HIQA is a statutory body that reports to the Minister for Health and engages with other Governmental ministers, including the Minister for Children, Equality, Disability, Integration and Youth Affairs. As an independent authority, it is tasked with developing quality standards for health and social care services, inspecting services and providing support for the delivery of services [408]. It ensures that high-quality and safe care is provided for people using health and social care services in Ireland, across public, private and voluntary sector services [408].

The HIQA develops standards for care provided to vulnerable patients in all care settings, and parallel guidelines on how these standards should be met [409]. The standards published by HIQA include the *National Standards for Special Care Units for hospital services* [410]; *National Standard for Safer Better Maternity Services* [411]; *National Standard for the prevention and control of healthcare associated*

*infections [412]; National Standard for Foster care and National Standards for the Protection and Welfare of Children for children's services [413, 414]; National Standards for Residential Services for Children and Adults with Disabilities [415] and the National Standards for Residential Care Setting for Older People in Ireland [113].*

HIQA develops their standards based on national and international evidence-base for health services and social services [416]. The HIQA board, which consists of 11 members from various health services and disciplines, has the final decision in developing or updating national standards and guidance [417]. The HIQA board also engages with the Department of Health, Department of Children, Disability, Equality and Integration, TUSLA (The Child and Family Agency), National Patient Forum and the HSE to prioritise areas for improvement, also referred to as the prioritisation process [416]. Within the prioritisation process, the team members meet at least every two years to discuss priorities for health services in the RoI. This process consists of eight stages: (i) completing a proposal form to develop/update a standard, (ii) screening brief where one member of the team is responsible for highlighting the screening criteria (*i.e.*, if the topic complies with definition of standards/guidance and HIQA) and sending the proposal for feedback by relevant team, (iii) the team members meet to decide if the topic requested for development/update meets the screening criteria, (iv) the decision of the screening meeting is made where eligible requests can be moved to the prioritisation process or be rejected, (v) the prioritisation process where the documents are prepared and sent to the team for their assessment before the decision-making meeting, (vi) the team members meet to discuss the proposal and make decisions, (vii) the meeting report is then sent to the Standards and Guidance Programme Advisory Group (PAG), where they (viii) meet to discuss the report and the meeting report is sent to the HIQA board members (who meet quarterly) for the final decision [416]. The prioritisation process was established to improve health-related outcomes for all service users and to maintain the high quality of standards described [416]. The standards related to the older population residing in NHs are called the *National Standards for Residential Care Setting for Older People in Ireland [113].*

#### The National Standard for Residential Care Setting for Older People in Ireland

The *National Quality Standards for Residential Care Setting For Older People in Ireland* were published in 2009 [418]. The standards were established due to the increase in demand for NH care, primarily due to the ageing demography of the population, which has been clearly described in Chapter 3, section 3.1.1. Throughout the standards, the terms 'residential care', 'nursing homes' and 'designated centres' are used interchangeably [418], however, the term 'nursing home' has been used in this chapter and throughout the thesis. Another factor that contributed to the development of the standards was the challenges in protecting and maintaining older people's rights, when transferred to the NH setting.



These rights, as defined by HIQA, include access to personal health and medication information, patient consent, the right to privacy and dignity, and the right to consult pharmacists or relevant HCP about medicines that are prescribed, to mention a few. These challenges formed the basis of the development of the initial standards, published in 2009 [418].

The 2009 document includes 32 standards of care. All of the standards apply to all NH residents, irrespective of the type of NH (*i.e.*, public, private or voluntary). The standards are categorised into seven 'domains of care': (i) rights for older people, (ii) protection, (iii) health and social care needs, (iv) quality of life, (v) staffing, (vi) care environment and (vii) governance and management (Figure 4.1). Each domain of care has a variety of standards, ranging from two to seven, and each standard has several individual criteria, ranging from two to 35. The health and social care needs domain incorporates standards relevant to the MMP (standards number 14 and 15) [418].



Figure 4. 1 Domains of care of the National Quality Standards for Residential Care Setting for Older People In Ireland, 2009 [418]

Standard 14, outlines that “each resident is protected by the residential care setting’s policies and procedures for medication management and, where appropriate, is responsible for his/her own medication”. The standard consists of thirteen discrete criteria, that describe how the Person in Charge (PIC) and nurses providing care ensure quality in the MMP. This includes adherence to medicines policies

and legislation pertaining to the administration, recording, handling, and receipt of medicines, recording and documenting of a medication error, record keeping, handling and disposal of medicines [418].

Standard 15, outlines that *“each resident benefits from their medication to increase the quality or duration of their life, they do not suffer unnecessarily from illness caused by the excessive, inappropriate or inadequate consumption of medicines”*. Standard 15 pertains specifically to medication monitoring and review aspects of the MMP. It specifies that NHs and pharmacists providing a service to NHs should review and update information on medicines management every 3 months or more, as needed. Prescribers are also required under this standard to review NH residents’ medication at the same quarterly interval as that for pharmacists, giving special attention to specific classes of high-risk medications: antipsychotics, sedating medications, non-steroidal anti-inflammatory drugs (NSAIDs), antiplatelets and vaccines [418].

In 2016, HIQA updated the 2009 standards, built on intelligence gained through inspections on NHs, evidence from local and international healthcare settings and panels of experts in this area. The new standards had a slight name change, removing the word ‘quality’ from the title. The revised title is: *“National Standards for Residential Care Settings for Older People In Ireland”* [113]. HIQA developed the 2016 revision document that consists of 35 standards categorised under eight themes: (i) Person-centred care and support; (ii) effective services; (iii) safe services; (iv) health and well-being; (v) leadership; (vi) governance and management; (vii) responsive workforce; and (viii) use of information. These themes were categorised under two dimensions (1) quality and safety; and (2) capability and capacity (Figure 4.2). The new standards are set to be more person-centred for all NH residents, including those living with dementia. Each theme has a variety of standards, ranging from one to eight. Each standard has a variety of individual criteria, referred to as features, ranging from four to 27. The “safe services” theme comprises a standard that is relevant to the MMP, namely: Standard 3.4 [113].

Standard 3.4, outlines that *“Each resident is protected through the residential services policies and procedures for medicines management”* and consists of nine distinct features relating to the MMP as follows: [113].

- 3.4.1: Medicines administered to NH residents must have a clinical indication and be administered as prescribed. Records must be maintained.
- 3.4.2: Stages of the MMP (e.g., prescribing, supplying, dispensing, administration, review and monitoring, storage, disposal, and reconciliation) should be safe and appropriate.
- 3.4.3: NH resident’s ability to self-administer and self-store their medicines should be assessed.
- 3.4.4: NH residents should be informed about side effects and any relevant information regarding their medicines. Any HCP involved with medicines management (nurse, pharmacist,

or prescriber) must be available to answer any concerns or questions from NH residents about their medications.

- 3.4.5: NH residents should have access to pharmacist services of their choice.
- 3.4.6: NH residents must be monitored and reviewed by each HCP in accordance with evidence-based practice.
- 3.4.7: Medication review must occur every 3 months, and specific attention given to antipsychotics, sedatives, anticonvulsants, antidepressants, anticoagulants, antimicrobials, diuretics, drug-drug interactions, pain and constipation medicines, and polypharmacy (appropriate and problematic; see Box 4.1).
- 3.4.8: All medication related problems should be recorded.
- 3.4.9: NH residents' medication must be reconciled at transition of care to or from other clinical settings.

***Box 4.1: Definition of appropriate and problematic polypharmacy, as defined by HIQA [113]***

- Appropriate polypharmacy: 'prescribing for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and where the medicines are prescribed according to best evidence'.
- Problematic polypharmacy: 'prescribing of multiple medications inappropriately, or where the intended benefit of the medication is not realised'



Figure 4. 2 Themes of the National Standards for Residential Care Settings for Older People In Ireland, 2016 [113]

#### 4.1.3. HIQA inspections

The standards for older people in residential care settings are underpinned by legislation, and all NHs services in the ROI are monitored against these standards. Each standard reflects multiple regulations and each regulation is mapped to several standards (Table 4.1)[312]. For instance, Regulation 29: Medicines and Pharmaceutical Services is mapped to standard 3.4 of the *National Standards for Residential Care Settings for Older People In Ireland, 2016* [113] (Section 4.1.2)

HIQA have registered, regulated and inspected designated centres such as NHs under the Health Act 2007, according to these standards [304]. HIQA's statutory officer, otherwise known as the Chief Inspector, is authorised by the Health Act 2007 (*Care and Welfare of Residents in Designated Centres for Older People* [303]) and Health Act 2007 (*Registration of Designated Centres for Older People* [112]) to register, inspect and monitor NHs and has the power to terminate the registration of a NH if deemed necessary [312].

Registrations of NHs are valid for three years. Inspections are carried out within three years but can be as often as yearly and can last for two to three days [112]. Each NH will have at least one announced inspection visit (weeks' notice of the inspector's arrival can range from two days to four weeks [112]), with an unlimited number of unannounced (the inspector does not inform the NH of the inspection

date, prior to their visit) inspections during the three-year registration period. During the inspection, compliance with regulations and standards must be evident to inspectors to maintain registration [312]. The *“Assessment judgment framework for designated centres for older people”* was published by HIQA to support NH inspectors when reviewing NHs Ireland [312]. The regulations within this framework are described in Table 4.1 NH inspectors should have (i) a Level 8 qualification degree OR equivalent in nursing, social care OR equivalent to the regulated profession; and (ii) HIQA Training- (either to accompany a senior inspector during an inspection (Level 1) or to act as the inspection lead (Level 2) [419].

The day prior to the inspection, the inspector familiarises themselves with all information on file in relation to the NH being inspected and previous inspection reports. On the inspection day, the NH inspector makes a judgement on compliance with regulations using the following mechanisms [312]:

- a- Conversations with residents and their visitors about their experiences.
- b- Conversations with the person in charge of the NH and staff working in the NH about the service they provide, their training and experiences.
- c- Observation of residents and staff.
- d- Review of documents and case files.
- e- Comparisons of the information retrieved from documents and case files (point d), and data retrieved from conversations and observations (points a-c).

Table 4. 1 Regulations of the Assessment Judgement Framework Ireland [312].

Regulation Number	Regulation Title	Standard Number and description
Capacity and capability		
N/A	Application for registration or renewal of registration	N/A
8 (Registration)	Annual fee payable by the registered provider of a designated centre for older people	N/A
3	Statement of purpose	<b>2.3:</b> The design and delivery of the residential service maintains and supports physical and psychological wellbeing for those who are cognitively impaired while achieving best health and social care outcomes. <b>5.3:</b> The residential service has a publicly available statement of purpose that accurately and clearly describes the services provided.
4	Written policies and procedures	<b>1.7:</b> Each resident's complaints and concerns are listened to and acted upon in a timely, supportive and effective manner.
14	Persons in charge	N/A
15	Staffing	N/A
16	Training and staff development	<b>7.2:</b> Staff have the required competencies to manage and deliver person-centred, effective and safe services to all residents. <b>7.3:</b> Staff are supported and supervised to carry out their duties to protect and promote the care and welfare of all residents. <b>7.4:</b> Training is provided to staff to improve outcomes for all residents.
19	Directory of residents	N/A
21	Records	<b>7.1:</b> Safe and effective recruitment practices are in place to recruit staff. <b>8.2:</b> Information governance arrangements ensure secure record-keeping and file-management systems are in place to deliver a person-centred safe and effective service.

Regulation Number	Regulation Title	Standard Number and description
22	Insurance	N/A
23	Governance and management	<p><b>5.1:</b> The residential service performs its functions as outlined in relevant legislation, regulations, national policies and standards to protect each resident and promote their welfare.</p> <p><b>5.2:</b> The residential service has effective leadership, governance and management arrangements in place and clear lines of accountability.</p> <p><b>5.4:</b> The quality of care and experience of residents are monitored, reviewed and improved on an ongoing basis.</p> <p><b>6.1:</b> The use of resources is planned and managed to provide person-centred, effective and safe services and supports to residents.</p> <p><b>8.1:</b> Information is used to plan and deliver person-centred, safe and effective residential services and supports.</p>
24	Contract for the provision of services	<b>2.8:</b> Each resident has a written contract/statement of terms and conditions with the registered provider of the residential care setting.
30	Volunteers	N/A
31	Notification of incidents	N/A
32	Notification of absence	N/A
33	Notification of procedures and arrangements for periods when the person in charge is absent from the centre	N/A
34	Complaints procedure	<b>1.7:</b> Each resident's complaints and concerns are listened to and acted upon in a timely, supportive and effective manner.
<b>Quality and Capacity</b>		
5	Individual assessment and care plan	<b>2.1:</b> Each resident has a care plan, based on an ongoing comprehensive assessment of their needs which is implemented, evaluated and reviewed, reflects their changing needs and outlines the supports required to maximise their quality of life in accordance with their wishes.

<b>Regulation Number</b>	<b>Regulation Title</b>	<b>Standard Number and description</b>
6	Health care	<b>4.1:</b> The health and wellbeing of each resident is promoted and they are given appropriate support to meet any identified healthcare needs.
7	Managing behaviour that is challenging	<b>4.3:</b> Each resident experiences care that supports their physical, behavioural and psychological wellbeing.
8	Protection	<b>3.1:</b> Each resident is safeguarded from abuse and neglect and their safety and welfare is promoted. <b>3.5:</b> Arrangements to protect residents from harm promote bodily integrity, personal liberty and a resident free environment in accordance with national policy.
9	Resident's right	<b>1.1:</b> The rights and diversity of each resident are respected and safeguarded. <b>1.2:</b> The privacy and dignity of each resident are respected. <b>1.3:</b> Each resident has the right to exercise choice and to have their needs and preferences taken into account in the planning, design and delivery of services. <b>1.4:</b> Each resident develops and maintains personal relationships and links with the community in accordance with their wishes. <b>1.6:</b> Each resident, where appropriate, is facilitated to make informed decisions, has access to an advocate and their consent is obtained in accordance with legislation and current evidence-based guidelines. <b>4.2:</b> Each resident is offered a choice of appropriate recreational and stimulating activities to meet their needs and preferences.
10	Communication	<b>1.5</b> Each resident has access to information, provided in a format appropriate to their communication needs and preferences.
11	Visits	No standard was reported for this regulation.
12	Personal possessions	<b>3.6</b> Each resident's personal property and finances are managed and protected.

*N/A: No standard is described by HIQA*



#### **4.1.3.1. Types of inspection reports**

There are three types of inspection reports: (1) inspection reports compiled based on an inspection of a designated centre for older people; (2) a report of a restrictive practice thematic inspection; and (3) a monitoring thematic inspection report [304] each of which is described below.

##### **Type 1- Report of an Inspection of a Designated Centre for Older People**

This report has four sections. Section 1 provides a description of the NH (brief summary including name, county and number of beds). Section 2 includes statements about conversations had with patients and the inspectors' observations. This includes observations made by inspectors in terms of physical structure, environment and healthcare services provided. It also includes information about residents' experiences with the care provided [304, 420].

The next section (section 3) includes a description from the inspector on the assessment judgement/findings framework. There are two dimensions to this: (i) capacity and capability and (ii) quality and safety, as described in section 4.1.2. In the capacity and capability component, the inspector reports findings on leadership, governance and management, education, training and ensures appropriate systems are in place to support adherence to the regulations related to the capacity and capability dimension. In the quality and safety component, the inspector reports findings on the quality and safety of people, including visits, transfer of care within healthcare settings, medicines management, infection control, risk management and residents' rights [312, 420]. Each dimension assesses compliance with specific regulations (Table 4.1). Each regulation is observed, assessed, and judged as being compliant, substantially compliant and not compliant (see Table 4.2 for definitions). Reasons for specific judgements provided by the inspector are explained, using pre-defined criteria to guide their decision-making [312]. After the inspection, inspectors and/or HIQA staff publish their reports on the HIQA website and these are made available to the public for three to four years [421].

Table 4. 2 Judgment provided in report summaries and their linked definitions [312]

<b>Judgment</b>	<b>Definition</b>
Compliant	<i>The provider is fully compliant with reviewed regulation</i>
Substantially compliant	<i>The provider is partially compliant with reviewed regulations; this is rated as low risk*</i>
Not compliant	<i>The provider is not compliant with reviewed regulation. If not, this is rated as a moderate risk*</i>
Non-complaint moderate risk*	<i>The inspector sets a deadline for the provider to take some actions to achieve compliance with the regulation reviewed.</i>
Non-complaint high risk*	<i>If non-compliance is associated with a safety, health and welfare risk of NH residents</i>

*\*Risk is described by HIQA as “risk to the safety, health and welfare of residents using the service”.*

The last section in this report is a ‘compliance plan.’ The Compliance plan is set by HIQA for the registered provider and referred to as SMART: (i) Specific to regulation, (ii) Measurable for monitoring the progress, (iii) Achievable, (iv) Realistic and (v) Time bound.

### **Type 2- Report of a Restrictive Practice Thematic Inspection**

Not all standards of the National Standards and their features are included in the thematic report of restrictive practice. The Health Act 2007 defines restrictive practices as ‘*the intentional restriction of a person’s voluntary movement or behaviour*’ which may include physically restricting NH residents and/or limiting the NH residents from their surroundings [304, 422]. Chemical restraints (*i.e.*, medicines) are not inspected in this report type.

This inspection report is not regulations-based. It includes a section of ‘*what the inspector observed and what residents said on the day of inspection*’ about their environment, daily activities, and physical structure of the NH. In the next section the inspector describes findings on the environment, management, restrictive practices (if any) and reviews the complaint log. The inspector can then make a judgment of compliance with the National Standards, providing justification similar to the Type 1 report, as described above: compliant; substantially compliant; and non-compliant [304, 422].

### **Type 3- Monitoring thematic Inspection Report**

These inspections form part of the dementia-specific thematic programme that focuses on services provided to NH residents with dementia. The inspection is based on eight outcomes (Table 4.3), for

each outcome, the person in charge self-assesses themselves before the inspection and then the inspector observes, talks to residents and their families and looks at records to assess compliance, described across the same three levels: compliant, substantially compliant and non-compliant [304, 423].

*Table 4. 3 Outcomes assessed in the Monitoring Thematic Inspection and Related Themes*

<b>Outcome Number</b>	<b>Outcomes</b>	<b>Related theme</b>
1	Health and Social Care	Safe Care and Support
2	Safeguarding and safety	Safe Care and Support
3	Resident’s Rights, Dignity and Consultation	Person-centred Care and Support
4	Complaints procedures	Person-centred Care and Support
5	Suitable Staffing	Workforce
6	Safe and Suitable Premises	Effective care and support
7	Health and Safety and Risk Management	Safe care and Support
8	Governance and Management	Governance, Leadership and Management

Additionally, HIQA publish an overview report of NH compliance with regulations on their website at least every year; such published reports were available for the years 2014, 2015, 2018 and lastly in 2019 [424]. The content of the report summarises the NH’s profile data, compliance findings, and the observed strengths and weaknesses of service provision to older people residing in the Irish NH setting [425]. The report summarises the HIQA inspectors’ findings on compliance with regulations based on the assessment judgment framework described in Table 4.1. In 2019, HIQA inspectors conducted inspections of approximately 80% of NHs in the RoI, the majority being unannounced inspections. It is also explained in the report that a single NH can be inspected more than once in one year if the inspector found a high-risk rating in certain areas. The report notes that 21.5% of all inspected NHs in the country were fully compliant with all regulations assessed. Compliance levels also presented similar proportions when private and public NHs were compared [425]. While compliance with regulations is closely monitored by HIQA, it is worth noting that these reports lack information on Regulation 29: Medicines and pharmaceutical services and/or any topic related to the MMP, despite the published evidence describing the challenges to providing MMP to older people in all care settings including the NH setting, and the standards and guidance published by HIQA for better MMP provision to this cohort [425, 426].

#### 4.1.4. The Medicines Management Guidance

HIQA sets the guidance to help HCPs achieve the best healthcare practice through managing medicines for all people residing in NHs in the RoI. In 2015, HIQA issued a *Medicines Management Guidance* to help HCPs to provide optimum and safe delivery of medicines to NH residents including older adults and children and adults with disabilities [144]. The MMP in the Irish NHs is governed by regulation and standards under relevant legislation. This guidance refers to Standard 3.4 of the *National Standards for Residential Care Setting* entitled ‘Each resident is protected through the residential services policies and procedures for medicines management’ (Section 4.1.3) [144]. The *Assessment Judgment Framework* (Table 4.1) describes one regulation relevant to the MMP (Regulation 29: Medicines and Pharmaceutical Services) [312]. The Medicines Management Guidance describes ten regulations (Regulation 29 plus nine others)[144, 312]. These regulations are described in Table 4.4 with a description of criteria assessed by inspectors [312].

Table 4. 4 Regulations relevant to the medicines management

Regulation number	Regulation title	Criteria assessed
4	Written policies and procedures	Has the registered provider prepared in writing, adopted and implemented policies and procedures on the matters set out in Schedule 5?
		Has the registered provider made the written policies and procedures referred to in paragraph (1) available to staff?
		Has the registered provider reviewed the policies and procedures referred to in paragraph (1) as often as the Chief Inspector may require but in any event at intervals not exceeding 3 years and, when necessary, reviewed and updated them in accordance with best practice?
6	Healthcare	Provider’s responsibilities: Has the registered provider, having regard to the care plan prepared under Regulation 5, provided appropriate medical and healthcare, including a high standard of evidence-based nursing care in accordance with professional guidelines issued by An Bord Altranais agus Cnáimhseachais from time to time, for a resident?
		Person in charge’s responsibilities: Has the person in charge, in so far as is reasonably practical, made available to a resident a medical practitioner chosen or acceptable to the resident?
		Person in charge’s responsibilities: Has the person in charge, in so far as is reasonably practical, made available to a resident where the resident agrees to medical treatment recommended by the medical practitioner concerned, the recommended treatment where the care referred to in paragraph (1) or other healthcare service requires additional expertise, access to such treatment?
7	Managing behaviour that is challenging	Provider’s responsibilities: Has the registered provider ensured that, where restraint is used in the designated centre, it is only done in accordance with national policy as published on the website of the Department of Health from time to time?

Regulation number	Regulation title	Criteria assessed
		<p>Person in charge's responsibilities: Has the person in charge ensured that staff have up-to-date knowledge and skills, appropriate to their roles, to manage behaviour that is challenging?</p> <p>Person in charge's responsibilities: Where a resident behaves in a manner that is challenging or poses a risk to the resident concerned or to other persons, has the person in charge managed and responded to that behaviour, in so far as possible, in a manner that is not restrictive?</p>
16	Training and staff development	<p>Has the person in charge ensured that:</p> <p>a. staff have access to appropriate training</p> <p>b. staff are appropriately supervised</p> <p>c. staff are informed of the Act and any regulations made under it?</p> <p>Has the person in charge ensured that copies of the following are available to staff:</p> <p>a. the Act and any regulations made under it?</p> <p>b. any relevant standards set and published by the Authority under section 8 of the Act and approved by the Minister under section 10 of the Act?</p> <p>c. relevant guidance published from time to time by Government or statutory agencies in relation to designated centre for older people?</p>
21	Records	<p>1. Has the registered provider ensured that the records set out in Schedule 2, 3 and 4 are kept in a designated centre and are available for inspection by the Chief Inspector?</p> <p>2. Are records kept in accordance with this section and set out in Schedule 2 retained for a period of not less than 7 years after the staff member has ceased to be employed in the designated centre concerned?</p> <p>3. Are records kept in accordance with this section and set out in Schedule 3 retained for a period of not less than 7 years after the resident has ceased to reside in the designated centre concerned?</p> <p>4. Are records kept in accordance with this section and set out in paragraphs (6), (9), (10), (11) and (12) of Schedule 4, retained for a period of not less than 4 years from the date of their making?</p> <p>5. Are records kept in accordance with this section and set out in paragraphs (7) and (8) of Schedule 4, retained for a period of not less than 7 years from the date of their making?</p> <p>6. Are records specified in paragraph (1) kept in such a manner as to be safe and accessible?</p>
23	Governance and management	<p>1. Has the registered provider ensured that:</p> <p>a. the designated centre has sufficient resources to ensure the effective delivery of care in accordance with the statement of purpose</p> <p>b. there is a clearly defined management structure that identifies the lines of authority and accountability, specifies roles and details responsibilities for all areas of care provision</p> <p>c. management systems are in place to ensure that the service provided is safe, appropriate, consistent and effectively monitored</p> <p>d. there is an annual review of the quality and safety of care delivered to residents in the designated centre to ensure that such care is in accordance with relevant standards set by the Authority under section 8 of the Act and approved by the Minister under section 10 of the Act</p> <p>e. the review referred to in subparagraph (d) is prepared in consultation with residents and their families</p> <p>f. that a copy of the review referred to in subparagraph (d) is made available to residents and, if requested, to the Chief Inspector?</p>

Regulation number	Regulation title	Criteria assessed
25	Temporary absence or discharge of residents	When a resident is temporarily absent from a designated centre for treatment at another designated centre, hospital or elsewhere, has the person in charge of the designated centre from which the resident is temporarily absent ensured that all the relevant information about the resident is provided to the receiving designated centre, hospital or place?
		When the resident returns from another designated centre, hospital or place, has the person in charge of the designated centre from which the resident was temporarily absent taken all reasonable steps to ensure that all relevant information about the resident is obtained from the other designated centre, hospital or place?
		Has the person in charge ensured that, in so far as practicable, a resident is discharged from the designated centre concerned in a planned and safe manner?
		Was the discharge discussed, planned for and agreed with a resident and, where appropriate, with their family or carer, and in accordance with the terms and conditions of the contract agreed in accordance with Regulation 24?
26	Risk management	Has the registered provider ensured that the risk management policy, set out in Schedule 5, included the following: a. hazard identification and assessment of risks throughout the designated centre b. measures and actions in place to control the risks identified c. measures and actions in place to control the following risks: ●abuse ●unexplained absence of any resident ●accidental injury to residents, visitors or staff ●aggression and violence ●self-harm d. arrangements for the identification, recording, investigation and learning from serious incidents or adverse events involving residents?
		Has the registered provider ensured that there is a plan in place for responding to major incidents likely to cause death or injury, serious disruption to essential services or damage to property?
27	Infection control	Has the registered provider ensured that procedures, consistent with the standards for the prevention and control of healthcare-associated infections published by the Authority are implemented by staff?
29	Medicines and pharmaceutical services	Has the registered provider ensured, in so far as is reasonably practicable, that a pharmacist of a resident's choice or who is acceptable to the resident is available to the resident?
		Has the person in charge facilitated the pharmacist concerned in meeting his or her obligation to a resident under any relevant legislation or guidance issued by the Pharmaceutical Society Of Ireland?
		Has the person in charge ensured that where a pharmacist provides a record of medication related interventions in respect of a resident, such record was kept in a safe and accessible place in the designated centre concerned?
		Has the person in charge ensured that all medicinal products dispensed or supplied to a resident are stored securely at the centre?
		Has the person in charge ensured that all medicinal products are administered in accordance with the directions of the prescriber of the resident concerned and in accordance with any advice provided by that resident's pharmacist regarding the appropriate use of the product?

Regulation number	Regulation title	Criteria assessed
		Has the person in charge ensured that a medicinal product which is out of date or has been dispensed to a resident but is no longer required by that resident has been stored in a secure manner, segregated from other medicinal products and disposed of in accordance with national legislation or guidance in a manner that will not cause danger to public health or risk to the environment and ensured that the product concerned can no longer be used as a medicinal product?

The content of the Medicines Management Guidance is set to support MMP service providers to meet the relevant standards and compliance with regulations [144]. These are described below:

- I. **Person-centered services:** support putting NH residents at the centre of care and target safe and effective medicines service provision. This services also supports multidisciplinary care of the NH residents (care team of different HCP groups).
- II. **Resident’s choice:** NH residents have the right to (i) choose their pharmacist; (ii) self-administer their medicines (if they have the capability); (iii) reject their medicines; (iv) have knowledge about why and how their medicines are given to them.
- III. **Policies and procedures for medicines management:** All NH residents must have records managed by the NH provider that documents policies and procedures covering prescribing, ordering, receipt, administration and storage of their medicines. Other areas include medicines management training, use of restraints, infection control, etc. These records should be reviewed regularly (at least every three months) by HCPs. The guidance advises that certain medicines require special attention from HCPs in the record, these include medicines that are administered via percutaneous endoscopically guided gastronomy (PEG) tube, suppositories, eye drops, inhalers, pens, medicines administered intravenously/intramuscularly/subcutaneously and PRN (as needed) medicines.
- IV. **Medication ordering:** NH residents should receive the right medicines at the required time. To achieve that, the process of ordering, receipt and checking of the right medicines is crucial. Records documenting who ordered the medicines and the time that the medicine was ordered should be maintained and should also include the pharmacy’s and prescriber’s name.
- V. **Medication prescribing:** Prescribers must write and sign the medication prescriptions. These prescribers are mainly the NH resident’s GP but can also be other specialists, hospital prescribers, and others. Information that should be included in the prescription the resident's name, age, allergies, medicines (name, dose, route, duration, directions for special management such as crushing or PRN) and name of prescriber.

- VI. **Medication transcribing:** NH residents' medicines information is transcribed by prescribers or nurses. This guidance recommends that a second person and a prescriber (including both a doctor and a prescribing nurse) must also sign the transcription to verify the accuracy minimize the risk of medication error. Additionally, the guidance also mandates that a copy of the prescription be attached.
- VII. **Verbal medicines orders:** Prescribers (excluding nurse prescribers) are only allowed to make verbal orders during an emergency. The medicine order is repeated to two staff to confirm the right medicine is heard.
- VIII. **Medication storing:** NH residents' medicines must be stored in the NH in a secure and correct place in terms of location, heat and light. Special attention must be put on the storage of controlled drugs and refrigerated medicines.
- IX. **Medication administration:** NH residents should only be administered medicines that are prescribed for them. The administration should be in accordance with the 10 rights of medicines administration, *i.e.*, being the right: resident, reason, drug, route, time, dose, form, action, documentation, and response. Special attention must be paid regarding medicines that require crushing or opening and mixing with water. Medicines cannot be changed from their original form or manipulated in any way unless indicated in the prescriptions.
- X. **Covert medication administration:** Covert administration is the administration of medicines to NH residents without them knowing, for example, disguised in their food or drink. A multidisciplinary assessment of residents and a consensus decision according to the legislation must be made to administer medicines to NH residents in a covert manner. HIQA also mandates that any such covert administration should be documented in the record.
- XI. **Review of medicines:** HCPs must conduct regular reviews of medicines. These reviews are preferred to take place in the presence of residents or their family members. Special attention should be paid to polypharmacy and some classes of medications such as antipsychotics, sedatives, NSAIDS, antidepressants, antiepileptics, antimicrobials, laxatives, diuretics, and others.
- XII. **Disposal of medications:** Out-of-date or unused medicines must be disposed of. The disposal process involves nursing staff contacting the supplying pharmacy and disposing according to regulations. The disposal of medicines should be documented and recorded.
- XIII. **High alert medicines:** HCPs should apply special care when dealing with high alert medicines. Examples of these medicines include warfarin, insulin, methotrexate, and digoxin.
- XIV. **PRN medicines:** Medicines prescribed as needed or as required must be indicated in the prescriptions and details of when it should be used, dose (including maximum dose) and



timings must be included. The administration of a dose of a PRN medicine can be decided by an HCP with a reason or by a resident's choice after discussion with their prescriber.

**XV. Medication incidents:** Any medication incident should be recorded and documented even if it doesn't cause harm. Residents and/or their families should be informed when a medicine incident occurs.

Furthermore, HIQA and the Pharmaceutical Society of Ireland (PSI) have mutual regulations and concerns in relation to the MMP provision in the NH setting in the RoI. As described in previous chapters, pharmacists are one of the main MMP service providers to older people residing in the NHs (Chapter 2, section 2.4.2), including those in the RoI (Chapter 3, section 3.1.1). Pharmacists in the RoI are regulated by the PSI, under the Pharmacy Act 2007, which aims at the safe delivery of person-centered care to NH residents [314]. For this reason, HIQA and the PSI signed a Memorandum of Understanding in 2010 and was updated in 2016 to outline the two organizations' cooperation in discharging regulatory functions for people residing in designated centers [402]. Within the report, multiple areas of cooperation are discussed: (i) agreements on sharing of information relating to pharmacies/pharmacists providing MMP services or any information related to the MMP practices by pharmacists such as dispensing, preparing, supplying, recording and disposal of medicines; (ii) Working together to ensure pharmacists are compliant and have the required knowledge of MMP regulations; (iii) Ensuring each regulator (HIQA and PSI) have a clear understanding of their roles and responsibilities in regulating the MMP services provided to people residing in designated centers. Moreover, both senior officers agreed to meet annually and discuss any mutual MMP-related concerns, in line with the memorandum [402].

Similarly, HIQA have a Memorandum of Understanding with the Nursing and Midwifery Board of Ireland (NMBI) and another with the Irish Medical Council addressing cooperation regarding shared interest with both organizations under relevant legislations [427, 428]. However, these memoranda are silent on the topic of medicines management.

Every stage of the MMP is susceptible to errors (*e.g.*, prescribing, dispensing, administering, and monitoring errors) making the provision of MMP challenging [154, 429]. Other factors associated with a challenging MMP include complex medication management for older NH residents (or polypharmacy), multimorbidity, and work systems elements and interactions [430]. In Chapter 3, seven work systems in the NH resident MMP journey were identified using the Systems Engineering Initiative for Patient Safety (SEIPS 3.0) model; each work system contains multiple elements: people, tasks, tools and technologies and internal environments embedded in an external environment [431]. More than five groups of professional and non-professional carers (*i.e.*, nurses, pharmacists, GPs,

other clinical experts, family members and others) were identified as contributing to the MMP services to NH residents (Chapter 3, Section 3.4.3). Chapter 3 also identified the external environment in which these work systems are embedded, namely: statutory regulators such as HIQA, PSI and NMBI, use of clinical guidance such as those published by HSE; and the COVID-19 pandemic.

The external environment, including HIQA regulation, has been described as one that *“incorporates macro-level societal, economic, ecological, and policy factors outside an organisation”* [432]. Carayon and colleagues proposed in the SEIPS 3.0 model how the interactions between work system components and the external environment interact over space and time to potentially influence processes and outcomes [331]. In this thesis, these are the processes and outcomes experienced by residents, their professional and non-professional caregivers, and organizations [433]. The findings reported in Chapter 3 identified relevant interactions between the HIQA and work system elements (Chapter 3, Section 3.4.7). Thus, HIQA as an external environment influencing the NH resident MMP journey is a crucial area to explore. While it is essential to study and explore the effect of interactions between the external environment and other work system components on the MMP and outcomes [434], the literature lacks evidence in this area. Likewise, while HIQA inspections are structured around regulations relevant to the MMP, the literature and HIQA’s overview reports lack detail about the scrutiny or findings from HIQA inspections regarding the MMP. This chapter presents further exploration of the MMP from HIQA inspections.

## **4.2. AIM AND OBJECTIVES**

The aim of this study was to explore the MMP in the NH setting in the RoI from the statutory regulator’s perspective.

The objectives were to:

- 1) Explore the extent of MMP-related regulations assessed for compliance in HIQA inspections of nursing homes.
- 2) Identify the proportion of reports that described assessment of the MMP and their findings regarding the NH’s compliance with the regulations.
- 3) Describe the relationship between NH characteristics and their compliance with regulations.
- 4) Describe the relationship between NH characteristics and the reported assessment of the MMP in an inspection report.
- 5) Apply the SEIPS 3.0 Model to the free text fields in the inspection reports to identify, from the regulator’s perspective, the work systems, elements, interactions, and outcomes experienced.

## 4.3. RESEARCH DESIGN AND METHODOLOGY

### 4.3.1. Rationale for the choice of research design

#### Secondary analysis

The study described in this chapter is a secondary analysis of previously published inspection reports. Heaton defined secondary as the “*re-analysis of data for the purpose of answering the original research question with better statistical techniques or answering new questions with old data*” [435]. Secondary analysis research can be used to re-analyse, validate results, or test new concepts from already published primary data [435]. Advantages of secondary research include the ease and speed of data retrieval and collection which are often free of charge or at a low cost. Secondary research can also be useful in follow-up studies to further explore or evaluate an intervention. There are several disadvantages to using secondary research where data is re-analysed to answer a new question, which include the fact that data collection was not undertaken for the purpose of answering the research question and therefore some required data might be missing, and also, data may not reflect the contemporary experience, depending on the amount of time between original data collection and secondary analysis [436].

Four broad types of secondary research have been described:

- 1- Statistical analysis of data sets, using appropriate statistical methods
- 2- Literature reviews of scholarly academic papers
- 3- Case studies of a specific person, group or phenomenon in detail, usually qualitative methods, content analysis of a subject, which can be quantitative or qualitative or both [436].

Combinations of these research methods, in other words, a mixed methods approach may also be used in secondary analysis, where quantitative and qualitative analysis are combined and used in an intentional manner to address the research question [437]. A mixed-methods analytical approach was chosen for the current study to ensure the aims and objectives were optimally answered with the available data in the HIQA reports, which includes quantitative and qualitative data. Combining both approaches allows a ‘*complete understanding of a problem; to develop a complementary picture; to compare, validate, or triangulate results; to provide illustrations of context for trends; or to examine processes/experiences along with outcomes*’ [438]. Mixed methods research is defined as the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purpose of deepening understanding and corroboration [439]. Mixed methods analysis can be:

- 1- Quantitative-driven: where the research is dominantly quantitative (*e.g.*, surveys) and qualitative analysis is used to explain findings.
- 2- Qualitative-driven: where the research is dominantly qualitative (*e.g.*, interviews) and quantitative methods are used to quantify findings.
- 3- Equal status: where quantitative and qualitative analysis are equally applied, and both are used iteratively.

Mixed methods research is widely used in health research [438]. Evidence suggests that using a mixed methods approach increases the validity and reliability of findings [440]. A variety of study design approaches are possible, for example, where either the qualitative or the quantitative component is considered more important than the other, or where each method is as important as the other, in other words, an equal status approach [441]. In mixed methods research, either the qualitative or the quantitative component may be undertaken first and used to inform the research content of the second method. This is called a sequential design. Or in other cases, the qualitative and quantitative phases may be performed in parallel, known as a non-sequential design or a parallel design [441]. Regardless of the approach used, a critical issue is to define and describe the point at which the integration of the qualitative and the quantitative components occurs, thereby clarifying the intended plan for applying a mixed methods approach. This integration may occur at any point on the research process, from study design, through to data collection, data analysis or data interpretation.

When applying a mixed methods approach to secondary data analysis, the data available often stipulates the type of analysis that can be undertaken. Both quantitative and qualitative data are available in the HIQA NH inspection reports, therefore both types of data were analysed to ensure a more complete understanding of the available data would be provided than with the use of either qualitative or quantitative analysis alone, and that the research aims and objectives would be optimally addressed. In other words, a mixed methods approach was applied with the intention of better understanding the extent to which HIQA inspection reports address the MMP and to describe the NHs' compliance with MMP regulations as set by HIQA (through quantitative descriptive analysis). Additionally, analysis of the qualitative data was informed by a systems-based exploration of work system components using the SEIPS 3.0 Model (described in Chapter 3, section 3.1.2). This mixed methods approach facilitated triangulation between the quantitative and qualitative data for the purpose of corroborating and deepening the understanding of the topic beyond that which would have been achieved with either qualitative or quantitative analysis alone. Furthermore, it has been suggested that adopting a mixed-methods approach in human factor ergonomics research helps simplify the understanding and exploration of complex processes and work systems components, and therefore this approach could greatly add to our understanding of the MMP in NHs in the RoI [442].

Hence, a mixed methods research approach incorporating both qualitative and quantitative analysis was used in this study.

#### **4.3.2. Qualitative research methodology**

As discussed in Chapter 3, section 3.3.2, qualitative research designs have been widely used in health research to gain an in-depth understanding of experiences, to investigate the process, and to aid in refining interventions and policies. For the purpose of this study, the data used was originally collected by HIQA using non-participant observation and discussions (or interviews) with staff or residents( Chapter 3, section 3.3.2). HIQA inspectors observed the residents and staff as they fulfilled their daily routines and completed tasks in relation to their role. Thus, The PhD candidate collected data in the form of inspection reports to qualitatively analyse the textual data generated from the inspectors' observations.

Qualitative analysis typically begins with coding the data, and then organising those codes into broad categories or themes, and as described in Chapter 3, this can be undertaken inductively or deductively. Qualitative data analysis most commonly employs one of the following four approaches: (i) Grounded theory; (ii) Content analysis; (iii) Thematic analysis; or (iv) Framework analysis. These are defined in detail in Chapter 3, section 3.3.2. In this study, the qualitative data were deductively analysed against the SEIPS 3.0 model components.

#### **4.3.3. Quantitative research methodology**

The quantitative research methodology includes collecting and analysing numerical or categorical data. This involves three main types of research including [443]:

- 1- Experimental studies, such as clinical trials where findings are compared between two groups (*e.g.*, experimental vs. control).
- 2- Cross-sectional or cohort studies, such as structured observations and questionnaires, where data are collected from participants at a single point in time.
- 3- Longitudinal studies, where data are collected at multiple points in time.

#### Quantitative data collection methods

Data for quantitative studies can be collected using: (i) Data from records/reports that can be found in databases, website data, previous research results, government data, journals, newspapers, public libraries and others; and (ii) Questionnaires/surveys that may be self-administered (through sending of questionnaires/ surveys using post, online web and email) or administered by the researcher (face-to-face or by telephone) [346].

## Quantitative data analysis

Quantitative data is typically one of the following types:

- 1- Numerical data: this is measurement data such as weight, height, or blood sugar level.
- 2- Categorical data: this data can be dichotomous data such as 'Yes/no' data or from answers which can be grouped into categories such as gender or marital status. This may contain two or more categories.
- 3- Ordinal data: this is a blended data of numerical and categorical data, where the number represents a ranking rather than a count. For example, a rating scale from lowest to highest can be expressed as numbers from 0 to 4.

Descriptive data analysis is the most frequently adopted statistical method to analyse and present quantitative findings. This includes tables or charts illustrating N (Number), central tendencies such as mean/ median and Chi-square ( $\chi^2$ ), Fisher's exact *p*-values for Cross-tabulation, with the former being used to explore associations between two or more variables and the latter providing a numeric probability that the findings are different to that expected by chance. Other statistics can be used including inferential statistics such as regression analysis (analysing the association between dependent and independent variables).

An important consideration when choosing which statistical methods to apply to a quantitative dataset is to understand whether the data are normal or not normally distributed, which informs whether to apply, parametric or non-parametric tests, respectively.

### **4.3.4. Integrating findings in mixed methods research**

The purpose of undertaking mixed methods research, and in this case, mixed methods secondary data analysis, is to provide a more complete response to the research question than that which could be achieved with the use of either quantitative or qualitative analysis alone. In mixed methods research, as outlined above, integration between the quantitative and the qualitative components is important, and this may occur at any stage of the research process, and in this study, integration occurred at the analysis stage. Appropriate integration of findings is important to ensure that the correct overall conclusions can be drawn. When undertaking mixed methods research, integration can be achieved through triangulation of data. One of the advantages of triangulating findings is that it allows for the strengths of individual methods to be utilised and to neutralise the potential limitations that are present if each individual method was used in isolation [444]. Throughout a mixed methods research programme, triangulation can indeed occur at any stage (*i.e.*, study design, during the research process, interpretation, and reporting). However, given the current study is a secondary analysis of

existing data, triangulation can only take place at the point of interpretation of data. There are currently no widely accepted guidelines for how data should be triangulated at the interpretation stage, however, there are two main types of triangulation approaches, a *connecting* approach, and a *merging* approach. Connecting represents a sequential approach, where results from one method are used to inform components of the subsequent method while merging analyses involve parallel integration or convergence of the qualitative and quantitative data [441, 445].

#### **4.3.5. Study design**

This was a mixed method secondary data analysis study.

#### **4.3.6. Identifying data sources**

As described in section 4.1.1, there are three types of HIQA inspection reports: (1) reports of an inspection of a Designated Centre for Older People, (2) thematic reports and (3) monitoring reports. Reports of an inspection of a Designated Centre for Older People include information about regulations, including those associated with the MMP. Therefore, this report type was chosen for analysis in this study and is referred to in the following sections as the *NH inspection report*. Type 2 and type 3 reports were not analysed.

#### **4.3.7. Sampling approach**

The index year for sampling inspection reports was arbitrarily chosen as 2019 because it enabled a baseline that occurred prior to the COVID-19 pandemic. The intention was to longitudinally follow-up inspection reports for the NHs where an index 2019 report was identified, with follow-up across the years 2020, 2021 and 2022. All NH inspection reports published in 2019 were accessed and downloaded from the HIQA website under 'Inspections and publications' ([Inspection Reports | HIQA](#)) in June 2022. The search filter 'Nursing home' was applied, along with the year '2019'. This approach initially retrieved 99 reports. However, not all of these reports were available on the HIQA website at study commencement. HIQA programmatically remove reports from their website three years after their date of publication (personal communication between HIQA and the PhD candidate). Therefore, the research candidate submitted a Freedom of Information (FOI) request to HIQA (Appendix 4.1) to access the 2019 reports which were not available on the website. The request was acknowledged by HIQA's FOI officer, but the FOI officer explained that retrieving all archived reports in the archive was not feasible and would incur a substantial cost. As this study was not funded, the PhD candidate was advised to access the Trinity Access for Research Archive (TARA) website to avail of freely available reports on this website. Ultimately, 22 additional reports from 2019 were retrieved from TARA as described in section 4.4.

All NHs that were identified as having been inspected in 2019 were included in the study, regardless of whether the index 2019 report was retrieved. Each of these NHs was followed forward to identify and retrieve any subsequent inspection reports for the years 2020, 2021 and 2022. These reports were identified and downloaded from the HIQA website and were all readily available because the inspections occurred within the three years prior to data collection.

#### **4.3.8. Data management**

Numerical data in the reports were quantitatively managed, whilst descriptive data and responses to open questions were analysed qualitatively. The relevant quantitative variables include:

- Number of NHs and their reports in each year
- NH characteristics:
  - NH size (Small/ Big): Defined by the number of residents, where 0-24 residents is categorised as a small NH, and more than 24 residents are categorised as big NH.
  - Geographic classification (Urban area/ Rural area).
  - Ownership type (Private/public).
- Type of inspection (announced/unannounced).
- Contractual information: Did the NH hold a contract with a GP or a pharmacy: (Yes/No).
- Regulation 29: Medicines and Pharmaceutical services reporting: (Reported/ Not reported).
- Compliance result (Compliant/ Substantially compliant/ Not compliant).

As described in section 4.1.1, several regulations are assessed by HIQA. Each member of the research team independently assessed each regulation for relevance to the MMP, and then compared outcomes. Any disagreement was resolved through discussion. Following this process, it was evident that only regulation 29 (Medicines and Pharmaceutical Services) was relevant to this study. The criteria/questions within Regulation 29 include:

- 1- Has the registered provider ensured, in so far as is reasonably practicable, that a pharmacist of a resident's choice or who is acceptable to the resident is available to the resident?

Has the person in charge (*i.e.*, the person in charge of the NH):

- 2- Facilitated the pharmacist concerned in meeting his or her obligation to a resident under any relevant legislation or guidance issued by the PSI?
- 3- Ensured that where a pharmacist provided a record of medication related interventions in respect of a resident, such record was kept in a safe and accessible place in the designated centre concerned?

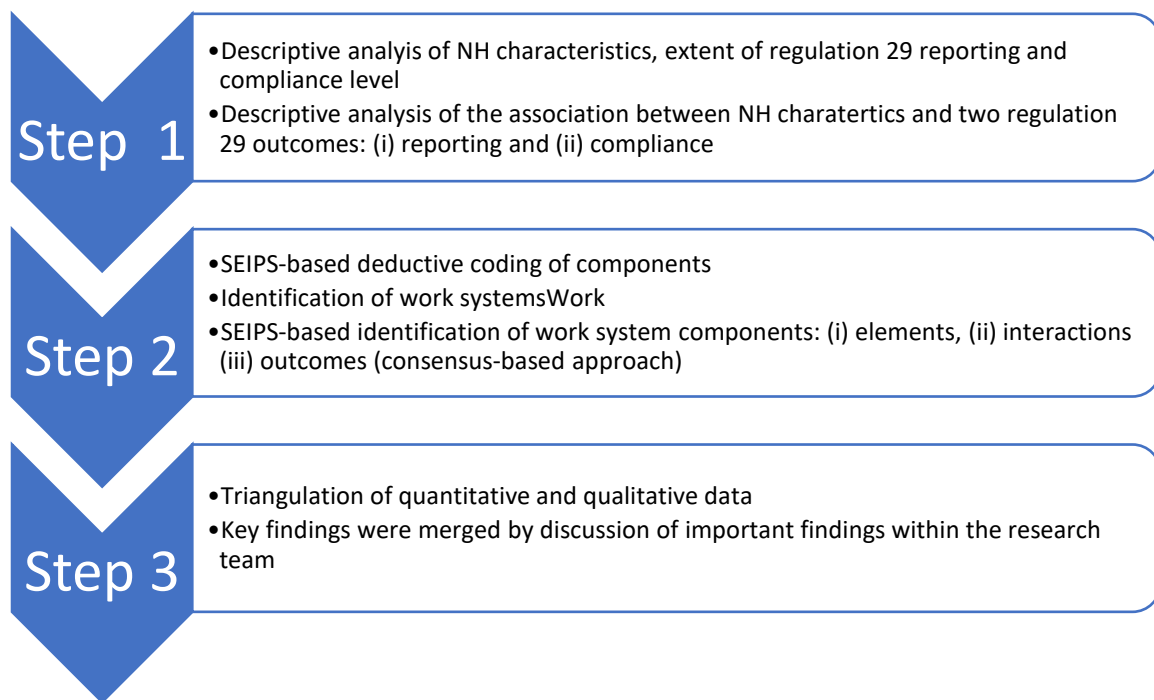


- 4- Ensured that all medicinal products dispensed or supplied to a resident were stored securely at the centre?
- 5- Ensured that all medicinal products were administered in accordance with the directions of the residents' prescriber(s) in accordance with any advice provided by relevant pharmacist(s)?
- 6- Ensured that out of date medicines were stored in a secure manner, segregated from other medicinal products, and disposed of in accordance with national legislation and national guidance?

In circumstances where there were multiple reports published for a single NH in one year, these were combined into a single document and this document was used for quantitative data analysis. However, because factors relating to medicines management could be noted in any open text sections of all retrieved HIQA inspection reports, all commentary available was included in the qualitative analysis.

#### 4.3.9. Data analysis

Data analysis was undertaken in 3 sequential steps: Step (1) *quantitative analysis*, Step (2) *qualitative analysis* and Step (3) *triangulation* of results from step 1 & 2. These are described in Figure 4.3.



NH: Nursing home; SEIPS: Systems Engineering Initiative for Patient Safety  
 Figure 4. 3 Summary of three data analysis steps

#### Step (1) Quantitative analysis

The retrieved quantitative data from the PDFs of the HIQA inspection reports were inputted into SPSS® version 27 and each NH was assigned a unique identifier (NH\_01, NH\_02.....NH\_100) by the PhD candidate. Variables on SPSS® were drafted by the PhD candidate and validated following discussion with the research team. All data entry was double-checked for accuracy by the PhD candidate.

Descriptive statistics (*i.e.*, *N* and percentage %) were employed to describe key characteristics of the NHs and reports. Chi-square ( $\chi^2$ ) and Fisher's exact statistics were employed to explore associations between NH variables (NH size and geographic class) and Regulation 29 Medicines and Pharmaceutical Services outcomes: (1) reporting and (2) compliance. A *p*-value of <0.05 was considered statistically significant. This was completed by the PhD candidate and confirmed by the research team.

### Step (2) Qualitative analysis

All written text and commentary on any stage of the MMP throughout the report were included in the qualitative analysis. For this, a framework approach was adopted. Following a familiarisation phase, SEIPS 3.0 (as described in chapter 3.1.2) was used to deductively code the data. Qualitative data analysis was undertaken in two stages: i) identification of the work system; and ii) identification of elements, interactions, and outcomes.

#### *i) Identification of work systems*

This stage began with extensive reading and familiarisation of all text content within the NH inspection reports. These reports were imported into NVivo®12 Plus, which assisted in managing data and coding. Coding was undertaken by the PhD candidate to index and categorise each report's data to identify component work systems. The research team members reviewed the identified work systems and engaged in a group-based discussion to validate the results. Any discrepancies were resolved in the discussion.

#### *ii) Identification of work system elements, interactions, and outcomes*

SEIPS 3.0 coding supported the identification and description of work system elements, interactions, and outcomes. The elements were people, physical environment, organisational conditions, tasks, tools and technologies, socio-organisational context and external in the NH resident MMP journey. A group-based meeting was conducted to review the elements, interactions, and outcomes.

### Stage (3) Triangulation of quantitative and qualitative data

Data triangulation (section 4.3.3) was undertaken using the approach described by O'Catháin *et al.*, [446] at the point of data interpretation. Findings from the quantitative and qualitative analysis were triangulated and informed the extent of MMP reporting and compliance in addition to the selection

of work system components/outcomes that can be targeted to improve the provision of MMP services. To achieve that, key findings from the two analyses were compared and contrasted to identify consistencies, inconsistencies and explanations. The PhD candidate prepared the list of key findings, and a consensus discussion was undertaken with the research team to validate triangulated findings.

#### **4.3.10. Ethical approval**

Ethical approval for this study was not required as the data were available in the public domain, via PDF reports published on HIQA's website. Additionally, the Data Protection Office in HIQA was contacted and confirmed that there were no data protection requirements regarding the use of information from their publicly published data (Appendix 4.2).

## **4.4. RESULTS**

### **4.4.1. Study population**

The initial search identified 121 reports published in 2019 for 120 NHs (two separate reports were published for one NH). One NH was excluded because no eligible inspection reports across any of the years 2019-2022 were retrieved. For this reason, the total number of NH identified for this study's analysis was 119 NHs. These NHs were followed forward to identify any published reports in 2020-2022, retrieving a total of 319 eligible NH inspection reports for this analysis. For the majority of NHs there was one report, however, a small number of NHs had more than one report published in the same year (Figure 4.4).

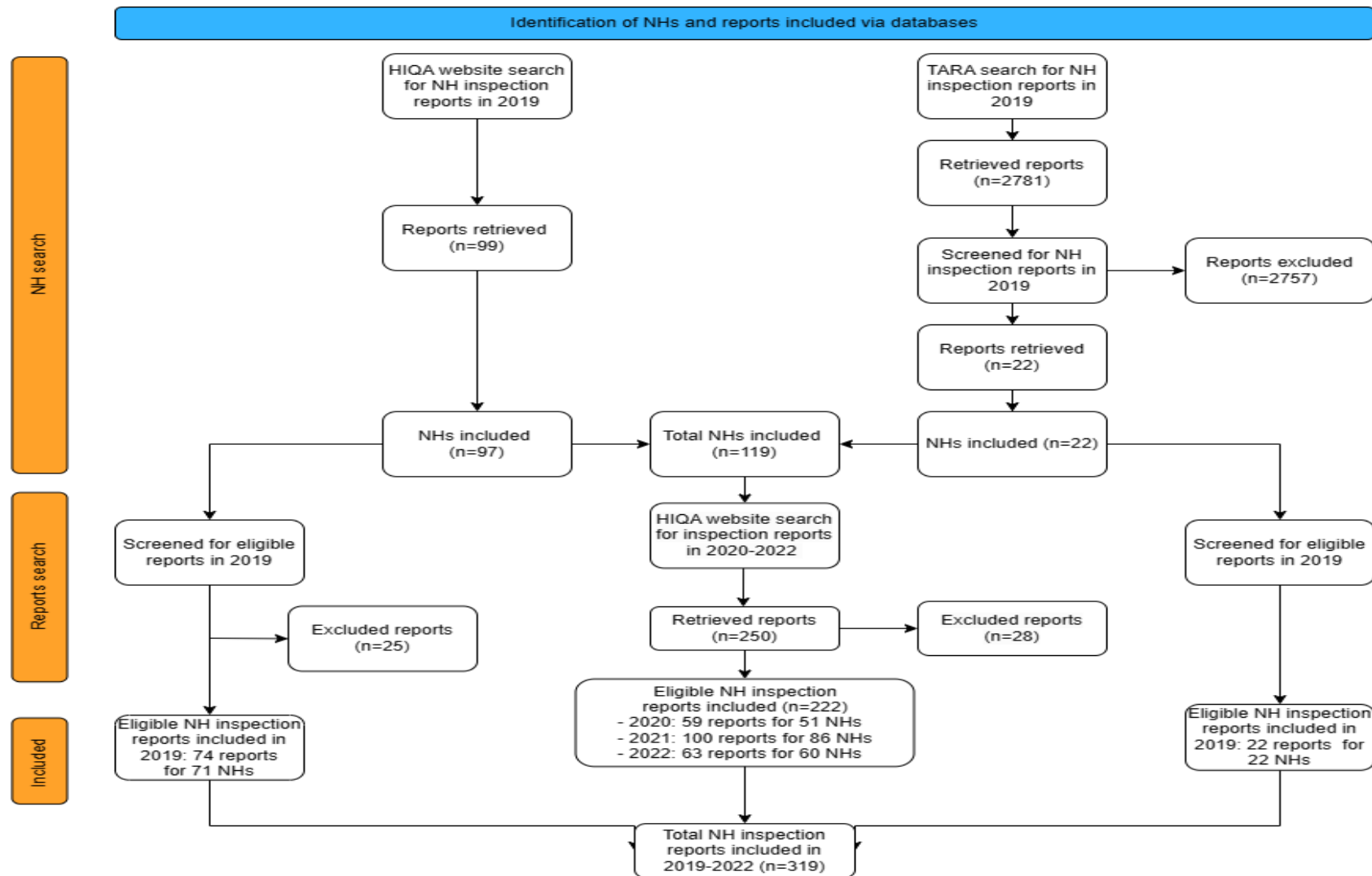
#### **Inspection reports of a designated centre for older people available for the year 2019**

A total of 99 reports were identified on the HIQA website for 97 NHs. All of these were screened to ensure they were NH inspection reports (inspection of a Designated Centre for Older People, type 1) and not thematic or monitoring reports, Types 2 and 3, respectively). A total of 25 NH inspection reports were excluded as they were either reports of a restrictive practice thematic inspection or monitoring thematic inspection reports), resulting in a total of 74 reports relevant for analysis. These 74 reports were for 71 NHs (more than one inspection report was published for one NH in 2019) (Figure 4.4).

Similarly, 22 NH inspection reports were identified from the TARA website and were screened for eligibility. All 22 reports were deemed eligible for inclusion and originated from 22 NHs, *i.e.*, one NH inspection report per NH. In total, 96 reports in 2019 were included in this study for 93 NHs (Figure 4.4).

*Inspection reports of a designated centre for older people available for the years 2020-2022*

All included NHs (n=97); *i.e.*, those that were identified as having had an inspection undertaken in 2019 (section 1.3) were longitudinally followed up to identify any published inspection reports for the years 2020, 2021 and 2022. The search retrieved a total of 250 inspection reports. Of these reports, 222 reports were eligible for inclusion, as follows: 2020 (n=59) for 51 NHs, 2021 (n=100) for 86 NHs and 2022 (n=63) for 60 NHs (Figure 4.4). The findings of this study are based on analysis of NHs with eligible HIQA inspection reports.



HIQA: Health Information and Quality Authority; TARA: Trinity Access for Research Archive; NH: Nursing home  
 Figure 4. 4 Nursing homes and inspection reports search

#### 4.4.2. Quantitative findings (Step 1)

##### 4.4.2.1. NH characteristics

Characteristics of included NHs (n=119) are provided in Table 4.5. The majority were privately owned (84.9%), 101 NHs (88.2%) were characterised as big and 90 NHs (75.6%) were located in a rural area (Table 4.5).

NH characteristics	N (%)
<b>NH size<sup>a</sup></b>	
<b>Big</b>	105 (88.2)
<b>Small</b>	14 (11.8)
<b>Ownership type</b>	
<b>Private NH</b>	101 (84.9)
<b>Public NH</b>	18 (15.1)
<b>Geographic classification</b>	
<b>Urban</b>	29 (24.4)
<b>Rural</b>	90 (75.6)
<b>Contract with pharmacy</b>	
<b>Yes</b>	17 (14.3)
<b>No</b>	3 (2.5)
<b>Not reported</b>	99 (83.2)
<b>Contract with GP</b>	
<b>Yes</b>	33 (27.7)
<b>No</b>	1 (1.8)
<b>Not reported</b>	85 (71.4)
<b>County</b>	
<b>Dublin</b>	21 (17.6)
<b>Cork</b>	15 (12.6)
<b>Tipperary</b>	12 (10.1)
<b>Galway</b>	7 (5.9)
<b>Wexford</b>	7 (5.9)
<b>Donegal</b>	6 (5)
<b>Meath</b>	6 (5)
<b>Limerick</b>	6 (5)
<b>Roscommon</b>	4 (3.4)
<b>Clare</b>	4 (3.4)
<b>Westmeath</b>	4 (3.4)
<b>Cavan</b>	4 (3.4)
<b>Waterford</b>	3 (2.5)
<b>Kerry</b>	3 (2.5)
<b>Mayo</b>	3 (2.5)
<b>Wicklow</b>	2 (1.7)
<b>Sligo</b>	2 (1.7)
<b>Kildare</b>	2 (1.7)
<b>Kilkenny</b>	2 (1.7)
<b>Louth</b>	2 (1.7)
<b>Carlow</b>	1 (0.8)

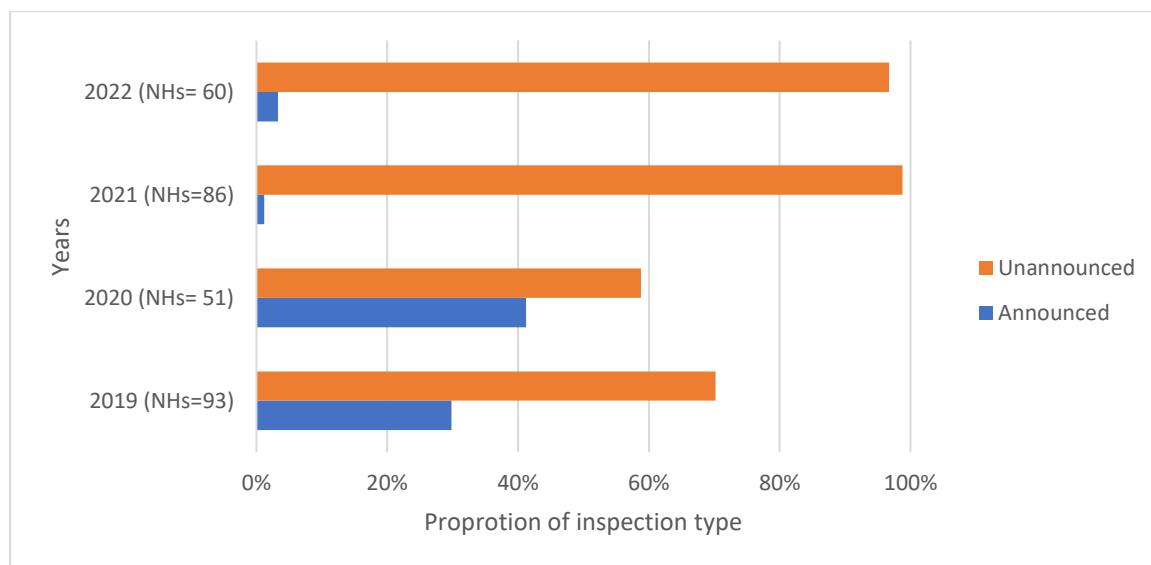
<b>Laois</b>	1 (0.8)
<b>Offaly</b>	1 (0.8)
<b>Longford</b>	1 (0.8)
<b>Total</b>	119 (100)

a: Nursing homes are categorized 4.4as big if the capacity is more than 25 beds.

N: Number; NH: Nursing homes; GP: General practitioner

#### 4.4.2.2. Types of inspection

The majority of inspections conducted during the four years were unannounced (mean= 81.1). Fewer announced inspections were recorded in 2021 and 2022, as presented in Figure 4.6.



NH: Nursing home

Figure 4. 5 The proportions of announced and unannounced inspections from 2019-2020

#### 4.4.2.3. Extent of Regulation 29 (Medicines and Pharmaceutical Services) reporting.

There was evidence that Regulation 29 was inspected in n=56 (59.6%) NHs in 2019, n=23 (45.1%) NHs in 2020, n=25 (29.4%) NHs in 2021 and n=23 (38.9%) NHs in 2022. While there were multiple reports for a given NH in one year, there was evidence of Regulation 29 inspection in no more than one of these reports. For the NHs with evidence of Regulation 29 inspection, the frequency of reporting of each of the six component questions is presented in Table 4.5.

Table 4. 5 Frequency of inspection of the six component questions within Regulation 29: Medicines and Pharmaceutical Services

Question No.	Question content	Year N (%)			
		2019 Assessment (n=56 NHs)	2020 Assessment (n=23 NHs)	2021 Assessment (n=25 NHs)	2022 Assessment (n=23 NHs)
Q1	Has the registered provider ensured, in so far as is reasonably practicable, that a pharmacist of a resident's choice or who is acceptable to the resident is available to the resident?	17 (30.4)	9 (39.1)	3 (12)	5 (21.7)
Q2	Has the person in charge facilitated the pharmacist concerned in meeting his or her obligation to a resident under any relevant legislation or guidance issued by the Pharmaceutical Society of Ireland?	20 (35.7)	8 (34.8)	5 (20)	7 (30.4)
Q3	Has the person in charge ensured that where a pharmacist provides a record of medication related interventions in respect of a resident, such record was kept in a safe and accessible place in the designated centre concerned?	22 (39.3)	9 (39.1)	19 (76)	3 (13)
Q4	Has the person in charge ensured that all medicinal products dispensed or supplied to a resident are stored securely at the centre?	42 (75)	18 (78.3)	15 (60)	16 (69.6)
Q5	Has the person in charge ensured that all medicinal products are administered in accordance with the directions of the prescriber of the resident concerned and in accordance with any advice provided by that resident's pharmacist regarding the appropriate use of the product?	50 (89.3)	22 (95.7)	17 (68)	17 (73.9)
Q6	Has the person in charge ensured that a medicinal product which is out of date or has been dispensed to a resident but is no longer required by that resident has been stored in a secure manner, segregated from other medicinal products and disposed of in accordance with national legislation or guidance in a manner that will not cause danger to public health or risk to the environment and ensured that the product concerned can no longer be used as a medicinal product?	17 (30.4)	6 (26.1%)	8 (32)	7 (30.4)

Q: Question; N: Number



#### 4.4.2.4. Regulation 29 compliance judgement

The NHS' summary compliance with Regulation 29 across the four study years is presented in Table 4.6. Full compliance with Regulation 29 were reported in approximately 50% to 75% of reports published between 2019 and 2022, as presented in Figure 4.6. The highest percentage of compliance was recorded in 2019 with 40 out of 56 NHs (%) complying with Regulation 29 and lowest percentage of compliance was recorded in 2022 with 13 out of 23 NHs (%) seen to be fully compliant to Regulation 29.

Table 4. 6 Summary compliance judgement with Regulation 29: Medicines and Pharmaceutical Services

Compliance judgement N (%)											
2019 (n=56 NHs)			2020 (n=23 NHs)			2021 (n=25 NHs)			2022 (n=23 NHs)		
C	SC	NC	C	SC	NC	C	SC	NC	C	SC	NC
40 (71.4)	11 (19.6)	5 (8.9)	14 (60.9)	6 (26.1)	3 (13)	17 (68)	4 (16)	4 (16)	13 (56.5)	8 (34.8)	2 (8.7)

C: Compliant; SC; Substantially compliant; NC: Not compliant

N: Number of NHs

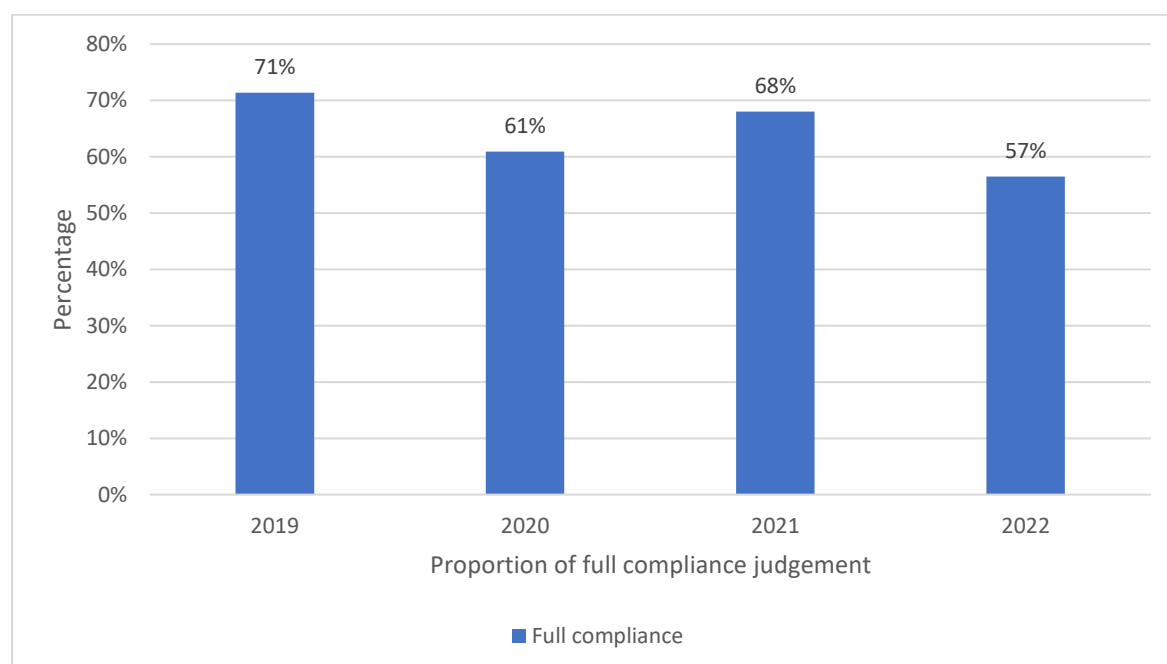


Figure 4. 6 The proportion of compliance judgement to Regulation 29: Medicines and Pharmaceutical services.

#### 4.4.2.5. Associations between Regulation 29 outcomes and nursing home characteristics

##### Outcome 1- Regulation 29 reporting vs. characteristics of NHs

No statistically significant associations were identified between NH characteristics and inspections reporting Regulation 29 across the four years;  $p\text{-value} > 0.05$  (Table 4.7). The cell counts and percentages underlying these results are described in Appendix 4.3.

Table 4. 7 Association between regulation 29 reporting and NH characteristics

	Year							
	2019 (n=93 NHs)		2020 (n=51 NHs)		2021 (n=86)		2022 (n= 60)	
	$\chi^2$	p-value	$\chi^2$	p-value	$\chi^2$	p-value	$\chi^2$	p-value
<b>NH size</b>	0.426	0.519	0.058	1	0.003	1	0.247	1
<b>Geographical class</b>	0.967	0.442	0.310	0.749	0.113	1	1.152	0.366
<b>Ownership type</b>	2.465	0.147	0.178	1	0.768	0.495	0.353	0.727
<b>Inspection type</b>	2.327	0.169	0.765	0.408	0.422	1	3.328	0.143

NH: Nursing home; Regulation 29: Medicines and Pharmaceutical Services

$\chi^2$  :Chi-square

p-value calculated using Fisher's Exact test

##### Outcome 2- Regulation 29 compliance judgement

No statistically significant associations were identified between any of the NH characteristics and level of compliance in NHs inspected for Regulation 29 in 2019-2022. (Table 4.8). The cell counts and percentages underlying these results are described in Appendix 4.4.

Table 4. 8 Association between Regulation 29 compliance and NH characteristics

	Year							
	2019 (n=56 NHs)		2020 (n=23 NHs)		2021 (n=25 NHs)		2022 (n=23)	
	$\chi^2$	p-value	$\chi^2$	p-value	$\chi^2$	p-value	$\chi^2$	p-value
<b>NH size</b>	0.854	0.565	0.808	0.640	2.022	0.547	0.353	1
<b>Geographical class</b>	1.213	0.856	1.308	0.805	3.033	0.167	0.847	1
<b>Ownership type</b>	0.522	0.858	0.672	1	1.023	1	0.365	1
<b>Inspection type</b>	3.288	0.199	3.248	0.334	0.488	1	4.107	0.281

NH: Nursing home; Regulation 29: Medicines and Pharmaceutical Services

$\chi^2$ : Chi-square

p-value calculated using Fisher's Exact test

#### 4.4.3. Qualitative findings (Step 2)

##### 4.4.3.1. Work systems

Using SEIPS 3.0 model, one work system was identified: the internal NH setting work system. Four related work systems: (i) GP practice work system; (ii) Community pharmacy work system; (iii) Hospital work system work system; (iv) Other clinical experts work system (Figure 4.7). All identified work systems were embedded in an external environment. These are the professional regulators, clinical guidance, and the COVID-19 pandemic (Figure 4.7).

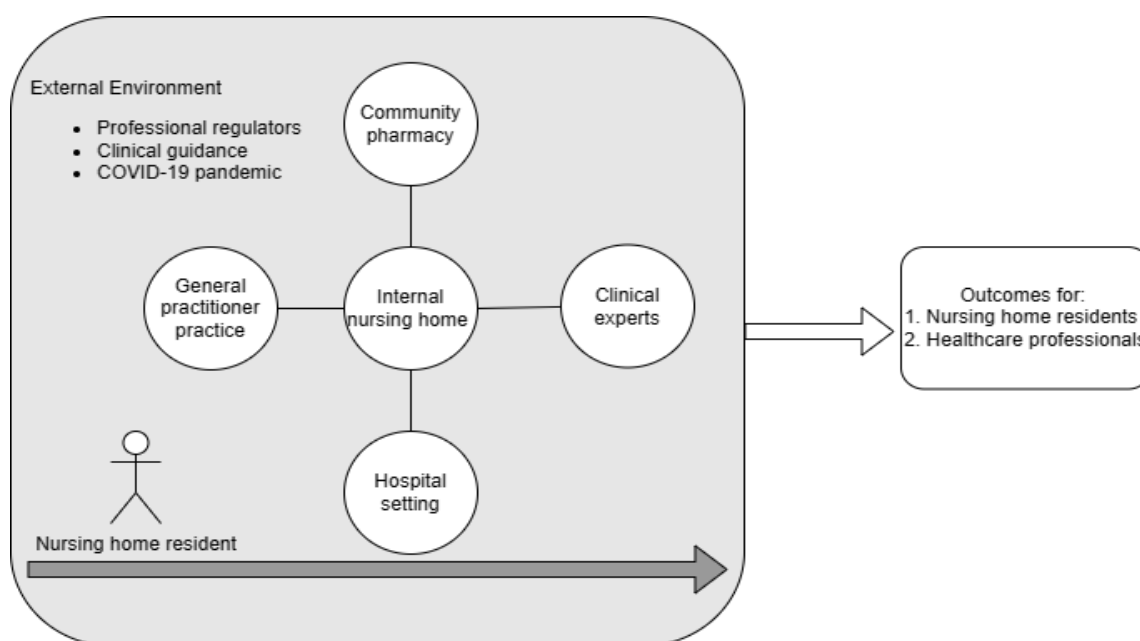
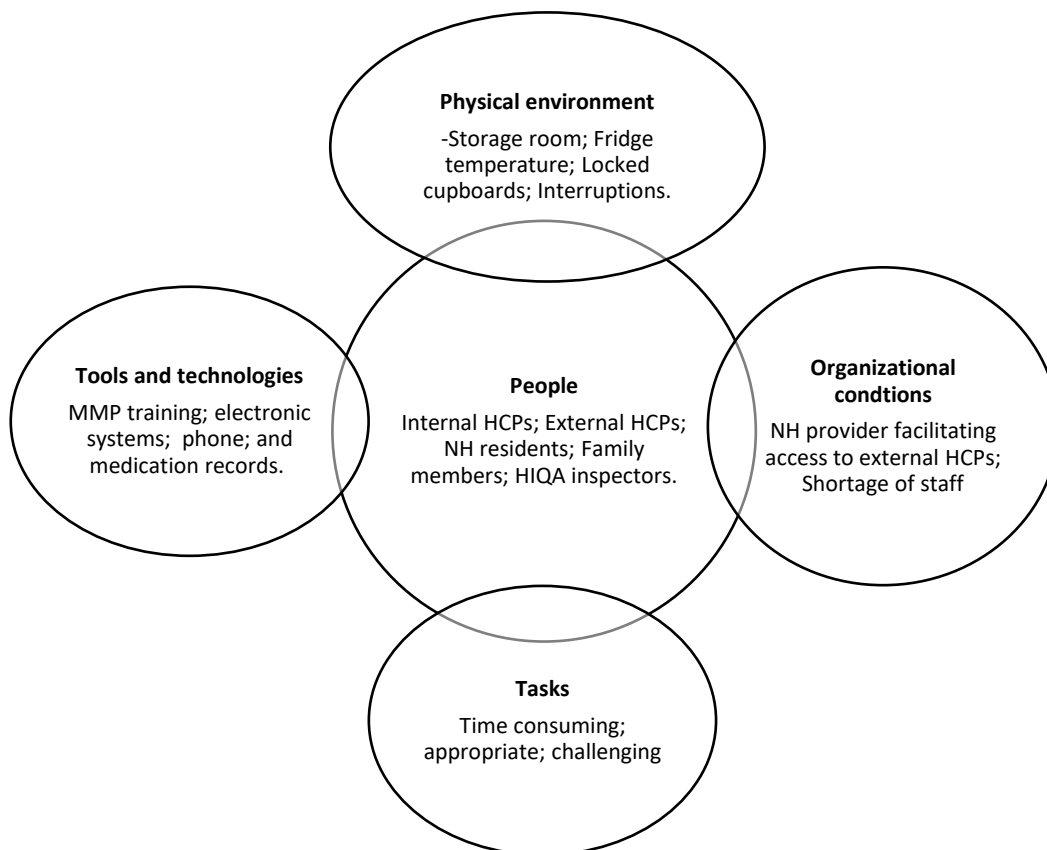


Figure 4. 7 Nursing home resident medicines management process journey map

The identification of work system components of the internal NH work system was within the scope of this study. These are described in detail in the sections that follow.

#### 4.4.3.2. Work system elements

The internal NH setting work system was identified to consist of five main elements: people, physical environment, organizational conditions, tasks and tools and technologies (Figure 4.8).



*MMP: Medicines management process; HCP: Healthcare professional; NH: Nursing home; HIQA: Health Information and Quality Authority*

Figure 4. 8 Internal NH setting work system elements

#### A) People

Five groups of people were identified who are involved in the providing MMP services to NH residents: (i) HCPs working within the NH (*e.g.*, nurses); (ii) HCPs who work external to the NHs, both those who visit regularly and those who are called upon for specialist services (*e.g.*, GPs, pharmacists and other clinical specialists); (iii) NH residents; (iv) families of NH residents; and (v) HIQA inspectors (discussed in the Section 4.4.3.5).

For example, one inspector noted:

*“Residents had adequate access to medical services and they had local pharmacy and general practitioner (GP) attention” [NH\_15].*

Another inspector described the range of external HCPs available to patients:

*“Residents had access to a range of services, including Old Age Psychiatry Services, gerontologist and additional expertise such as diabetic specialists, dietetics, optician and chiropody” [NH\_88].*

Another report spoke of residents and their family’s inclusion in decisions around end-of-life care:

*“Residents and/or their families were encouraged to make their preferences for end-of-life care known and this was recorded in their care plan records” [NH\_17].*

Several characteristics of the care team were identified, which included external HCPs’ availability for NH residents, NH residents’ dependency on HCPs, nursing staffs’ knowledge of the MMP and residents and families’ satisfaction.

#### External HCPs’- availability for NH residents

Several reports noted how available HCPs were to residents. For example, it was noted that pharmacists were available to residents:

*“The pharmacist who supplied residents’ medicines was facilitated to meet their obligations to residents and made themselves available to answer any queries individual residents had regarding their medicines” [NH\_28].*

Medical care needs of residents were met by availability of nursing staff.

*“Inspectors found that the nursing and medical care needs of residents were assessed, and appropriate interventions and treatment were given” [NH11].*

In some cases, inspectors said that residents had the choice to retain their own GP:

*“The local general practitioner (GP) provided medical services to the centre and residents also had a choice to retain the services of their own GP. Residents said they were glad that the doctor was readily available whenever there was a need or they requested a visit” [NH\_15].*

#### NH residents’ dependency on HCPs

Inspectors reported that NH residents seemed content not to be concerned about their medicines anymore (*i.e.*, since they became NH residents, relied on the HCPs to look after their medicines and did not appear to have an active involvement in managing their medicines).

*“One resident mentioned that they get to see the doctor when they need to and that they don't have to worry about managing their medication anymore” [NH\_1].*

#### Nursing staffs' knowledge of the MMP

Throughout the reports, there was evidence that inspectors felt the nursing staff were knowledgeable about the various components of the MMP, such as administration, storage, and disposal of medicines. One report noted:

*“Nursing staff were aware of the policies and procedures relating to the ordering, safe administration, storage, and disposal of medicines” [NH\_42].*

A further inspector reported observing a medicines administration round and noted:

*“The inspector observed a medicine administration round and found that the nurses were knowledgeable” [NH\_105].*

#### Residents and family's satisfaction

There appeared to be a sense of satisfaction from residents and their families regarding the care provided.

Several reports noted

*“Residents and relatives expressed satisfaction with the medical care provided and inspectors were satisfied that residents' healthcare needs were well met” (identified in reports for [NH\_10], NH\_19] and NH\_108]).*

### **B) Physical environment**

There were four components of the physical environment noted throughout the reports. These include (i) storage rooms for medications; (ii) fridge temperature; (iii) locked cupboard; and (iv) interruptions during medication administration.

#### Storage rooms for medications

Medications were noted to be securely stored in a dedicated room in the NH facility. The room was characterised as safe if it was found secured, locked and only accessible by the nursing staff. For example, one inspector noted:

*“All medicines were stored securely in a locked room” [NH\_104].*

Another noted a variety of options for safe keeping of medicines.

*“Medicines were stored in a locked cupboard, medication trolley or within a locked room only accessible by nursing staff” [NH\_108].*

It was also noted that rooms in which the medicines were locked were required to have a controlled temperature.

*“The labelling of some of the medications stored stated that storage was required at a temperature maximum of up to 25 degrees Celsius” [NH\_112].*

The same inspection reported noted a breach of this temperature requirement.

*“The records showed a room temperature of 26 to 27 degrees Celsius for a number of days in both rooms. This poses a risk for safe storage of the medicinal products” [NH\_112].*

It was also identified that medication storage rooms required attention.

*“Inspectors observed that the clinical room currently used for the storage of medicines required attention. The room in use was a bathroom converted into a clinical room. The room was packed with storage boxes and equipment. The toilet had not been removed and was covered with equipment. The room was poorly lit and had no surface to enable nurses to prepare medicines safely” [NH\_35].*

### Fridge temperature

It was noted that certain medicines required cold temperature storage, e.g., in a fridge, and therefore the fridge temperature had to be locked, controlled, and checked daily to ensure appropriate storage of such medicines. This requirement was fulfilled according to most reports. For example, several inspectors wrote:

*“Medicines requiring refrigeration were stored appropriately and the temperature of the refrigerator was monitored and recorded daily” (Identified in reports for [NH\_66], [NH\_69] and [NH\_75].*

However, other reports noted that the fridge temperature was not monitored appropriately, and that the fridge was not locked. One inspector noted:

*“There were gaps in temperature monitoring for medicine fridges. Records seen showed that one fridge was not maintained at the correct temperature to ensure the efficacy of the medication stored in them” [NH\_91].*

While another inspector wrote:

*“There was one medication management fridge that was not locked”* [NH\_35].

Issues with fridge temperatures were also noted, even though daily temperature checks were recorded. One report noted:

*“Inspectors viewed the records of two fridges used to store medicines. Numerous entries of temperatures showed that medicines had been stored outside of the recommended temperature range”* [NH\_11].

While another report stated:

*“Medicine that required refrigeration were not stored at the required temperature, despite fridges being checked daily”* [NH\_62].

#### Locked cupboard

For medicines other than fridge items, they are required to be stored in a locked medication cupboard and stored at room temperature. In most reports, the inspectors’ commentary was positive. For example, one inspector wrote:

*“Medicines that required special control measures were appropriately managed and kept in a secure cabinet in keeping with professional guidelines”* [NH\_113].

However, only one report noted unsafe practices in this regard

*“There was evidence of unsafe storage of medicines in a cupboard. The cupboard lock was broken and the key was left in it. Staff reported that the key was usually left in a wooden box on the wall which is not safe practice”* [NH\_11].

#### Interruptions

Inspectors reported that there were some interruptions from NH residents calling nurses to assist them or other nurses calling on them to help them with other duties.

*“Although residents received the correct medications, inspectors observed that the administration of their medicines at night was delayed on the first evening of the inspection. The delays were caused by frequent interruptions in which the nurses were called to assist staff with resident care. These interruptions increased the risk of drug errors occurring and were not in line with the safe administration of medications”* [NH\_103].

### **C) Organizational conditions**



Two organizational conditions were identified: (i) NH provider facilitating access to external HCPs; and (ii) shortage of staff.

#### NH provider facilitating access to external HCPs

Several inspectors reported that the provider or the person in charge of the NH facilitated the residents to have access to external HCPs such as pharmacists. For example, one inspector said:

*“The registered (person in charge) ensured that the centre had a pharmacy service to meet the need of the residents”* [NH\_38].

Other reports noted that the provider also facilitated NH access to GPs and other specialists as needed onsite.

*“Residents had very good access to medical care with the residents’ general practitioners providing on-site reviews. Residents were also provided with access to other healthcare professionals in line with their assessed need”* [NH\_14].

Another inspector said that the NH provided facilitated access to HCPs outside the NH such as in the community or hospitals.

*“The person in charge had made efforts to access community services for the residents in the centre, despite their limited availability. There was access to specialist medical services as well. Residents had been seen by community mental health services when required and had attended different hospitals if they required specific medical care”* [NH\_98].

#### Shortage of staff

Inspection reports identified that some centres had a shortage of nursing staff to care for the number of residents in the NHs, especially during the night shifts.. For example, one report noted:

*“There was only one nurse on duty to administer the night-time medication and provide nursing needs to 41 residents on two levels”* [NH\_30].

And another inspector noted:

*“The one nurse on duty for the evening and night shift provided care for up to 40 residents both upstairs and downstairs and also supervised the care staff providing care to residents throughout the centre. This nurse also had to administer medications on night duty and should not be disturbed throughout this process and this would be particularly problematic if there was a resident who was very unwell, had a fall or was at end of life requiring nursing care”* [NH\_97].

It was noted that staffing concerns were raised by nursing staff:

*“The nurses had voiced to the nurse management team that they felt the reduction of the availability of registered nurses rostered on at weekends posed a potential risk to the safe administration of medications” [NH\_03].*

#### D) Tasks

The individual tasks relating to the MMP, in other words, the sub-processes, included: assessment, prescribing, transcribing, supply, dispensing, administration, storage, medication review, monitoring return and disposal of medications, and governance. These processes were described interchangeably in the reports as ‘tasks’ or ‘processes’. HCPs tasks as identified from NH inspection reports are described in Table 4.9.

*Table 4. 9 Healthcare professional tasks within the MMP, as reported by HIQA inspectors*

	<b>Nurse</b>	<b>GP</b>	<b>Pharmacist</b>
<b>Assessment</b>	<ul style="list-style-type: none"> <li>● Provide assessment within 24 hours of admission</li> <li>● Determine residents’ medical history</li> <li>● Record keeping of assessments</li> </ul>	Provide full medical assessment within 24 hours of admission	Medication reconciliation
<b>Prescribing tasks</b>	Prescribe medicines indicated for <ul style="list-style-type: none"> <li>● Observe infections and apply antimicrobial stewardship policies as appropriate</li> <li>● Record keeping of medicines prescribed</li> </ul>	<ul style="list-style-type: none"> <li>● Prescribe appropriate medicines.</li> <li>● Choose the appropriate dose, duration, and format of medicines (e.g., crushed medicines)</li> <li>● Signing the prescription.</li> <li>● Transfer prescription to pharmacy for medication supply</li> </ul>	Involvement in consultation of medications prescribed and their formats (e.g., crushed medicines)
<b>Transcribing tasks</b>	<ul style="list-style-type: none"> <li>● Transcribing prescription into the NH resident medication chart within 72 hours post admission.</li> <li>● Sign the transcribed prescription.</li> <li>● Verify if the transcribed prescription matches the medication chart (by a second nurse).</li> <li>● Record keeping</li> </ul>	Not reported	Not reported
<b>Supplying tasks</b>	<ul style="list-style-type: none"> <li>● Record keeping</li> </ul>	Not reported	Supplying medicines to NH residents

<b>Dispensing tasks</b>	<ul style="list-style-type: none"> <li>●Record keeping</li> </ul>	Not reported	<ul style="list-style-type: none"> <li>●Dispensing the medications.</li> <li>●Writing expiry date on medication that are not dispensed in their original packages</li> </ul>
<b>Administration tasks</b>	<ul style="list-style-type: none"> <li>●Prepare medications for administration.</li> <li>●Administer medications according to prescription.</li> <li>●Engage with NH residents when administering their medications to them.</li> <li>●Crush medications if prescribed in crushed format.</li> <li>●Put dates on multi-dose medicines.</li> <li>●Sign that the medication/dose has been administered.</li> <li>●Record keeping</li> </ul>	Not reported	Not reported
<b>Storage tasks</b>	<ul style="list-style-type: none"> <li>●Lock cupboard or medication rooms where medicines are stored</li> <li>●Controlled drugs and appropriate records</li> <li>●Check fridge temperature twice daily.</li> <li>●Record keeping</li> </ul>	Not reported	Not reported
<b>Review tasks</b>	<ul style="list-style-type: none"> <li>●Medication review regularly (at least monthly).</li> <li>●Meet with pharmacists or GPs or both to discuss medications.</li> <li>●Facilitate medication reviews for pharmacists and GPs.</li> <li>●Document, sign, and date all medication reviews conducted in the facility.</li> <li>●Record keeping</li> </ul>	<ul style="list-style-type: none"> <li>●Medication reviews during visit, on monthly basis, and every three/four month.</li> <li>●Meeting with other HCPs for MDT medication review meeting.</li> </ul>	<ul style="list-style-type: none"> <li>●Medication reviews monthly, and every three months.</li> <li>●Meeting with other HCPs for MDT medication review meeting.</li> </ul>
<b>Monitoring tasks</b>	<ul style="list-style-type: none"> <li>●Monitoring residents' vital signs, and laboratory results (<i>i.e.</i>, blood tests) and residents' response to medications</li> <li>●Facilitate MDT monitoring meeting</li> <li>●Participate in MDT meetings and provide monitored medicines information of the NH resident.</li> <li>●Record keeping</li> </ul>	<ul style="list-style-type: none"> <li>●Monitor residents' vital signs, and laboratory results (<i>i.e.</i>, blood tests) and residents' response to medications.</li> <li>●Meet with other HCPs to discuss medication monitoring needs of NH residents.</li> </ul>	<ul style="list-style-type: none"> <li>●Monitor residents' vital signs, and laboratory results (<i>i.e.</i>, blood tests) and residents' response to medications.</li> <li>●Meet with other HCPs to discuss medication monitoring needs of NH residents.</li> </ul>
<b>Return and disposal tasks</b>	<ul style="list-style-type: none"> <li>●Segregate medicines no longer required</li> <li>●Arrange the return of medicines to the pharmacy</li> <li>●Record keeping</li> </ul>	Not reported	Receipt of return medicines from the NH.
<b>Governance tasks</b>	Maintaining and implementing policies and procedures	Not reported	Not reported

NH: Nursing home; HCPs: Healthcare professionals; HIQA: Health Information and Quality Information; GP: General practitioner; MDT: Multidisciplinary team

The assessment of NH residents was reported to be completed on admission and at transition of care from acute setting (i.e., hospitals) back to the NH, and medication management is a standard part of this practice. For example, one inspector noted:

*“Each resident had a pre-admission assessment prior to their admission to the designated centre and a full medical and nursing assessment was completed within 24 hours of their admission. The resident’s needs were assessed against a range of validated nursing assessment tools and these were kept with the resident’s nursing records” [NH\_17].*

Prescribing priorities were evident from the inspection reports. These included prescribing of antipsychotics and antibiotics. Indications for prescribing antipsychotics were noted:

*“Psychotropic medication which has a sedating effect was used as required and as prescribed for the management of responsive behaviours” [NH\_95].*

As was the practice of reducing the use of antipsychotics:

*“There was evidence of efforts to reduce the use of psychotropic medications, in line with best practice” [NH\_12].*

Inspectors also reported that the rationale for prescribing of PRN (as needed) medications was also noted:

*“Residents requiring PRN as required psychotropic medications had this information recorded along with the rationale for the prescription” [NH\_16].*

All reports that mentioned the transcribing tasks of nurses, described it as an unsafe practice. Some reports did not include details:

*“The procedures for transcription of residents’ medicines were not in accordance with professional standard” [NH\_103].*

This was because the 72 hours’ timeframe for transcribing a prescription was not adhered to, transcribing was not always accurate, and they were not signed by a second nurse or prescriber for verification. For example, one inspector noted:

*“As per the policy medications that are transcribed should be prescribed within 72 hours. There was clear evidence that this time frame is not adhered too” [NH\_104].*

Another inspector said:

*“Transcribed prescriptions that were used to administer medicines did not always correlate with original prescriptions” [NH\_83].*

Challenges in signing of transcribed medicines were described as follows:

*“Medication prescriptions were transcribed by nursing staff and not all were signed by the transcribing nurse; not all were co-signed by another member of staff to verify they were correct; and not all were signed by a GP” [NH\_95].*

Medication administration was largely described as safe and appropriate. For example, one report noted:

*“The inspectors found that medications were administered safely and in accordance with the directions of the resident's General Practitioner (GP)” [NH\_17].*

While another inspector stated:

*“Administration practices were in place and were supported by effective pharmaceutical services” [NH\_108].*

Specifically, the administration of crushed medicines were accompanied with instructions,

*“Medications that required crushing had an instruction on each individual medication that could be crushed in accordance with best practice” [NH\_77].*

as was the administration of covert medication:

*“Covert administration of medicines was an option on their administration form; however, this was not in keeping with current professional guidelines” [NH\_16].*

On the other hand, it was noted from one report that medication administration is time consuming.

*“The night-time medication took a length of time to administer and during this time the nurse should not be disturbed, therefore if a resident required nursing care, sustained a fall or was at end of life the nurse would not be available or would have to leave the medication round” [NH\_95].*

Throughout the inspection reports, three types of medication reviews were identified: (i) regular reviews; (ii) three monthly medication review; and (iii) multidisciplinary team medication reviews. HIQA inspectors used the terms ‘reviews’ and ‘audits’ interchangeably in their inspection reports. The majority of inspectors noted:

*“Medicine practices in the centre required proactive and stronger oversight. Regular medicine reviews and audits were carried out by pharmacist, a general practitioner (GP) and the nursing management” [NH\_71].*

*“There were regular audits of medicine management both by the staff and the pharmacist”*  
[NH\_113].

Medication reviews were reported to be conducted very often by GPs during their regular visits to the NH facility,

*“The medical officer attended the centre twice a week and documentation showed that medications were regularly reviewed”* [NH\_44].

Some reports noted the interval at which the reviews were undertaken, ranging from every one to three months.

*“Medication management audits were undertaken on a monthly basis per unit following the findings of the last inspection and audit results demonstrated good compliance level”* [NH\_82].

*“The general practitioner (GP) reviewed medicines on a three-monthly basis”* [NH\_41].

However, more reports noted a time interval relating to nurses undertaking reviews:

*“The nursing management team completed in house medication audits on a monthly basis”*  
[NH\_03].

Some reports noted the time interval for pharmacists undertaking reviews, also ranging from every one to three months, with commentary on the comprehensiveness at stages. Some reports mention that their regular reviews are also conducted on a monthly interval.

*“There is a check of the system completed monthly by a pharmacist”* [NH\_102].

*“The pharmacist also conducted quarterly medication management audits”* [NH\_23].

Multidisciplinary team (MDT) involvement was also noted in several reports:

*“This was also evidenced by audits carried out by the pharmacist and person in charge which found good levels of compliance in relation to receipt, storage, administration and return of medications”* [NH\_83].

*“Multi-disciplinary team inputs were evident in the care documentation reviewed”* [NH\_34].

Several reports noted an involvement of the MDT in monitoring. For example, one report noted:

*“Quarterly medication advisory meetings were facilitated with the pharmacist and GPs attending the centre to provide support and guidance to the service... Residents' responses to medication were monitored to ensure best outcomes for them”* [NH\_16].

The terms 'return' and 'disposal' of medications were used interchangeably throughout inspection reports. The majority of reports described how medicines for return and disposal were separated from core stock, and the nursing staff had responsibility for this task. For example, one inspector said:

*"Out-of-date medicines and medicines which were no longer in use segregated from in-use medications and were returned to the pharmacy promptly" [NH\_114].*

However, this process was not well managed in all NH, with several reports noting a time delay in the return of unwanted medicines to pharmacies for safe disposal. For example, one report noted:

*"Inspectors found large quantities of medicines that were not returned. Therefore, the systems in place to check the receipt of and return of medicines was not robust" [NH\_32].*

Inspectors noted procedures and policies were in place to ensure MMP services were delivered safely and compliance with regulations was achieved. For example, one inspector noted this one through keeping policies and procedures in place:

*"There were written operational policies and procedures in place on the management of medications in the centre" (Identified in reports [NH\_10] and [NH\_17]).*

And another noted that was achieved through keeping records of interventions:

*"The record of medication related interventions and the storage of medicines. Inspectors found that the registered provider had safe systems in place" [NH\_11].*

Regular medication audits and discussions of medication errors were noted in some reports as positive steps to ensure the delivery of a safe MMP in the NH. One report noted for example:

*"The management team met regularly to discuss and review key performance indicators including ..... medication errors, ....." [NH\_21].*

Similarly, another inspector noted:

*"Medicine management practices were reviewed, and policies were in place to support practice. There was a system in place to ensure that all medicines were reviewed on a regular basis by the pharmacist and GP" [NH\_31].*

## **E) Tools and technologies**

Various tools and technologies were evident from the reports as being used throughout the MMP including medicines management training, electronic systems (*i.e.*, electronic software for records, electronic prescribing); phone; and medication records.

There was evidence from the report medicines management training was provided to nurses. Detail of the amount or content of training was not noted in any report; however, it was reported in several reports that training was held in the NH facility. For example, inspectors wrote:

*“Medication management training was provided to staff”* [NH\_10].

Some inspectors indicated the frequency of training:

*“The centre's medication management policy outlined that medication management training should be undertaken by registered nurses annually”* [NH\_86].

Reports noted the use of electronic software for records. For example, one report noted:

*“Review chart that was recorded on the electronic system”* [NH\_23].

It was also noted in some instances that records could be accessed remotely:

*“GPs, nurses and the pharmacist also had access to the electronic care record system and to medication records maintained and were able to access and review these remotely to update them as and when required”* [NH\_09].

Another inspector noted the use of electronic prescribing:

*“Prescriptions were in an electronic format and overall contained the necessary details for safe administration including name, photograph, allergy status, route, dose and time”* [NH\_118].

Electronic prescribing was undertaken via secure email, remotely. For example, one noted:

*“During the lock down period, resident's general practitioners (GP) were providing a service remotely and advised staff over the phone. This included remote prescribing of medicines”* [NH\_32].

Several inspectors said that the phone was also used as a means of remote communication.

*“Resident's general practitioners (GP) were providing a service remotely and advised staff over the phone”* [NH\_104].

#### **4.4.3.3. Interactions between work system elements**

Interactions were identified between work systems elements (Figure 4.9). People were identified as being involved with all interactions identified.



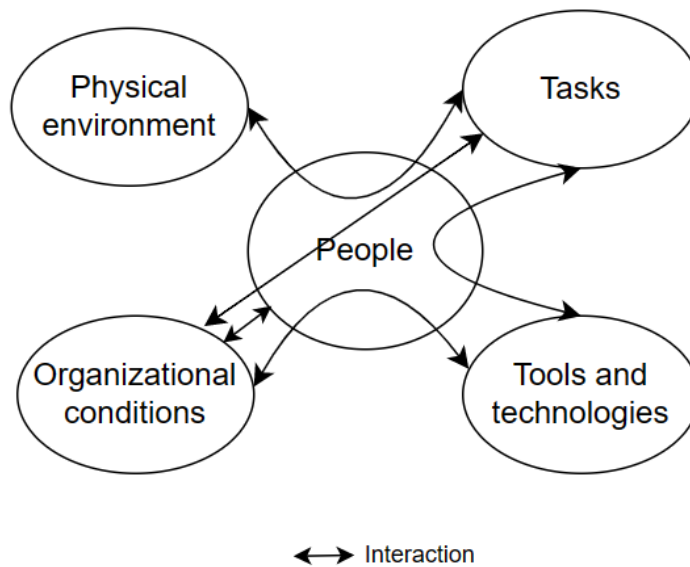


Figure 4. 9 interactions between work system elements

People and organizational conditions

The NH resident’s access to external HCPs was influenced by the NH’s organization of a contract with a GP:

*“The local general practitioner (GP) provided medical services to the centre and residents also had a choice to retain the services of their own GP. Residents said they were glad that the doctor was readily available whenever there was a need or they requested a visit. Specialists’ appointments were facilitated” [NH\_15].*

Organizational conditions, tasks, and people

The availability of nursing staff had an impact on the quality of the tasks being undertaken. For example, one report noted:

*“The nurses had voiced to the nurse management team that they felt the reduction of the availability of registered nurses rostered on at weekends posed a potential risk to the safe administration of medications” [NH\_03].*

Organisational conditions, tools and technologies and people

Inspectors noted that the MMP training conducted by the NH staff fulfilled a policy requirement. For example:

*“All staff nurses had completed the online HSE medication management training as per the centre’s policy” [NH\_11].*

#### Organizational conditions, tasks, tools and technologies and people

The availability of tools and technologies in the NH facility had an impact on the nature of communication and the range of tasks conducted by HCPs. For example, one inspector said:

*“During the lock down period, resident ‘s general practitioners (GP) were providing a service remotely and advised staff over the phone” [NH\_32].*

Another inspector wrote:

*“The electronic system in use prompted the administering nurse to check and sign for each medication, which minimised the risk of errors” [NH\_114].*

#### Tasks, physical environment, and people

Interruptions during medication administration rounds influenced the safety of MMP tasks performed by HCPs. for example, one report noted:

*“On the first evening of the inspection, the staff nurses administering residents' medicines were being constantly interrupted to assist with caring for residents and, as a result, their administration of residents' medicines were delayed” [NH\_103].*

#### **4.4.3.4. The external environment**

Three external environments were identified as interacting with other elements of the work system (Figure 4.10):

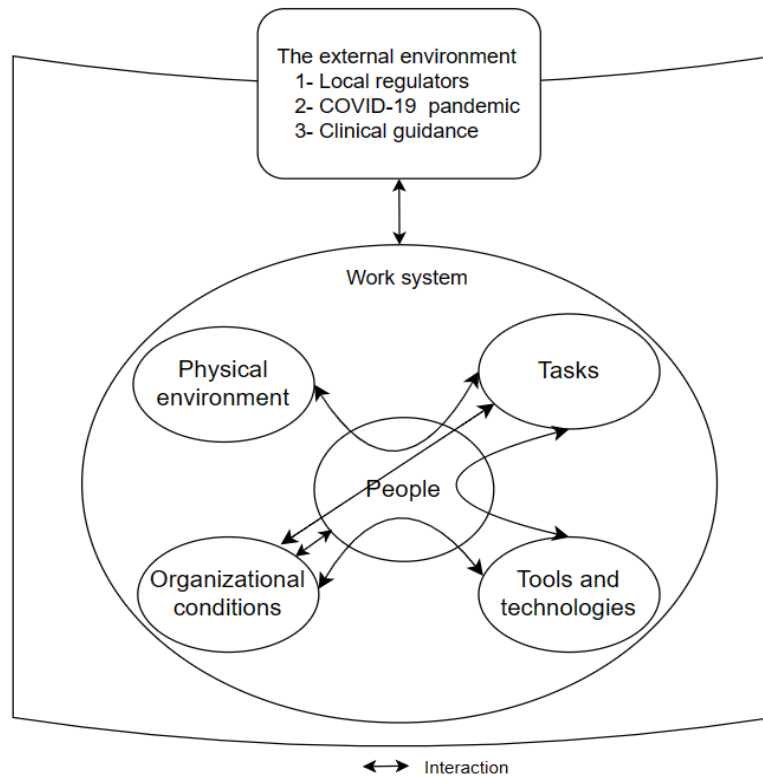


Figure 4. 10 Interactions between the external environment and work system elements

Work system tasks were performed in line with the relevant regulatory body’s standards and guidance. These included national standards from HIQA, the NMBI (*An Bord Altranais agus Cnáimhseachais*) and the PSI. This was noted from several reports where inspectors said:

*“Residents were protected through medication management and practices that were in line with national standards”* [NH\_64].

*“Medicines were recorded as administered in accordance with guidance issued by An Bord Altranais agus Cnáimhseachais”* [NH\_108].

*“The pharmacist was facilitated to fulfil their obligations under the relevant legislation and guidance issued by the Pharmaceutical Society of Ireland”* [NH\_6].

Other inspectors noted that some MMP practices were not in line with standards from the NMBI and were noted to reduce the safety of the MMP:

*“The inspector observed practices in medication administration during the inspection that did not abide by the ten rights of medication administration. These practices were rectified during the inspection but required ongoing monitoring to ensure all staff were compliant with best practice guidelines is required”* [NH\_97].

The ongoing COVID-19 pandemic was identified as impacting on tasks, with reports noting medication reviews tasks were delayed:

*“The system of clinical audit in place includes monthly review of restrictive practice, falls, accidents/injuries, pressure ulcers, medication errors and complaints and staff were reminded of the importance of maintaining these audits up to date. However, in this current climate with more urgent priorities addressing COVID 19, staff have been instructed to maintain these items under review to ensure any issues are identified and appropriate responses put in place to address any concerns. Full audit will commence once the current situation stabilizes” [NH\_11].*

Inspectors reported that antibiotic prescribing tasks were in line with antibiotic stewardship clinical guidance requirements:

*“Good oversight was demonstrated regarding antibiotic stewardship which improved outcomes for residents” [NH\_60].*

#### **4.4.3.5. Outcomes**

The interactions between components of the work system were identified to impact outcomes experienced by NH residents and HCPs. The outcomes evident from interactions between the work system elements are described in Table 4.10 and categorised as being desirable or undesirable.

Table 4. 10 Identified outcomes

Outcome type	Outcomes for residents	MMP-related stages	Details of SEIPS component
Desirable	Reduced medication error	Storage	Fridge temperature and storage rooms ( <i>Physical environment</i> )
		All MMPs	Medication error ( <i>Tools and technology</i> ) Record keeping ( <i>Tasks</i> ) NH residents' dependency on HCPs ( <i>People</i> ) Adherence to obligations from relevant regulators ( <i>External environment</i> ) Access and availability of all HCPs ( <i>People</i> ) ( <i>Organisational</i> )
		Review and monitoring	Three-monthly medication review/audit ( <i>Task</i> ) ( <i>External environment</i> )
		Prescribing, transcribing, administration, review, and monitoring	Electronic systems, MMP training and communication tools ( <i>Tools and technologies</i> )
		Prescribing	Following clinical guidance ( <i>External environment</i> )
Undesirable	Increase medication error	Storage	Temperatures and storage conditions ( <i>Physical environment</i> ) Non-adherence to tasks set by professional regulators ( <i>Tasks</i> ) ( <i>External environment</i> )
		Administration	Interruptions ( <i>Physical environment</i> ) Shortage of staff ( <i>Organisational conditions</i> ) Non-adherence to tasks set by professional regulators ( <i>Tasks</i> ) ( <i>External environment</i> )
		Disposal	Non-adherence to tasks set by professional regulators ( <i>Tasks</i> ) ( <i>External environment</i> )
		Review	Delayed tasks due to COVID-19 pandemic ( <i>Tasks</i> ) ( <i>External environment</i> )
Outcome type	Outcomes for HCPs	MMP-related stage	Details of SEIPS component
Desirable	Simplified task complexity -Improved communication	Prescribing, transcribing, administration, review, and monitoring	The use of secure mail, remote access to electronic systems, communication tools and medication records ( <i>Tools and technologies</i> )

Undesirable	Time-consuming task and increase workload	Administration	Interruptions ( <i>Physical environment</i> ) Shortage of staff ( <i>Organisational conditions</i> )
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*MMP: Medicines management process; NH: Nursing home; HCP: Healthcare professionals*

#### 4.4.4. Triangulation of data

Quantitative and qualitative results were triangulated using the framework proposed by O’Cathain *et al.*, where key findings and/or themes were summarized into a table and interpretation of both analyses were then compared for convergence, complementarity, or discrepancy [446]. This method allowed better interpretation of results from separate analyses (quantitative and qualitative analysis). The triangulation table is summarised in Table 4.11.

Table 4. 11 Triangulation

Theme	Quantitative	Qualitative
Compliance	More than half of the NHs included were fully compliant to Regulation 29	Not all components of medicines management were described within the content of Regulation 29 The identified interaction between work system components have resulted in reduction of medication error and thus contributing to the proportion of NHs level fully compliant to Regulation 29.
Medication Administration	Medication administration was the most targeted stage in NHs inspected for Regulation 29; in up to 90% of NHs.	Barriers and facilitators to safe medication administration practice were identified in NHs inspected.
Medication storage	The second most targeted process of the MMP is the storage which was inspected in 60-80% of what.	Inconsistent storage practices were identified within NHs inspected for medication storage.
Other MMP	Other processes that were inspected throughout the four years included return and disposal of medicines (in 25-35% of NHs).	The SEIPS3.0 analysis identified other processes of the MMP that were inspected in the free text, these included assessment, prescribing, transcribing, supply, dispensing, medication review, monitoring, and implementation of policies and procedures. Of these, the majority of inspectors have focused on the transcribing and its association with increasing the risk of medication error.

Pharmacist tasks	PIC tasks in ensuring that pharmacist meet their obligatory tasks in the MMP from relevant regulators was inspected in 20-35% of NHs.	SEIPS 3.0 analysis identified that pharmacists tasks were described within the assessment, prescribing, supplying, dispensing, review, monitoring return and disposal of medicines.
Medicines-related records	Record keeping of pharmacists' interventions in a safe and accessible place in the NH [Regulation 29: inspected in 30-36% of NHs].	While the majority of inspections reported that records were safe and accessible, these records were not exclusive to pharmacists' interventions but to all medicines-related records from other HCPs involved and in all stages of the MMPs. These records were identified to reduced risks of medication errors for NH residents.

NH: nursing home; MMP: medicine management process; SEIPS: system engineering initiative for patient safety; PIC: person in charge

## 4.5. DISCUSSION

The current chapter outlines key findings from a mixed methods secondary analysis study that sought to explore the MMP in the Irish NH setting from the statutory regulator's perspective using NH inspection reports. This study quantitatively described the NHs' characteristics and the extent of MMP-related regulation reporting. In a similar approach used to explore the MMP in the NH setting from HCPs' and non-HCPs' perspectives (Chapter 3), it also used the SEIPS 3.0 model as a framework to qualitatively analyse the free text of the NH inspection reports to explore, from the inspector's perspective, the work systems, their component elements, interactions and outcomes. Finally, triangulation of the quantitative and qualitative findings was undertaken. Triangulation of data identified three key emergent themes (i) barriers to medication administration; (ii) tools and technologies to facilitate the MMP; and (iii) medication error reporting.

### 4.5.1. Barriers to medication administration

Medication administration was the most inspected stage in the NH inspection reports across the four years. Medication administration errors contribute to one third of MRPs across all settings, as reported by the WHO [66]. Ferrah *et al.*'s systematic review also reported that medication administration errors were experienced by up to 31% of NH residents [227]. While medication administration is the most targeted component of the MMP and more than 50% of included NHs were in compliance with



Regulation 29, the SEIPS 3.0 analysis and identifications of some work system elements and interactions presented risk of medication administration error to NH residents and the associated burden of work for nurses. These include the *physical environment* (e.g., interruptions from residents) and *organisational conditions* (e.g., shortage of nursing staff). This was consistent with findings from the HCPs' perspective (Chapter 3) and from a systematic review conducted by Al Jumaili and Doucette [447], and a qualitative interview and observational study conducted by Odberg and colleagues [376, 382] using the SEIPS model to explore work system factors contributing to barriers in the medicines administration process in the NH setting. These barriers can contribute to explaining the focus of HIQA inspectors on medicine administration component throughout the four years.

Schoreors's integrative review of observational studies conducted in the hospital setting identified that nurses experience at least one interruption per medication administration round from other staff and concluded that knowledge of reasons for interruptions can support managing such interruptions [448]. In contrast, this study identified that interruptions occur from the NH residents. Further research could explore the nature of this, and the supports available to the nurse conducting the medicines administration round, or strategies to divert these interruptions to other less critical tasks. Equally, staffing is a frequent barrier to safe medication administration in various clinical settings including the NH setting [449, 450]. The literature presents evidence of the effect of a shortage of staff on increasing the burden of work for NHs. For instance, Qureshi *et al.*'s study using a simulation model reported that insufficient nursing staff contributed to reduced patient safety and increase workload for nurses in the hospital setting [451]. These barriers contribute to MRPs such as increasing the risk of medication administration error as reported by Hammoudi and colleagues' cross-sectional study in Saudi NHs [452]. Thus, this study suggests that balancing the nurse-patient ratio in the NH setting can contribute to improving outcomes for nurses (decrease burden or workload) and NH residents (improve patient safety). To our best knowledge, there is an absence of studies reporting the prevalence or the nature of the medication administration process in the Irish NH setting. Thus, this study suggests that a complementary qualitative study with an observational component in the Irish NH setting, that is guided by the SEIPS model, could beneficially be used to comprehensively explore (i) the medication administration work system (including elements, interactions and outcomes) in the Irish NH setting, (ii) the impact of these on patient safety and HCP outcomes; and (iii) strategies to enhance patient safety and outcomes for NH staff.

#### **4.5.2. Tools and technology to facilitate the medicines management process**

The SEIPS analysis of the inspection report content identified that *tools and technology* were key facilitators to multiple stages of the MMP. These included the use of Healthmail (described in detail in Chapter 1, Section 1.6.1; and Chapter 3, Section 3.5.3), communication tools such as phones,

training in MMP and the use of electronic systems. Not only that, but it helped to link MMP stages together, across multiple work systems, thus improving interprofessional MMP practice. A systematic review conducted by Mebrahtu and colleagues which included studies from all clinical settings, including the NH setting, reported that electronic systems facilitated nurses' tasks across various stages of the MMP (e.g., medication administration, and monitoring)[453]. Rodley *et al.*'s study in Australian hospitals compared the impact of electronic systems versus the traditional paper system and identified lower medication administration errors rates in the electronic system group [454]. The interactions identified between the tools and technology and task elements of the work system in this study contributed to positive outcomes for NH residents (reduced risk of medication error) and for HCPs (simplified task complexity). Thus, this study provides systems-based evidence of the benefits of technology and suggests that the wider implementation of integrative technological approaches across the Irish NH healthcare system could be a positive move.

Findings of HIQA inspection reports showed a degree of interprofessional MMP practice in the medication review stage of the MMP with the aid of technologies such as Healthmail and virtual conferences. However, it is not clear from the reports if the interprofessional practice represents a good team collaboration "*those who share an integrated approach and interact on a regular basis*" or poor team collaboration "*those who do not work in an integrated fashion and interact infrequently*" as described by Reeves and colleagues [379]. While there is an absence of interventional studies in the Irish NH setting targeting stages of the MMP, the literature has some evidence on the prescribing stage [120, 455]. Heinrich and colleagues' recent qualitative study of HCPs on deprescribing practices reported that there is an absence of an integrated interprofessional system between HCPs and this was identified as a barrier to deprescribing in the NH setting [456]. In like manner, GPs in the RoI have reported a similar absence and their preference for using a multifaceted electronic system that allows mutual access for the healthcare staff who need it, to access medicines information that would support prescribing, dispensing, administration, review and monitoring of residents' medications [400]. Correspondingly, this study suggests the need for an electronic system that can be accessible by all HCPs. This in turn, could support better interprofessional MMP practice and communication, which could potentially contribute to positive outcomes.

Moreover, transcribing practices we identified in all retrieved inspection reports was described by HIQA inspectors as unsafe practices, these practices included discrepancies between the prescription and transcribed Kardexes, and non-adherence to regulatory requirements such as duration between prescribing and transcribing, presence of signatures by nurses or verification of the transcriptions being accurate by the prescribers. Doormaal and colleagues reported that more than half the medication orders involved at least one transcribing error in the hospital setting [457]. Shawahna and

colleagues also reported that the variation between prescriptions and Kardexes has been reported to contribute to the increased risk of administering the wrong medications [458]. However, given the inspectors' focus on this task and universal identification of this in all reports, it is reasonable to suggest that there should be another approach to overcome the consistent nonadherence to this practice. This represents an important human factors and ergonomics case study and suggests that the elements that the people interact with need to change to alter the outcome. Furthermore, this study suggests that the mutual electronic system between HCPs could ideally support automated recording of prescribing and administration of medications, thereby overcoming the identified issues associated with Kardex (re)generation. This suggestion is consistent with GPs' desire for a mutual electronic system that can support Kardex generations and improve prescribing and administration practices [400]. This therefore might simplify nurses' tasks, reduce the burden of medication error, improve compliance with regulations and enhance safe MMP provision to NH residents. Brenner and colleagues' systematic review provided evidence from approximately 40% of the included studies on the positive impact of technologies on improving patient safety [459].

#### **4.5.3. Medication error reporting**

Researchers in the last decades have reported the prevalence of medication error and the benefits of learning from medication error reporting systems in other settings, such as the hospital setting [460]. The findings of this study suggest that medication error occurs frequently in the Irish NH setting, with evidence of medication administration, storage, and disposal errors. Despite this, there was no data in the reports, or described in the data reported in Chapter 3, describing the management of these errors, for example the use of error logs, error reporting or analysis of such data. Santell and colleagues' study used an electronic medication reporting system and identified that the most common errors in American hospitals were prescribing omission and wrong dose administration errors [461]. Vrbnjak and colleagues' systematic review of factors contributing to the 'under-reporting' of medication error included the organisational conditions (*e.g.*, supportive reporting culture) and person characteristics (*e.g.*, psychological fear of unpleasant consequences) [462]. Haw *et al.*, and Sanghera and Dhillon's qualitative studies reported that the burden of work involved in error reporting as another barrier [463, 464]. These barriers are consistent with the findings from a systematic review on underreporting errors in American hospitals [465]. Little is known about medication error reporting in the NH setting internationally although it would be useful to understand the nature of current practice and facilitators and barriers of error reporting in this context through a systems-based exploration of this area. The SEIPS-based analysis provides evidence reported from the NH inspections across four years about observed unsafe MMP practices across various components of the MMP. However, not all of these components are the focus of the inspections. Additionally,

there is no data reported on a medication error reporting system, which can be adapted to prioritise MMP components inspected. This suggests the need for a medication error reporting system in the RoI. Future research should explore the medication error management systems in place within and across the nursing home sector in the RoI and strategies to enhance learning and improvement associated with these.

#### **4.6. STRENGTH AND LIMITATIONS**

This is the first study to make use of a SEIPS 3.0 model as a theoretical basis to explore the MMP from NH inspection reports published by the statutory regulator. A key strength of this study was the use of mixed methods and triangulation of findings using O’Cathain *et al.*’s approach; which enhanced the (i) the generalisability and validity of reported findings; and (ii) allowed solid and comprehensive exploration of the MMP system from the statutory regulator’s perspective. The considered choice of the appropriate statistical tests to apply, relative to the sample size (*e.g.*, chi-square tests and Fisher’s exact test) enhances the robustness of the statistical approaches applied. To our knowledge, this is the first study undertaken in the NH setting in the RoI to provide a quantitative overview of Regulation 29 reporting and compliance from HIQA inspection reports. Furthermore, this study followed recommendations from the MRC framework on using theory to support the development of complex interprofessional interventions by explicitly targeting the facilitators and barriers identified. The current study contributes to the growing literature on the value of using the third version of SEIPS which adds the concept of the patient journey, to identify work systems and their components within the NH resident MMP journey. The SEIPS-based findings have supported the generation of evidence-based recommendations for researchers to develop, implement or evaluate as complex interprofessional MMP interventions.

As a limitation of this study, the small sample size of NH reports may have contributed to the finding of no statistically significant association between any of the NH characteristics and Regulation 29 outcomes. However, the selection of the sample size was out of our control as all retrieved NH reports from the 2019 search in both databases (HIQA website and TARA) were included in the analysis. The data were not collected by the researcher and as with all secondary data analysis, were generated for an alternate purpose [466, 467]. These reports were not written to directly answer the research question posed, therefore it is possible that data which would have been recorded if this was a primary study, were not recorded in the reports. Finally, it was challenging to draw meaningful conclusions and comparisons between years, as there was an absence of longitudinal qualitative reporting of findings across the four included years.

#### **4.7. CONCLUSION**

To the best of our knowledge, this is the first study conducted in the ROI exploring the MMP from the statutory regulator's NH inspection reports. Findings from both quantitative and qualitative analyses identified that the internal NH setting work system consists of elements and interactions that formed barriers (*e.g.*, physical and organisational conditions) to positive outcomes. These findings can guide future researchers in this area to develop suitable interventions and to apply the SEIPS model to observational studies in NHs that aim to exploring reasons for these barriers and the extent of their impact on outcomes. A system redesign based on these findings can then be piloted, as recommended by the MRC framework, to develop a robust interprofessional MMP intervention with the involvement of pharmacists and targeting NH residents. The tools and technology element of SEIPS interacted with other components of the work system which facilitated positive outcomes experienced by HCPs and correspondingly, improved NH residents' safety. Further research is needed to explore the impact of a mutually accessible technology, between the multiple professionals, on interprofessional teamworking and patient safety.

## **Chapter 5**

### General discussion and conclusion

## 10.1. GENERAL DISCUSSION AND TRIANGULATION

The research presented in this thesis has focused on exploring the medicines management process (MMP) provided to older people residing in nursing homes (NHs) in the Republic of Ireland (RoI). Older NH residents commonly have age-related health decline, multimorbidity and other factors that are associated with medication-related problems (MRPs) such as polypharmacy, medication error, potentially inappropriate prescribing (PIP) and adverse events (*i.e.*, hospitalisations and falls associated with medication use). These MRPs and their consequences can happen during any stage of the MMP, making the process challenging [148]. Not only that, but also the involvement of multiple healthcare professionals (HCPs) from different settings, the level of interprofessional teamworking and regulatory requirements of MMP-related roles, largely contribute to a challenging MMP. The MMP in this setting is a complex process, defined by the Health Information and Quality Authority (HIQA) as *“Medicines management covers a number of tasks including assessing, supplying, prescribing, dispensing, administering, reviewing and assisting people with their medicines”* [144]. Many interprofessional interventions have been conducted over the last decade that target stages of the MMP and may have a degree of evidence to support reducing MRPs and improving the MMP. However, there is a lack of theory underpinning the development of these interventions despite recommendations to theoretically underpin complex interventions in health research [208, 209]. Theory helps identify what works, and what does not work and explain reasons why [210]. Additionally, there is a lack of Irish research that describes the landscape of the MMP services and components in the NH setting.

The research presented in this thesis has therefore focused on exploring the MMP provided to older people residing in Irish NHs, using theory. The methods adopted throughout this thesis have followed the framework for developing complex interventions from the United Kingdom (UK)’s Medical Research Council (MRC) with a focus on the developmental phase and recommending future improvements to guide researchers and policymakers in this area.

Chapter 1 introduced the topic of the MMP, MRPs in the older population and interprofessional practice. It also presented some of the methodological approaches adapted in this thesis, which were then employed to enhance the rigour of the methods applied and the study findings. Chapter 2 outlined the findings from a systematic review and meta-analysis that aimed to systematically identify and describe interprofessional MMP interventions, involving pharmacists, provided to older people in the NH setting. This was achieved by describing interprofessional MMP interventions in this area, the main care providers of MMP, their roles, the impact of these interventions on outcomes and by exploring any theoretical basis of these interventions. The findings described in Chapter 2 supported

the development of the study described in Chapter 3, which involved the use of a human factors and a systems-based framework; the Systems Engineering Initiative to Patient Safety (SEIPS 3.0) model, to qualitatively explore the MMP from the main HCPs' and family members' opinions through identifying work systems, components of the work systems, interactions, and perceived outcomes experienced by NH residents and HCPs. Moreover, the NH resident MMP journey map in the RoI was established. The work presented in Chapter 4 further explored the MMP and compliance with MMP-related regulations from the statutory regulator's (HIQA) perspective using mixed methods secondary analysis of NH inspection reports. It is also worth noting that none of the included studies in the systematic review reported in Chapter 2 were conducted in the RoI. The literature also lacks information about the nature of the MMP in the Irish NH setting, which was the focus of Chapters 3 and 4.

The key findings from the component studies presented in this thesis are discussed and triangulated below, and evidence-based recommendations for future research, practice, and policy to advance this area are presented. A final conclusion is then provided.

#### **10.1.1. Theory-based Interprofessional MMP Interventions, with the Involvement of pharmacists, provided to older people in the NH setting: evidence gap**

As described above, the guidance from the MRC recommends using theory in intervention development. Craig *et al.*, suggest that interventions with underpinning theories are more likely to be effective compared to those without [209]. This suggestion by Craig *et al.*, has been evident by health researchers across a variety of settings and contexts, for instance, Gourlan *et al.*, reported the positive impact of a theoretically-grounded interventions on physical activity behaviour in adults [468]; McDermott *et al.*, reported improvements in GP's self-efficacy in antibiotic prescribing using an intervention based on behaviour change theory [469]; Bonner *et al.*'s, systematic review of theory-based interventions reported an increase in self-care behaviours in diabetic patients [470].

To determine the extent to which interventions are theory-driven, Michie and colleagues have developed the theory coding scheme (TCS) tool, which allows researchers to identify and describe the theoretical basis of interventions and behavioural change [249]. The same author also added that experts in this area acknowledge theory in its effect on the after-effect of interventions [249]. On the other hand, some authors cited the theory underpinning their intervention development but did not report on assessing the effectiveness of theory-use (in intervention development) on outcome measures. Additionally, many systematic reviews have explored interventions across a variety of health research topics but could not assess the effectiveness of included interventions using the TCS due to the limited number and/or lack of references to targeted interventions [470-472]. Similarly in the area of medicines management, McGrattan and colleagues' systematic review identified only one



theoretically driven randomised controlled trial (RCT) of interventions to support medication management in people with dementia, which was conducted by Lingler and colleagues in the community setting, but which reported no statistically significant difference in outcomes between the intervention and control group [473].

Previous systematic reviews of pharmacists-led interprofessional MMP interventions in the NH setting did not appraise the theoretical underpinnings, did not include RCTs or did not systematically describe the nature of the interprofessional interventions [151, 291, 474]. The research presented in Chapter 2 of this thesis addressed these gaps by systematically reporting results on eighteen interprofessional MMP interventions, identifying the intervention components and any reported theoretical underpinning.

The lack of reporting of any theoretical underpinning of the included RCTs is a key finding in this study. Despite the body of evidence in the literature that supports using theory and its benefits on understanding aspects of interventions and their effectiveness on outcomes measures [249], the MRC did not recommend the use of theory as a core component of intervention development until their updated version of the framework in 2022 [208, 209]. Additionally, Consolidated Standards of Reporting Trials (CONSORT) guidelines for reporting RCTs do not guide researchers to report on theory use [302]. Moreover, the literature is inconsistent on whether interventions should adapt/or report a theoretical basis in intervention design and suggest that more evidence is needed to inform this debate [251, 468, 475]. These issues could explain the absence of any theoretical basis having been reported about the interventions included in the systematic review (Chapter 2). While this systematic review is helpful and provides evidence to suggest a beneficial effect from pharmacists' involvement within an interprofessional team on the appropriateness of prescribing for this cohort, it does not provide any explanation about how or why these interventions work. Therefore, complementary pieces of work to pool data from other study designs (such as a qualitative or realist synthesis) could be useful to draw out how and in what circumstances these complex interventions work, thus enabling the development of a theoretical framework to further guide intervention development [476]. For instance, key questions which could be addressed in such a review would be, whether the involvement of pharmacists and/ or non-HCPs in these interventions is the underlying reason for the successful improvements in prescribing, or why interventions were not effective in reducing adverse drug events. Such deeper explanation is important to aid understanding about the inconsistency of this study's results with other similar systematic reviews. For instance, Lee and colleagues' systematic review of interventions conducted by pharmacists alone and/or within an interprofessional team for NH residents reported reductions in the number of falls [291]. While the literature provides evidence on the impact of medicines (*i.e.*, psychotropic medications) on resident's falling risk [477], the meta-

analysis conducted in Chapter 2 did not identify a benefit from the interprofessional interventions to significantly reduce falls in this cohort. This finding suggests that further research is needed to develop a theoretical basis of a complex interprofessional MMP intervention, with the involvement of the pharmacist to improve patient safety. This suggestion is consistent with Schobber *et al.*, and Ellet *et al.*, in hospital and nursing home settings, respectively [478, 479]. Noar and colleagues also suggested that the use of theory to understand what works and does not work in interventions aids in refining components of interventions [480].

<b>RECOMMENDATION</b>
A future systematic review of interprofessional MMP practice, with the involvement of a pharmacist and provided to older NH residents, for example using qualitative or realist synthesis, could inform development of a theoretical framework to guide further intervention development or refinement.
More research in the RoI is needed to understand how pharmacists can optimally be involved in interprofessional MMP practice, provided to older NH residents.

### **10.1.2. Complexity of the interprofessional medicines management process practice**

The systematic review (Chapter 2, section 2.4) identified considerable variation in intervention components (*e.g.*, duration and frequency of intervention provision, classes of medicines targeted), provider characteristics, participant (*i.e.*, NH resident) characteristics, and tools applied to measure outcomes. This speaks to the complexity of interprofessional MMP which is consistent with findings from chapters 3 and 4. Although Chapter 2 did not provide evidence about which intervention component(s) were the most effective or contributed to the complexity of the MMP. The findings of Chapters 3 and 4 suggest that multiple component work systems within the MMP contribute to the complexity. These work systems encompassed multiple MMP providers caring for a single NH resident. The people in the internal NH setting work system include internal NH staff, external HCPs such as pharmacists, GPs and clinical experts, and non-HCPs such as family members. Additionally, these people (with the exception of nurses) operate within different work systems, organisations and professional regulators. For example, pharmacists also operate in the community pharmacy and/or hospital work systems and are regulated by the PSI, while GPs also operate in the GP practice work system and are contracted by the NH/ or the Health Service Executive (HSE) to deliver General Medical Services (Chapter 3, section 3.4.2).

Findings from the pooled data of three RCTs (Chapter 2) provide evidence of the impact of interprofessional MMP interventions, involving a pharmacist, in significantly improving the

appropriateness of prescribing. All three of these trials involved a medication review component and targeted the prescribing stage of the MMP, therefore providing evidence of the importance of pharmacists' medicine expertise within the prescribing stage. While the systematic review findings suggest that pharmacists can also be involved within the monitoring stage of the MMP, the SEIPS-based findings from Chapters 3 and 4 suggest that the pharmacist's role in the RoI extends even further to other stages of the MMP, including assessment (at admission to the nursing home), supplying, dispensing and return and disposal of medicines (Chapter 3, section 3.4.2; and Chapter 4, section 4.4.2).

The interprofessional provision of these stages is inconsistently identified in the RoI from multiple viewpoints. For example, while HIQA inspectors (Chapter 4) identified evidence of an interprofessional medication review, there was an absence of this evidence from participant interviews (Chapter 3). The people (*e.g.*, GP's preference to channel information intended for pharmacists through nurses), organisational conditions (*e.g.*, busy workplace) and multiple socio-organisational contexts (*e.g.*, pharmacists and GPs being located in different settings) were some of the main barriers to interprofessional communication. These findings suggest that the interprofessional "*pseudo team*" contributed to undesirable outcomes for both residents (*e.g.*, medication error) and HCPs (*e.g.*, task complexity) (Chapter 3, section 3.4.7). Similar results were reported by researchers in different healthcare setting. For instance, a cross-sectional study conducted by Faves et al., in Swiss NHs described the limited teamworking between pharmacists and other HCPs who provide care in NH residents, despite the availability of electronic transmission of medicine-related information between these HCPs in different organisations [481]; Matziou and colleagues' study in a Greek hospital setting identified a gap in interprofessional collaboration and reported it as a cause of medication errors experienced by patients [482]. Karam and colleague's qualitative synthesis of interprofessional collaboration discussed the difficulty of constructing a team due to the organisational, physical, and external environments of each HCP and suggested implementing communication strategies to overcome these barriers [483]. Another strategy was suggested by Batten and colleagues' trial which implemented an on-site pharmacist in seven Australian NHs for a duration of nine months, and have reported improved interprofessional teamworking between pharmacists, nurses and prescribers [484]. This project highlights the lack of structured interprofessional communication between the GP and the pharmacist in the NH setting. Given the evidence in the literature discussing the beneficial effects of interprofessional collaboration in improving patients' outcomes (*i.e.*, patient safety and quality of care) and healthcare professionals' outcomes (*i.e.*, job satisfaction) [485-488], addressing this gap should be the focus of future research.

RECOMMENDATION
Future research should focus on understanding the human factors and/or behaviours contributing to interprofessional collaborations.
Intervention development should focus on strategies to enhance interprofessional collaboration, with the involvement of pharmacist, aimed at improving NH residents' safety.

### 10.1.3. The involvement of informal carers in the medicines management process

Eight of the included studies in the systematic review reported the active involvement of residents and/or family members (Chapter 2, section 2.4.2). However, this review was unable to determine the benefit of that intervention component. Nonetheless, it is interesting to note that residents' and/or family members' involvement was not routine in the Irish MMP as evident from the findings reported in chapter 3 and 4. The findings of the qualitative study (Chapter 3) were that the NH resident's typical cognitive function and level of dependence on HCPs (Chapter 3 and 4) limited their involvement in their own MMP. Likewise, family members' involvement was reported as atypical in Chapter 3 (HCPs and non-HCPs) and Chapter 4 (HIQA inspection reports). While researchers argue the importance of including residents and family members [432, 489], it remains unclear from this project's findings whether and how such involvement can be facilitated and influence outcomes.

Researchers in this area have inconsistent opinions on non-HCPs involvement in the MMP. For instance, Andersson and colleagues recommended that non-HCPs' involvement in the MMP can improve patient safety [490]. Similarly, Odberg and colleagues' qualitative analysis combining observations and interviews of HCPs in NHs in Norway identified NH residents as being involved in reporting medicines-related observation to staff, and that this was a facilitator to the medicines administration process [491]. However, other literature is ambiguous about the effect of resident and family member's involvement in the MMP on outcomes. Willeboordse and colleagues' systematic review that explored the extent to which NH residents were actively involved in medication reviews, reported poor engagement with HCPs in regard to any medicines-related issue [492]. Damiaens *et al.*'s and Garcia *et al.*'s qualitative interviews with HCPs also concluded that non-HCPs involvement is limited in Belgium and American NHs, respectively [394, 493]. HIQA's suggests that a good medication review in NHs "should involve the resident, his or her representative as appropriate" [144]. Given the lack of consensus in the literature and limited evidence from the Irish NH context, findings from this project identified that residents and/or family members involvement is the assessment on admission, review and monitoring. Thus, this project suggests more research in this area to explore the extent of non-HCPs involvement in the Irish context.

<b>RECOMMENDATION</b>
Future research should explore whether and how residents and their family members can ideally contribute to the MMP and whether and how this influences outcomes.

#### **10.1.4. Professional regulators influence on the medicines management process**

The interventions reported in the systematic review (Chapter 2) varied in their frequency and duration of provision. Some trials reported one medication review per month, others reported delivery of the intervention every three, four or six months (Chapter 2, Table 2.4). The findings from Chapters 3 and 4 demonstrate the importance of professional regulation and observation of clinical guidance within the MMP journey's external environmental context. Thus, the variation in the frequency of conducting medication review is largely related to the professional regulator's and policy maker's requirements. For instance, the UK's NICE guidance recommends that duration between medication review for a single resident should not exceed one year [494]; the American Omnibus budget Reconciliation Acts recommends that medication reviews should be conducted every month [495]; and The Pharmaceutical Society in Australia recommends a quarterly medication review [496]. Also in the RoI, HIQA require medications to be reviewed for NH residents as needed and at a minimum every three months [144].

HIQA also set guidance for other stages of MMP practice in the NH setting, such as assessing, prescribing, administration, ordering, supply and dispensing, and monitoring [144]. Having said that, it is important to note that HIQA do not directly regulate pharmacists or GPs. In other words, if an incident or issue is observed during a HIQA inspection where a medicine-related practice is not adherent to regulations (*e.g.*, incomplete prescription or no expiry date on a medicine dispensed), HIQA can only assess non-compliance to regulations by the NH and not by the pharmacist or GP. Findings from the Interviews with pharmacists suggest that pharmacists do indeed deliver quarterly medication reviews, adherent to the regulatory requirements from both the HIQA and the PSI [314, 402]. On the other hand, interviews with GPs identified some challenges to their quarterly provision of medication reviews: (i) absence of the three monthly medication review regulations by the medical regulator and funding from the contractors; (ii) the reporting of quarterly medication review as a time-consuming task in the context of the GP's lack of time; (iii) peer-pressure from nurses on GPs to perform the reviews so that the nurses can adhere to their HIQA requirements, which was consistent with findings from the qualitative analysis in Chapter 4 where HIQA inspectors reported evidence of 'individual' and 'interprofessional' medication reviews conducted by GPs and others as required by

regulations. The in-depth exploration of the GP practice work system was beyond the scope of this PhD but could provide better insights regarding the benefits and facilitators to quarterly interprofessional medication review. Thus, future research should apply a systems-based exploration of the GP practice work system components and interactions. Findings of this future exploration can then be combined with our in-depth analysis of the internal NH work system findings (Chapters 3 and 4) to gain a more comprehensive understanding of (i) barriers and facilitators to positive outcomes; and (ii) the interlink between professional regulators in medicine-related concerns.

The HIQA inspection reports (Chapter 4) provide evidence of unsafe MMP practices by HCPs, for example, incomplete prescriptions (*e.g.*, no duration of treatment); variations between prescription and transcribed Kardex; medicines administered as crushed without a prescription; unlabelled medications, *etc.* (Chapter 4, section 4.4.3.2). This was consistent with findings from Chapter 3, where the SEIPS analysis identified components of the work system that contributed to increasing the risk of medication error (*i.e.*, tasks and organisational condition). This provides evidence that patient safety incidents involving medications occur in the Irish NH context. Despite this, the data from either the NH inspection reports (Chapter 3) or the participant interviews (Chapter 4) provided no information about the reporting of such patient safety incidents within an organisation context or to any relevant authority. The safety incident reporting regulation (Regulation 31: Notification) from HIQA (under the Health Act 2007) requires NHs to report safety incidents to the Chief inspector in HIQA [312, 497]. However, the nature of these safety incidents, as described in Box 5.1, are not medication focused [497]. It is also not clear whether 2-(d) 'adverse incidents the Chief inspector may require' (Box 5.1) involve any sort of medication error reporting or near miss reporting or others not relevant to the MMP. This highlights the need for clarity in terms of medication safety incident reporting from the statutory regulators. Correspondingly, this PhD project recommends the need for integrating a medication incident reporting system both internally (within the NH facility) and externally (to the relevant regulator or authority).

**Box 5.1: Safety incidents reporting to the Chief inspectors, under Regulation 31: Notifications**

1- Safety incidents reporting within three days:

- (a) Unexpected death;
- (b) Fire;
- (c) Loss of power, heating or water;
- (d) Unplanned evacuation of the NH;
- (e) Disease outbreak;
- (f) Serious injury;

- (g) Unexplained absence of a resident;
  - (h) Allegation of misconduct by NH provider or staff.
- 2- Safety incidents reporting at quarterly interval:
- (a) Use of restraint;
  - (b) Fire alarm operating for purpose other than fire practice, drill or testing;
  - (c) Recurring pattern of theft or burglary;
  - (d) Adverse incidents the Chief inspector may require.

Evidence over the last two decades that improving patient safety can be achieved through improving healthcare reporting systems. Donaldson *et al.*, from the Institute of Medicine and Marcae *et al.*, suggested that reporting safety incidents and active learning from these incidents forms the foundation to improving health systems (from an external and organisational environment)[498, 499]. Leistikow *et al.*, reported on the positive impact of this foundation on quality improvement of hospital healthcare systems in Netherlands [500]. Jayaram and colleagues' study in the psychiatry clinics resulted in reductions in ME occurring at various stages of the MMP by adapting a medication incident reporting environment [501]. According to the Health Quality Ontario, the first step towards successful implementation is the knowledge of barriers and facilitators to the reporting system [502]. Some researchers have studied these barriers, for example, Farley and colleagues' study in the Dutch hospital setting identified that professional embarrassment limits prescribers' reporting of adverse events [503]. McGrane *et al.*'s, secondary analysis of safety incident reporting identified barriers such as a deficit in the NH management system and the high burden of regulations placed on those providing care for older adults in NHs and disability centres in the RoI [504]. McGrane *et al.*, also identified an absence of learning from these reports [504].

<b>RECOMMENDATION</b>
An in-depth systems-based exploration of the GP practice work system to gain a better understanding of elements, interactions, and their influence on patient safety outcomes.
Further research is needed to explore the extent of medication safety incident reporting in the Irish NH context.
Integration of "medication safety incident" as a component of the safety incidents currently reported to the regulator.
NH organisations and statutory regulators to support the constructive use of medication safety incident data management ( <i>e.g.</i> , active learning environment and maintenance of error logs)

### 10.1.5. Tools and technologies: facilitators of the medicines management process

The systematic review (Chapter 2) identified that all included interventions have used tools and technologies (*i.e.*, explicit tools and criteria, national guidance, electronic health systems) to facilitate the targeted stage of the MMP. Consistent with findings from Chapters 3 and 4, tools and technologies were also identified as facilitators to the NH resident’s MMP journey in the RoI. The findings suggested benefits from the Healthmail to generate electronic prescriptions and transfer them electronically between multiple organisations and HCPs. The use of electronic prescribing and transfer of prescriptions is an advantage of the COVID-19 pandemic that triggered a change in legislation in the RoI to accommodate and legalise the transmission of prescriptions by this method. This is an important interaction between the tools (Healthmail, prescriptions) the external environments (legislation and COVID-19 pandemic) that resulted in simplifying tasks for HCPs within the prescribing stage and overcoming physical environment barriers, such as challenges for the GP to physically attend the NH to prescribe and the time taken for the prescription to reach the pharmacist for dispensing. Roumeliotis and colleagues’ systematic review of interventional studies conducted in the hospital setting reported that electronic prescribing can better improve patient safety when compared to non-electronic prescribing [505]. Grag and colleagues’ systematic review identified that electronic clinical decision support systems are also beneficial in improving GPs’ quality of work in 60% of included study, where approximately 30% of which involved electronic prescribing [506]. Mebrahtu and colleague’s recent systematic review including studies conducted in all clinical settings also reported that electronic systems facilitated medication administration, monitoring and record keeping tasks conducted by nurses [453]. The same author highlighted that the existing trials in the literature on nurses’ use of electronic systems lack a theoretical basis [453]. The literature has inconsistent reporting about the benefit of these systems on patient safety outcomes such as MRPs and adverse events [507] [453, 508, 509]. In contrast, findings from this PhD project (Chapters 3 and 4) which adapted the system-based approach (SEIPS 3.0) provides evidence of improved outcomes experiences by all stakeholders in the NH settings.

<b>RECOMMENDATION</b>
Future research should explore how tools and technologies can best support achieving positive NH resident’s safety outcome
Future research can also explore the impact of mutual tools and technologies on these MRPs and adverse drug events ( <i>e.g.</i> , mortality, hospitalisation and falls)



## 10.2. IMPLICATION ON RESEARCH, PRACTICE AND POLICY

The exploration of interprofessional MMP components using a theoretical systems-based approach (SEIPS 3.0), as recommended by the MRC framework for developing complex interventions, supported the rigour identification of work systems and their components, contributing to the interactions (barriers and facilitators) that produce outcomes experienced by NH residents and HCPs. The findings of the project can be utilised by researchers to develop complex interprofessional MMP interventions that are targeted at improving NH residents' safety. Policymakers and regulators can also value the evidence-based findings in refining requirements. The potential improvements in MMP practices in this setting can therefore have positive impact on practice providers in this area.

The evidence finding from this PhD thesis on the existence of medication error and unsafe MMP practice (from multiple perspectives) has not been reported previously in the Irish NH context. Thus, this project suggest more research and attention to this area to improve healthcare systems provided to older NH residents in the RoI. There is an inconsistency of findings regarding the interprofessional MMP collaboration and teamworking in the Irish NH context in this thesis which highlights the need for researchers to consider conceptualising interprofessional MMP interventions that target stages of the MMP. Additionally, the little evidence reported from HCPs, non-HCPs and statutory regulators on residents and/or family members involvement suggest that more research is needed to explore how residents and family members can ideally contribute to the interprofessional MMP and whether and how this influences outcomes.

The identification of multiple work systems in the NH resident MMP journey is a key finding that explained the complexity of the MMP system. An in-depth SEIPS-based analysis of two of the total nine work systems (Chapters 3 and 4) provided a prodigious identification and understanding of the dynamics of the work systems components. Additionally, the identification of the other work systems components to support understanding of interactions between studied work systems and others (*i.e.*, GP practice and hospital setting work systems) supports the recommendation for future complementary work of in-depth systems-based exploration, using SEIPS, of all other work systems to gain a better understanding of elements, interactions, and their influence on patient safety outcomes. This thesis findings also support prioritising the exploration of the GP practice and hospital setting work systems and build on the established MMP journey map through mapping their workflow and interactions. Furthermore, more research is needed to understand the use of tools and technologies as facilitators to the MMP and improving outcomes for NH residents and caregivers to answer three questions: (1) which of the tools and technologies are most supportive of the interprofessional MMP practice and NH residents' safety; (2) how their broader application can be optimised?; and (3) what

are the benefits of integrating a mutual electronic system between HCPs for use in multiple stages of the MMP?

The findings of this thesis support the future exploration of the interactions and feedback between the various statutory regulators identified in the macro work system analysis. This exploration could elaborate the barriers and facilitators to their collaboration, using a systems-based perspective. More research is also needed to explore medication safety incident reporting area, to better understand who and how this is regulated and to optimise the learning cultures in the Irish NH context.

To our knowledge, no previous research conducted in the RoI has explored the interprofessional MMP practice, with the involvement of a pharmacist in the NH settings, nor established a NH resident journey map (Section 3.4.8), which consists of a summary of work systems identified, workflow of tasks, barrier, and facilitators. Thus, the findings of this PhD project, which have a strong theoretical basis, can support (i) researchers in designing an interprofessional MMP intervention provided to older NH residents; and (ii) regulators in refining their regulatory functions and requirements. For instance, the MMP related regulation by HIQA (Regulation 29: Medicines and Pharmaceutical Services) focuses on nurse-related stages and ensuring pharmacists meeting their obligations to the PSI (Chapter 4). While the MMP provided in this setting is interprofessional by its nature and each profession have their own regulator, this project highlights that there is an ambiguity in the interlink between multiple professional regulators in medicines-related aspects in NHs. Thus, this PhD thesis recommends policymakers in the RoI to integrate strategies for improving the inter-regulatory requirements for safer MMP practice provision.

All these contribute to improving the practice and outcomes experienced by MMP services providers and users in the RoI and internationally.

### **10.3. IMPACT OF COVID-19 ON THE PHD PROJECT**

Due to the COVID-19 pandemic and its influence on increasing pressure on the health systems and social distancing measures globally, many health research projects proposed prior to COVID-19 were interrupted and a change to original protocol had to be made [510-512]. Similarly in the RoI and this PhD project, the COVID-19 imposed high pressure on healthcare systems, NHs, staffing and HCPs caring for patients in various settings including the NH setting. Additionally, the study proposed at the beginning of the doctoral studies, which involved face-to-face and observational methods, was not ultimately feasible as physical access to NH sites was not possible. Thus, the choice of study designs and methods was influenced by the COVID-19 pandemic to reduce risk of transmission and to adapt to 'working from home' circumstances. The PhD student and the supervisory team discussed these options and

amended the original thesis plan to more feasible study design and methods during the pandemic. It is important to note that due to the COVID-19, the timeline of the PhD project was altered, which contributed to some limitations (described in section 5.4.1).

On the other hand, the COVID-19 pandemic influence to change face-to-face interviews to virtual interviews on Microsoft teams® platform positively impacted the commencement of the PhD project and allowed conducting interviews with participants from various geographic locations across the RoI, allowing better representation of the Irish NH context. Researchers have reported on the benefits of video-conferences in overcoming geographical challenges with interview participation [513, 514]. Sah and colleagues also add that using Microsoft teams® has expanded data collection during the COVID-19 pandemic and reporting on the likelihood of researchers to accommodate the use of virtual interviews due to its benefits [515].

Furthermore, the choice of secondary analysis of HIQA inspection reports instead of an observational study did not alter the scope of the PhD project and served as a complementary study to explore the landscape of the MMP from an alternative, and important, perspective. This was evident from the findings of the triangulation of findings from the component studies.

#### **10.4. STRENGTH AND LIMITATIONS OF THIS THESIS**

This PhD followed the developmental stage of the MRC framework for developing complex interventions [208, 209]. Craig *et al.*, recommended using a systematic review to identify existing similar interventions and methods used [208]. Thus, the systematic review and meta-analysis of RCTs which have a strong level of evidence was the first study conducted in this thesis [516]. The design of the systematic review and meta-analysis (Chapter 2) protocol followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses- Protocol (PRISMA-P) for the reporting of results and other criteria followed the PRISMA guidelines [255] and Cochrane collaboration methodology [254].

Secondly, Craig *et al.*, recommends primary data to construct a theoretical understanding of what works and does not work in an intervention [208]. Thus, a qualitative study (Chapter 3) and secondary analysis used mixed methods (qualitative and quantitative) was conducted. The qualitative study in Chapter 3 was (i) reported in accordance to Consolidated Criteria for Reporting Qualitative Research (CORE-Q) checklist; (ii) the supervisory team who are experts and have a previous experience in qualitative studies have closely monitored and engaged with consensus discussion of all study steps; (iii) the involvement of Patient and Public Involvement (PPI) in Chapter 3 of this PhD thesis has enhanced the rigour of the study and its findings. The use of PPI is recommended by the MRC and became an essential component of health research [217]. PPI in health research means engaging ‘with’

the public and patients as parts of the research rather than working 'for' them. Hardavella and colleagues also report that PPI provide an important contribution to research from an end user perspective [218]. To our knowledge, this is the first multifaceted PPI panel created for the topic of interprofessional MMP in the NH setting. PPI contributors for this study consisted of both HCPs (i.e., two pharmacists, advanced nurse practitioner, clinical nurse expert, a GP, a consultant geriatrician, previous director of nursing in a NH, director of Nursing Home Ireland) and non-HCPs (i.e., one family member of a NH resident) that were representative of the sample being interviewed. Their main tasks were in supporting the design of the study components (i.e., sampling, recruitment, topic guide refining and piloting, recruitment) and to support dissemination of findings. Feedback and suggestions from the PPI contributors have strengthened the approaches undertaken for a well-designed methodology that positively impacted clearer and unbiased findings; (iv) in line with recommendations from the MRC framework to using theory. The qualitative methodology in Chapters 3 and 4 adapted a systems-based approach with the use of Systems Engineering Initiative for Patient Safety (SEIPS) model. According to Werner and Colleagues, SEIPS model can be used to guide developing a study and/or intervention design, collecting data and analysis of data [319] Consistently, the development of topic guides in Chapter 3 and framework analysis of Chapters 3 and 4 were guided by SEIPS 3.0 which is the latest version of SEIPS family by Carayon and colleagues. It focuses on the concept of the 'patient journey' which supported establishing the first NH resident MMP journey map in the RoI. The value of SEIPS findings that are reported in the literature in various clinical settings, including the NH setting, strengthens the quality and use of findings in future implementation to research, practice and policy makers in this area [334, 335, 337-339]; (v) the use of mixed methods (qualitative and quantitative) in Chapter 4 provided a deeper understanding of HIQA inspection report data to address the rationale of the study and increase the validity of findings; (vi) Triangulation of qualitative and quantitative findings (Chapters 4) and various study designs in this thesis (Chapter 5) supported better understanding of the overall interprofessional MMP provision to older NH setting from various perspectives (i.e., HCPs, non-HCPs and statutory regulator of NHs), strengthening of evidence of what is known and future implications.

#### **10.4.1. Limitations**

Despite the number of strengths of this PhD thesis, there were two main limitations. Firstly, the time of the PhD project have limited the recruitment duration (given the challenges in recruitment during the COVID-10 pandemic) which influence data saturation in topics that may have allowed a better understand of MMP services provided to NH residents. In addition, the limited time of the PhD project and meeting submission deadlines limited interpretation of results by the PPI contributors and dissemination of results. However, arrangements were planned with the members of PPI to interpret

data findings prior to publication of the project findings in scientific journals. Secondly, the lack of funding of the PhD project contributed to recruitment challenges (Chapter 3) and retrieval of deleted HIQA's NH inspection reports in 2019. This has contributed to the third limitation which is the small sample size of NHs analysed (Chapter 4). However, this PhD project provided robust identification and highlighted key uncertainties, gaps, facilitators and suggested recommendations to research, practice, and policy makers.

## **10.5. GENERAL CONCLUSION**

The need to improve interprofessional MMP practice for older people residing in NHs is widely acknowledged due to the nature of aging, multimorbidity and the high prevalence of MRPs. The research presented in this thesis aimed to add to the research literature a theory-based understanding of the interprofessional MMP practice, with the involvement of a pharmacist from multiple perspectives. Initially, a systematic review and meta-analysis was conducted to report on the nature and impact of interprofessional MMP interventions, that involve a pharmacist and are provided to older people in the NH setting. The outcome of the systematic review identified involving a pharmacist in MMP provision to older NH residents is beneficial to improve the appropriateness of prescribing. However, there is an absence of reporting of the theoretical basis of these interventions. Exploration of the extent of MMP service provision in the RoI using SEIPS 3.0 model was feasible and provided evidence that the MMP is a complex process, with opportunities to overcome barriers to achieving desirable outcomes from the MMP. The SEIPS-based analyses facilitated identifying dimensions of the MMP that can be used by researchers in this area to develop a complex interprofessional MMP intervention, that has a theoretical basis. Deeper exploration of additional work systems and their components that contribute to the complexity of the MMP will complement the work presented in this thesis and further serve to optimise patient safety in the RoI. The gap in a consolidated approach to interprofessional MMP in the RoI could encourage national and international regulators to refine the current suggested approach to the MMP in the Irish NH setting and therefore improve outcomes experienced both by NH residents and HCPs.

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## **Appendices**

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Systematic Review | [Published: 04 October 2022](#)

# Interprofessional Interventions Involving Pharmacists and Targeting the Medicines Management Process Provided to Older People Residing in Nursing Homes: A Systematic Review and Meta-Analysis of Randomised Controlled Trials

[Asil Sadeq](#) , [Monica Strugaru](#), [Maryam Almutairi](#), [Derek Stewart](#), [Cristin Ryan](#) & [Tamasine Grimes](#)

[Drugs & Aging](#) **39**, 773–794 (2022) | [Cite this article](#)

## Appendix 2.2: Completed PRISMA checklist

Section and Topic	Item #	Checklist item	Location where item is reported
<b>TITLE</b>			
Title	1	Identify the report as a systematic review.	Page 22
<b>ABSTRACT</b>			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Page 23-27
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Page 31
<b>METHODS</b>			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Page 32
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Page 32 and 33
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Pages 33-37
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Page 37
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Page 37
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g., for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Page 32
	10b	List and define all other variables for which data were sought (e.g., participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	This PhD project was not funded. 23: participants and intervention characteristics
Study risk of bias	11	Specify the methods used to assess risk of bias in the included studies, including details of the	Page 38

Section and Topic	Item #	Checklist item	Location where item is reported
assessment		tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Pages 39-40
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g., tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Page 40
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	40
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Page 40
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Page 40
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Page 40
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Page 40
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Page 38
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Page 39
<b>RESULTS</b>			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Page 40
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Page 40
Study characteristics	17	Cite each included study and present its characteristics.	Pages 40, 42-49
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Pages 50 and 53
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Pages 55- 61
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing	Pages 40, 42-50 and 53

Section and Topic	Item #	Checklist item	Location where item is reported
		studies.	
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pages 58- 61
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Pages 58- 61
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Pages 58- 61
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Pages 50 and 53
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Pages 50 and 54
<b>DISCUSSION</b>			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pages 61-63
	23b	Discuss any limitations of the evidence included in the review.	Pages 63-64
	23c	Discuss any limitations of the review processes used.	Pages 63-64ge 16
	23d	Discuss implications of the results for practice, policy, and future research.	Pages 64-65
<b>OTHER INFORMATION</b>			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	31
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	31
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	31
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	This PhD project was not funded.

**Appendix 2.3:** Data extraction form

Introduction	
Title (as published)	
Author (surname of first author with year of publication e.g., Smith 2004)	
Region	
Other reports of this study (Yes/ NO)	
If yes above, title (as published)	
Eligibility (x)	
Type of study (RCT)	
Participants	
<ul style="list-style-type: none"> <li>Age/ mean age= 65 years or above</li> </ul>	
<ul style="list-style-type: none"> <li>Nursing home residents</li> </ul>	
Intervention	
<ul style="list-style-type: none"> <li>Interventions involving a multidisciplinary team, which must include a pharmacist</li> </ul>	
Control	
<ul style="list-style-type: none"> <li>Usual care/Non exposed to any intervention done by a multidisciplinary team involving a pharmacist</li> </ul>	
Outcomes (Specify)	
Methods	
Aim of study	
RCT or Cluster RCT	
Duration of Study (recruitment to last follow-up)	
Ethical approval obtained (Yes/No)	
Participants:	
Population description:	
<ul style="list-style-type: none"> <li>Mean Age (years) "mean and range"</li> </ul>	
<ul style="list-style-type: none"> <li>% Dementia</li> </ul>	
<ul style="list-style-type: none"> <li>% gender</li> </ul>	
<ul style="list-style-type: none"> <li># Medicines</li> </ul>	
<ul style="list-style-type: none"> <li>Other special characteristics</li> </ul>	
Mean number of medical condition (if mentioned)	
Number of NHs in Control group	
Number of NHs in intervention group	
Number of Participants in Control group	
Number of Participants in Intervention group	
Other treatment received (additional to the study intervention)	
Intervention	
Description	



Pharmacist role within intervention	
Specific medicines management aspect targeted ( <i>e.g.</i> prescribing, monitoring, review)	
Specific medicines targeted (if mentioned)	
Specific condition targeted (if mentioned)	
Duration of intervention	
Timing (Duration of each episode)	
Follow-up time	
Intervention Location ( <i>e.g.</i> NH, video, practice.)	
Intervention providers	
guidelines/tool used	
Theory used within intervention (YES/NO)	
<i>If yes</i>	
Theory name	
Theory description	
<b>Outcome</b>	
Outcome name	
Outcome definition	
Time points measure	
Method of measuring/tool + unit of measurement	
Scale description (indicate whether high or low score is good)	
Intervention group score:	
<ul style="list-style-type: none"> <li>• Pre-intervention (baseline)</li> <li>• Post-intervention (follow-up)</li> </ul>	
<u>Change</u>	
Control group score	
<ul style="list-style-type: none"> <li>• Pre-intervention (baseline)</li> <li>• Post-intervention (follow-up)</li> </ul>	
<u>Change in two groups</u>	
Imputation of missing data	
Other results reported	
Other information	
Key conclusion of study authors	
Further study information requested	

## Appendix 2.4: Outcomes data

Study author	MEAN/ median		SD , if not SE, if not CI (Confidence interval) + OR		EVENT/ how many times did it happen?		TOTAL- total # of residents assessed within this outcome	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Frankenthal <i>et al.</i>	N/A	N/A	N/A	N/A	36	79	160	146
Wouters <i>et al.</i>	N/A	N/A	N/A	N/A	57	91	193	233
Desborough <i>et al.</i>	0.69	0.85	0.93	1.26	283	330	227	275
Strauven <i>et al.</i>	2.66	N/A	N/A	N/A	N/A	N/A	847	957
Van Der Spek <i>et al.</i>	19.1	28.2	26.6 16.72	59.05 34.8	N/A	N/A	172	151
Crotty <i>et al.</i>	3.5	3.7	7.576	7.686	N/A	N/A	50	54
Patterson <i>et al.</i>	N/A	N/A	N/A	N/A	25	62	128	125
Zermansky <i>et al.</i>	0.8	1.3	1.7	3.1	84	106	277	278
Wouters <i>et al.</i>	N/A	N/A	N/A	N/A	23	16	193	159
Lapane <i>et al.</i>	N/A	N/A	N/A	N/A	797	747	2793	2371
Patterson <i>et al.</i>	N/A	N/A	N/A	N/A	277	186	1698	1626
Frankenthal <i>et al.</i>	0.8	1.3	1.3	2.4	N/A	N/A	160	146
Crotty <i>et al.</i>	N/A	N/A	N/A	N/A	97	73	381	334
Desborough <i>et al.</i>	3.35	3.00	8.30	5.49	N/A	N/A	381	445
Tadrous <i>et al.</i>	N/A	N/A	N/A	N/A	249	314	2303	3060
Lapane <i>et al.</i>	17.7	19.6	?	?	221	215	10,139	9300
Roberts <i>et al.</i>	4.86	12.4 8	265.7 0	357.49	N/A	N/A	604	1258
Zermansky <i>et al.</i>	N/A	N/A	N/A	N/A	51	48	277	278
Desborough <i>et al.</i>	N/A	N/A	N/A	N/A	125	153	381	445
Strauven <i>et al.</i>	N/A	N/A	N/A	N/A	226	207	475	510
Kua <i>et al.</i>	N/A	N/A	N/A	N/A	10	23	415	437
Lapane <i>et al.</i>	39.4	40.6	352.8 1	343.13	317	265	8184	7741
Roberts <i>et al.</i>	1.30	- 16.8 6	346.2 6	344.6	N/A	N/A	604	1604
Zermansky <i>et al.</i>	N/A	N/A	N/A	N/A	47	52	277	278
Desborough <i>et al.</i>	0.88	0.72	2.01	2.09	N/A	N/A	227	275
Strauven <i>et al.</i>	N/A	N/A	N/A	N/A	70	88	475	510
Kua <i>et al.</i>	N/A	N/A	N/A	N/A	56	97	415	437
Frankenthal <i>et al.</i>	0.5	0.5	1.0	0.9	N/A	N/A	160	146
Tadrous <i>et al.</i>	N/A	N/A	N/A	N/A	405	551	2303	3060
Crotty <i>et al.</i>	N/A	N/A	N/A	N/A	266	227	381	334
Kennedy <i>et al.</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Roberts <i>et al.</i>	N/A	N/A	N/A	N/A	268	525	478	850

Study author	MEAN/ median		SD , if not SE, if not CI (Confidence interval) + OR		EVENT/ how many times did it happen?		TOTAL- total # of residents assessed within this outcome	
	Interven tion	Con trol	Interv ention	Contr ol	Interv ention	Contr ol	Interve ntion	Contr ol
Frankenthal <i>et al.</i>	N/A	N/A	N/A	N/A	36	79	160	146
Wouters <i>et al.</i>	N/A	N/A	N/A	N/A	57	91	193	233
Schmidt <i>et al.</i>	2.08	2.20	32.47 57	33.298 4	433	983	562	1243
Smeets v	55	42	13	16	N/A	N/A	172	151
Kua <i>et al.</i>	9.48	9.68	4.78	4.48	N/A	N/A	448	437

N/A: Not applicable, SD: deviation, SE: Standard error, CI: Confidence interval, OR: Odds ratio

**Appendix 2.5:** Effect of interprofessional interventions on most commonly reported outcomes

<i>Study</i>	<i>Outcomes Measured</i>	<i>Appropriateness of prescribing</i>	<i>Frequency of prescribing</i>	<i>Falls</i>	<i>Mortality</i>	<i>Hospitalisation</i>
<i>Roberts et al.</i>	<b>Method of Measurement</b>		<i>Number of drugs prescribed</i>		<i>Mortality rate</i>	
	<b>Result</b>		<i>No significant change *</i>		<i>No significant change (% change number: 0.696)</i>	
<i>Crotty et al.</i>	<b>Method of Measurement</b>		<i>Proportion of resident prescribed any psychotropic drug</i>	<i>Proportion of residents fell 3 months prior to follow-up</i>		
	<b>Result</b>		<i>No significant change (RR &amp; 95% CI: 0.89 (0.69 – 1.15))</i>	<i>No significant change (RR &amp; 95% CI: 1.17(0.86 – 1.58))</i>		
<i>Zermansky et al.</i>	<b>Method of Measurement</b>					<i>Number of hospitalisations per resident</i>
	<b>Result</b>					<i>No significant change *</i>
<i>Patterson et al.</i>	<b>Method of Measurement</b>	<i>STOPP/START</i>		<i>Number of falls per resident</i>		
	<b>Result</b>	<i>Improved (p-value&lt;0.001)</i>		<i>No significant change *</i>		
<i>Lapane et al.</i>	<b>Method of Measurement</b>			<i>Incident rate per resident</i>		
	<b>Result</b>			<i>No significant change (HR (95% CI) = 1.03 (0.92–1.15))</i>		
<i>Frankenthal et al.</i>	<b>Method of Measurement</b>	<i>Percentage of PIP using STOPP criteria</i>				
	<b>Result</b>	<i>Improved (p value &lt; .001)</i>				

Kennedy et al.	<b>Method of Measurement</b>	Proportion of resident prescribed 1) vitamin D ( $\geq 800$ IU/day) 2) Calcium ( $\geq 500$ mg/day) 3) 'Osteoporosis medications'	
	<b>Result</b>	1) Reduced (prescribing change for IG= 22% while CG= 7.5%) 2) Reduced (prescribing change for IG= 8.8% while CG= 1.8%) 3) No significant change (prescribing change between the two groups was 3.4%)	
Wouters et al.	<b>Method of Measurement</b>	Proportion of resident successfully discontinued at least 1 inappropriate medication.	Number of falls
	<b>Result</b>	Improved (IG= 39.1% and CG= 29.5% at follow up)	No significant change (IG= 11.9% and CG= 10.1% at follow up)
Strauven et al.	<b>Method of measurement</b>	Number of PIM and PPO	Percentage number of residents hospitalised.
	<b>Result</b>	Improved (p-value $<0.001$ )	No significant difference *
Kua et al.	<b>Method of measurement</b>		Number of residents hospitalised
	<b>Result</b>		Reduced (p-value $<0.001$ )

<i>Tadrous et al.</i>	<b>Method of measurement</b>		<i>Fall rate at 12 months follow-up.</i>		<i>Percentage number of residents hospitalised at 12 months follow-up</i>
	<b>Results</b>		<i>No significant change *</i>		<i>No significant change *</i>
<i>Cateau et al.</i>	<b>Method of measurement</b>	<i>Number of potentially inappropriate defined daily dose per resident</i>	<i>Number of falls</i>	<i>Mortality rate</i>	<i>Number of days in hospital</i>
	<b>Results</b>	<i>No significant change *</i>	<i>No significant change *</i>	<i>Reduced (p-value=0.005)</i>	<i>No significant change *</i>
<i>Sluggett et al.</i>	<b>Method of measurement</b>		<i>Number of events</i>	<i>Mortality rate</i>	<i>Number of events</i>
	<b>Result</b>		<i>Reduced (p-value=0.002)</i>	<i>No significant change *</i>	<i>No significant change *</i>

RR= Risk Ratio; CI= Confidence Interval; HR; Hazard Ratio; IG= Intervention Group; CG= Control Group; STOPP; Screening Tool of Older Persons Potentially Inappropriate Prescriptions; START= Screening Tool to Alert doctors to Right Treatment; STRIP: Systematic Tool to Reduce Inappropriate Prescribing; PIP= Potentially Inappropriate Prescription; PIM= Potentially Inappropriate Medications; PPO= Potentially Prescribing Omissions.

\*P > 0.05

**Appendix 3.1:** COREQ checklist

No. Item	Guide questions/description	Reported on Page #
<b>Domain 1: Research team and reflexivity</b>		
<i><b>Personal Characteristics</b></i>		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 87
2. Credentials	What were the researcher's credentials? E.g., PhD, MD	Page 82
3. Occupation	What was their occupation at the time of the study?	Page 82
4. Gender	Was the researcher male or female?	NR
5. Experience and training	What experience or training did the researcher have?	Page 79
<i><b>Relationship with participants</b></i>		
6. Relationship established	Was a relationship established prior to study commencement?	N/A
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g., personal goals, reasons for doing the research	Pages 242-256 and 274-300 Participants were briefed on the purpose of the study and understood it. Ethical had granted, participants reviewed the participant information documentation prior to giving their written informed consent to be involved.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g., Bias, assumptions, reasons and interests in the research topic	NR
<b>Domain 2: Study design</b>		
<i><b>Theoretical</b></i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? E.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Page 76
<i><b>Participant selection</b></i>		
10. Sampling	How were participants selected? E.g., purposive, convenience, consecutive, snowball	Pages 82-86
11. Method of approach	How were participants approached? e.g., face-to-face, telephone, mail, email	Pages 82-86
12. Sample size	How many participants were in the study?	Page 95
13. Non-participation	How many people refused to participate or dropped out? Reasons?	N/A
<i><b>Setting</b></i>		
14. Setting of data collection	Where was the data collected? e.g., home, clinic, workplace	Page 90

15. Presence of non-participants	Was anyone else present besides the participants and researchers?	Page 90
16. Description of sample	What are the important characteristics of the sample? <i>e.g., demographic data, date</i>	Pages 89 and 90
<b>Data collection</b>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Pages 86 and 87
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	N/A
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 87
20. Field notes	Were field notes made during and/or after the interview or focus group?	N/A
21. Duration	Were field notes made during and/or after the interview or focus group?	N/A
22. Data saturation	Was data saturation discussed?	Page 85
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	N/A
<b>Domain 3: analysis and findings</b>		
<b>Data analysis</b>		
24. Number of data coders	How many data coders coded the data?	Pages 93-95
25. Description of the coding tree	Did authors provide a description of the coding tree?	
26. Did authors provide a description of the coding tree?	Were themes identified in advance or derived from the data?	Pages 93-95
27. Software	What software, if applicable, was used to manage the data?	Page 88 and 92
28. Participant checking	Did participants provide feedback on the findings?	N/A
<b>Reporting</b>		
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? <i>e.g., participant number</i>	Page 103
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Page 96-97
31. Clarity of major themes	Was there consistency between the data presented and the findings?	Page 96-97
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Page 96-97



**Appendix 3.2:** TCD IT Department guidance on undertaking qualitative research during COVID-19

# Using Microsoft Teams for recording and transcribing qualitative research interviews

Guidance Notes, Version 1.1

[Click here](#) to access the guidance document

### Appendix 3.3: Participant information leaflet



**Name of Study: Work system analysis to explore the medicines management process in the nursing home setting in Ireland: A qualitative study using the Systems Engineering Initiative for Patient Safety model.**

*You are being invited to take part in a research study that is being done virtually using a video-call*

Site	Trinity College Dublin
Principal Investigator(s) and Co-Investigator(s)	<b>1. Asil Sadeq, PhD student in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin. Email: <a href="mailto:sadeqa@tcd.ie">sadeqa@tcd.ie</a></b> <b>2. Prof. Cristín Ryan, MPharm, PhD, PGCHET, FHEA, Trinity College Dublin. Email: <a href="mailto:cristin.ryan@tcd.ie">cristin.ryan@tcd.ie</a></b> <b>3. Associate Professor, Tamasine Grimes, MSc, PhD, Trinity College Dublin. Email: <a href="mailto:tagrimes@tcd.ie">tagrimes@tcd.ie</a></b>
Study Organiser/ Sponsor	<b>Trinity College Dublin</b>
Data Controllers	<b>Trinity College Dublin (for research data)</b>
Data Protection Officer	<b>Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2</b>

*using Microsoft Teams platform, by a PhD student- Asil Sadeq, at the time your convenience.*

*Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask Asil Sadeq any questions on the email provided. Don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.*

**This leaflet has five main parts:**

**Part 1 – The Study**

**Part 2 – Data Protection**

**Part 3 – Costs, Funding and Approval**

**Part 4 – Future Research**

**Part 5 – Further Information**

## Part 1 – The Study

### Why is this study being done?

*This study will help to explore the medicines management process (MMP) work system in the Irish nursing homes (NHs) and opportunities to improve it. The study will also help describe different stakeholder involvement in MMP and their perceived barriers and facilitators to safe and effective MMP in NHs in Ireland.*

### Why have I been invited to take part?

*As a key stakeholder involved in the MMP in Ireland, you have been invited to take part because we would like to learn from your experience on the MMP work system in NHs in Ireland.*

*The following checklist is a self-assessment for your participation in this study. If you answer with YES to ALL points below, you are eligible to participate in this study.*

Eligibility Criteria	Yes	No	N/A
<i>Am I currently involved in the medicines management process in the Republic of Ireland?</i>			
<i>Am I not currently involved in another medicines management/ similar study?</i>			
<i>I have more than 1-year experience in the MMP in the Irish NH setting from the study start date?</i>			
<i>For healthcare professionals: Am I currently registered with the regulator. (If you are not a healthcare professional and your answer is "N/A", you are still eligible for participation in this study)</i>			
<i>Do I have access to the Microsoft teams Platform?</i>			

### Do I have to take part? Can I withdraw?

- *You don't have to take part in this study; it is entirely voluntary.*
- *You can change your mind and opt out at any time up to the beginning of the data processing stage, where data anonymisation occurs.*
- *If you decide to opt out, it won't affect your current or future research participation or practice.*
- *You don't have to give a reason for not taking part or for opting out. If you wish to opt out, don't hesitate to get in touch with Asil Sadeq [email: Sadeqa@tcd.ie], who will be able to organise this for you.*
- *Additionally, all your data records will be destroyed when deciding on withdrawal from the study (prior to data processing and anonymisation).*

### What happens if I change my mind?

- *You can change your mind at any time by contacting Asil Sadeq at [email: sadeqa@tcd.ie].*
- *If you choose not to continue to take part, this will not affect your practice or participation in any other health research in any way.*
- *If you choose not to participate anymore, you will be asked to complete a withdrawal form (Appendix D).*
- *If you wish, you can ask that your data stored that haven't been anonymised be destroyed.*
- *If you request this, we will destroy all data still in our possession that hasn't been anonymised.*
- *We will no longer use or share your data for research from this point onwards. However, it will not be possible to destroy data already used in conferences, published in an academic journal, or used in other research studies prior to this time.*

### How will the study be carried out?

*The study involves one-to-one virtual interviews with stakeholder in the MMP. One interview will be carried on virtually via Microsoft teams platform. The virtual interview will be audio-recorded. The interview will take place at the time of your convenience and will last around 60 minutes.*

### What will happen to me if I decide to take part?

- *If you decide to participate in this study, you will be asked to electronically sign a consent form attached at the end of this information leaflet and send it back to us in the email.*
- *After we receive the consent, we will contact you to arrange an interview time that is totally at the time of your convenience.*
- *We will interview you about the MMP in Ireland.*
- *At the interview, the interviewer will let you know when the recorder is turned on.*
- *To CEOs/managers: You will be asked questions to describe the resident journey in your nursing home through the MMP. Medicines management is a process that encompasses the entire way that medicines are selected, procured, prescribed, reviewed, delivered, administered, stored, and monitored, to optimise the contribution that medicines make to producing informed and desired outcomes of patient care.'*
- *To stakeholders: You will be asked questions on the MMP work system, your perceived barriers and facilitators to providing effective and safe MMP to nursing home older people In Ireland and finally identify opportunities to improve MMP in the nursing home setting. Medicines management is a process that encompasses the entire way that medicines are selected, procured, prescribed, reviewed, delivered, administered, stored, and monitored, to optimise the contribution that medicines make to producing informed and desired outcomes of patient care'.*

## What will happen to my Data?

Data storage and backup will comply with the data protection rules in health research, as follows:

- We will collect data about the MMP work system in the Irish NHs.
- Any personal data collected will be for identification purposes to apply matching codes across the data set.
- All personal identifiers and identifiers will be removed and decoupled at the transcription stage of the interview and another unidentifiable codes will be applied- participants' names will be permanently deleted from the file and the study number will remain; there will be no way from this point forward to connect an interview to a named participant.
- All quotes used during the write-up and dissemination of results will be anonymised and not traceable to any individual person or organization.
- Due to COVID, the data will be electronically stored and backed up.
  - All electronic computerised data throughout the study will be stored in a limited access one drive folder through Trinity College Dublin staff facility and encrypted password-protected laptop/computer.
  - All electronic computerised data will be electronically backed up onto a Trinity College Dublin encrypted server.
- All data will be stored until the end of the study. Then it will be kept in an encrypted Trinity College Dublin server for and retained then permanently deleted after the following durations:

Type of data	Retention time
Contact details(.xlsx)	7 years beyond study completion.
Consent form(.pdf)	7 years beyond study completion.
Audio recording (.vtt)	28 days from the interview date.
Transcribed interview (.docx, .xlsx)	7 years beyond study completion.
Code keys (.xlsx)	Identifiable Code keys will be deleted at the point of interview transcription validation.

- Access to the data will be limited to the research team: PhD student (Asil Sadeq), gatekeeper (Ms Connie Brennan), academic supervisors (Prof. Cristin Ryan and Assoc. Prof. Tamasine Grimes)
- The PhD candidate Asil Sadeq, will be responsible for ensuring data security under the supervision of Prof. Cristin Ryan and Assoc. Prof. Tamasine Grimes.
- You can request to register for receiving the results of the study if you wish.

**Are there any benefits to taking part in this research?**

*Taking part in this study will not directly benefit you. However, your participation in this study will help contribute to improving the MMP in NHs in the Republic of Ireland.*

**Are there any risks to me or others if I take part?**

- *Health Information (Data): There is a risk that a connection to your identity could be made. However, to reduce this risk, participants' identifiers will not be used and will be removed during the transcription process, and a unique identifier will be given. All quotes used during the writing of findings will be anonymised. The original recording will be saved on Microsoft teams stream for 28 days and then permanently deleted; interview transcript data and your consent form will be saved on an encrypted limited access one drive folder through Trinity College Dublin staff facility and a password encrypted laptop/computer. The data will be backed up onto a Trinity College Dublin encrypted server.*
- *You might feel inconvenient or uncomfortable in providing your opinion on service provision. However, we will be asking questions to evaluate the process NOT your personal behaviour. Remember, you have the right not to answer any question asked by the interviewer during the interview. You also have the right to withdraw from the study at any stage before data processing where interview data anonymisation take place.*
- *You might disclose poor practice during the interview, and we expect that this will be rare. If a poor practice is identified, the case will be discussed with the supervisors Prof. Cristin Ryan and Assoc. Prof. Tamasine Grimes (Trinity College Dublin) who will review it, and if necessary, refer it to the health professionals concerned and if appropriate, to the appropriate professional regulatory authority such as Health Information and Quality Authority (HIQA).*

**What happens if something goes wrong when I'm taking part in the study?**

*There is a minimal risk of anything going wrong as the study involves participation in a single interview. However, if something did go wrong, the PhD student will inform her supervisors at the School of Pharmacy and Pharmaceutical Sciences in Trinity College Dublin. They will take the required steps and procedures to resolve the issue.*

**Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?**

*The study results will be reported in medical/scientific journals and disclosed at medical/scientific conferences and in the thesis dissertation.*

## Part 2 – Data Protection

### What information about me (personal data) will be used as part of this study?

*Before the interview:*

- *Your name, gender and profession will be used for identification to apply matching codes across data sets.*
- *Contact details will be used as identification if we need to re-contact you or you want to withdraw and destroy your record and data collected from you.*

*Data collected during the interview:*

- *The sector of employment (i.e., community pharmacy/ hospital /nursing home) will be used as identification to apply matching codes across data sets and for data analysis.*
- *Years of providing services to nursing home older people will be used as identification to apply matching codes across data sets and for data analysis.*
- *Location by city/county will be used as identification to apply matching codes across data sets and for data analysis.*

### What will happen to my personal data?

- Your personal data will be electronically stored and saved in a limited access one drive folder through Trinity College Dublin staff facility and encrypted password-protected TCD computer at Panoz institute in TCD for the study period.
- Your personal data will also be backed up onto Trinity College Dublin encrypted server.
- Upon completion of the study, your personal data will be securely stored in Trinity College Dublin encrypted server, then will be destroyed and permanently deleted. The retention period is in line with the GDPR. Please see the table below.
- We will record the interview using Microsoft team platform recording option. The original audio record will be saved on Microsoft team Stream (under the control of Trinity College Dublin) for 28 days and will be automatically and permanently deleted after.
- Microsoft teams will redact the original audio redact option where any and all identifiers will be removed. A research team member will also listen to ensure the removal of any personal data/identifier not redacted by Microsoft teams redact option.
- In addition, you will be assigned a unique identifier. Access to the code between you and your study identifier will be restricted to the PhD student (Asil Sadeq) and the supervisors (Cristin Ryan and Tamasine Grimes). The identifier, not your personal details, will be used to label and name your interview file.

- Only anonymised data will be used for academic publication, conference presentation and thesis dissemination.

Personal data type and media format	Format	Retention time, when it will be destroyed
Personal data: <i>Contact details; name, address of nursing home/practice/hospital/pharmacy; work phone number; work email address.</i> (electronic)	Original (.xlsx).	7 years beyond study completion.
Consent (electronic)	Original (.pdf).	7 years beyond study completion.
Audio recordings (electronic)	Original (.vtt).	28 days on Microsoft Teams platform from the interview date.
Code keys (electronic)	Pseudonymised (.xlsx)	Identifiable code keys will be deleted at the point of transcription validation.

**Who will access and use my personal data as part of this study?**

- The following individuals will have access to the participant's personal data as part of this study:

Name	Contact details
<i>Ms. Asil Sadeq (PhD student)</i>	Email: <a href="mailto:sadeqa@tcd.ie">sadeqa@tcd.ie</a>
<i>Ms. Connie Brennan (Research nurse/gatekeeper)</i>	Email: <a href="mailto:brennc41@tcd.ie">brennc41@tcd.ie</a>
<i>Prof. Cristin Ryan (Supervisor)</i>	Email: <a href="mailto:cristin.ryan@tcd.ie">cristin.ryan@tcd.ie</a>
<i>Assoc. Prof. Tamasine Grimes (Supervisor)</i>	Email: <a href="mailto:tagrimes@tcd.ie">tagrimes@tcd.ie</a>

**Will my personal data be kept confidential? How will my data be kept safe?**



- Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe:

<b>Personal data type</b>	<b>Media format</b>	<b>Storage details</b>
<i>Personal data: Contact details; name, address of nursing home/practice/hospital/pharmacy; work phone number; work email address.</i>	<i>Electronic document (.xlsx)</i>	<i>The electronic excel sheet will be stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD. Any participants' identifiable information will be removed after validation of interview transcription.</i>
<i>Personal data: Consent.</i>	<i>Electronic document (.pdf)</i>	<i>The electronic consent document will be stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD.</i>
<i>Research data: Audio record and transcription</i>	<i>-Interview audio: MS teams audio recording (.vtt)</i>  <i>-Transcription (.docx) or (.xlsx), which will then be imported into NVivo file</i>	<i>- The original audio record will be saved on TCD Microsoft Steams platform for up to 28 days via TCD server and will be irreversibly deleted after interview data transcription validation.</i>  <i>- The anonymised electronic document will be stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD.</i>
<i>Code keys.</i>	<i>Electronic document (.xlsx)</i>	<i>The electronic excel sheet will be stored and saved in a limited-access one drive folder</i>

		<p>through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD. Identifiable code keys will be removed and decoupled after validation of interview transcription.</p>
<p>Research data: Demographic data collected- Sector of employment (i.e., pharmacy/hospital/nursing home), years of providing services to nursing home residents and Location by city.</p>	<p>Electronic document (.xlsx)</p>	<p>The electronic excel sheet will be stored and saved in a limited-access one drive folder through TCD staff facility one drive and in a C: drive TCD encrypted pass-word protected TCD computer, Panoz institute, TCD. Any participants' identifiable information will be removed after validation of interview transcription.</p>

- A data protection risk assessment was applied to this study identified that this study is low risk in personal data processing.
- All personal data and collected data will be saved in a limited-access one drive Trinity College Dublin staff facility folder and a Trinity College Dublin encrypted password Trinity College Dublin computer, Panoz institute, Trinity College Dublin.
  - Access to the data/information will be limited to the research team: PhD student (Asil Sadeq), research nurse/gatekeeper (Ms. Connie Brennan) and academic supervisors (Prof. Cristin Ryan and Assoc. Prof. Tamasine Grimes)
- The research team members have completed the required training on data protection law.
- The PhD student Asil Sadeq will be responsible for ensuring data security under the supervision of Prof. Cristin Ryan and Assoc. Prof. Tamasine Grimes.
- All collected data will be anonymised. The results of the study will be reported in medical/scientific journals and disclosed at medical/scientific conferences and thesis dissertations. No information which reveals your identity will be disclosed.
- However, suppose something did go wrong or a data protection breach was suspected. In that case, a report will be submitted to the Data Protection Officer in Trinity College Dublin and comply with legislation regarding a suspected Data Protection breach.

### What is the lawful basis to use my personal data?

*The lawful basis for the use of your personal information is scientific research<sup>1</sup> (in the public interest<sup>2</sup>). We will also ask for your explicit consent to use your data as the Irish Health Research Regulations requirement.*

### What are my rights?

*You have the right to:*

- *Access your data and receive a copy of it.*
- *Restrict or object to the processing of your data.*
- *Object to any further processing of the information we hold about you (except where it is de-identified).*
- *Have inaccurate information about you corrected or deleted.*
- *Receive your data in a portable format within 30 days of interview time and to have it transferred to another data controller.*
- *Request the deletion of your data.*

*By law, you can exercise the above rights in relation to your personal data unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting the PhD student Asil Sadeq on email: [Sadeqa@tcd.ie](mailto:Sadeqa@tcd.ie) , or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: [dataprotection@tcd.ie](mailto:dataprotection@tcd.ie). Website: [www.tcd.ie/privacy](http://www.tcd.ie/privacy).*

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<sup>1</sup> Article 9(2) (j))

<sup>2</sup> (Article 6(1)(e)

## Part 3 – Costs, Funding and Approval

**Has this study been approved by a research ethics committee?**

*Yes, this study has been approved by the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee in Trinity College Dublin (pharmacy.ethics@tcd.ie).*

*[Approval date: INSERT DATE AND REFERENCE NUMBER].*

**Who is organising and funding this study? Will the results be used for commercial purposes?**

*The PhD student- Asil Sadeq, is conducting this research to obtain an academic qualification. This research is not being funded by any organization. The researcher is not being paid for recruiting participants for this study. The results will not be used for commercial purposes.*

**Is there any payment for taking part? Will it cost me anything if I agree to take part?**

*There is no payment for undertaking a part in the study. However, if you wish, you will be given a letter of participation in health research from TCD.*

## **Part 4 – Future Research**

### **Will my personal data be used in future studies?**

- The anonymised data may be used in future studies, but only if approved by the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.
- Your participation is voluntary and you can withdraw your consent to future research at any time, only prior to the data processing and anonymisation stage.

## Part 5 – Further Information

### Who should I contact for information or complaints?

*If you have any concerns or questions, you can contact:*

- *Researcher:*  
*Name: Asil Sadeq*  
*Email: [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)*  
*Phone: 01 896 2943*
- *Researcher 2:*  
  
*Name: Connie Brennan*  
*Email: [BRENNC41@tcd.ie](mailto:BRENNC41@tcd.ie)*
- *Principal investigator 1:*  
*Name: Cristin Ryan*  
*Email: [cristin.ryan@tcd.ie](mailto:cristin.ryan@tcd.ie)*
- *Principal investigator 2:*  
*Name: Tamasine Grimes*  
*Email: [tagrimes@tcd.ie](mailto:tagrimes@tcd.ie)*
- *Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: [dataprotection@tcd.ie](mailto:dataprotection@tcd.ie). Website: [www.tcd.ie/privacy](http://www.tcd.ie/privacy).*

*Under GDPR, if you are not satisfied with how your data is being processed, you have the right to complain with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: [www.dataprotection.ie](http://www.dataprotection.ie).*

### Will I be contacted again?

*If you would like to participate in this study, you will be asked to electronically the **consent form**. We will then contact you to arrange an interview time that is at the time of your convenience.*

### **Appendix 3.4:** Person in charge invitation email



#### **Work system analysis to explore the medicines management process in the nursing home setting in Ireland: a qualitative study using the Systems Engineering Initiative for Patient Safety model.**

Dear participant,

My name is Asil Sadeq, a PhD student in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin. The research team members and I (Prof. Cristin Ryan, Assoc. Prof. Tamasine Grime) are interested in healthcare and medicines management for older people residing in nursing homes (NHs) in Ireland.

We are contacting you to invite you to take part in the above research study.

This study aims to explore the medicines management process (MMP) in the Irish NH by understanding the work systems involved and exploring key stakeholders' views of how these work systems ensure safe and effective medicines management. We also aim to explore the impact that COVID-19 has had on the MMP and identify opportunities to improve the MMP in Irish NHs.

You are a key member involved in the MMP in the Irish NH setting, and we would like to learn from your experiences. If you decide to take part, you will be invited to one virtual interview at a time of your convenience. Prior to this interview, we request that the enclosed consent form be signed and sent to me.

We have included a detailed information sheet to explain the study. Within the information sheet, you will find an eligibility checklist to self-assess your participation in this study.

Please do not hesitate to contact us on the following contact details for any further information or concerns:

Name	Role	Email
Asil Sadeq (main)	PhD student	<a href="mailto:sadeqa@tcd.ie">sadeqa@tcd.ie</a>
Connie Brennan	Research nurse	<a href="mailto:Brennc41@tcd.ie">Brennc41@tcd.ie</a>
Prof. Cristin Ryan	Supervisor	<a href="mailto:cristin.ryan@tcd.ie">cristin.ryan@tcd.ie</a>
Assoc. Prof. Tamasine Grimes	Supervisor	<a href="mailto:tagrimes@tcd.ie">tagrimes@tcd.ie</a>

Thank you.

Yours sincerely,

Asil Sadeq.

On behalf of the research team members at the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin.

**Appendix 3.5:** Consent form



**Trinity College Dublin**  
 Coláiste na Tríonóide, Baile Átha Cliath  
 The University of Dublin

**Study name: Work system analysis to explore the medicines management process in the nursing home setting in Ireland: a qualitative study using the Systems Engineering Initiative for Patient Safety model.**

**Identification Number for study: 2021-01-01**

**Consent Form**

Please ask **any** questions you may have when reading each of the statements. Thank you for participating.

Please **initial** the box if you agree with the statement. Please feel free to ask questions if there is something you do not understand.

General	Initial
I confirm I have read and understood the <b>Information Leaflet</b> for the above study. The information has been fully explained to me, and I have been able to ask questions, all of which have been answered to my satisfaction.	
I understand that this study is <b>entirely voluntary</b> . <b>If I decide that I do not want to participate, I can stop taking part in this study before the data processing and anonymisation stage without giving a reason.</b> I understand that deciding not to take part will not affect my future participation in the research study.	
I understand that my <b>personal data</b> may be looked at by the study research team at Trinity College Dublin, where it is relevant to the research. I agree that these individuals can access my data. I understand that all information will be kept private and confidential and that my name will not be disclosed.	



I understand that I <b>will not be paid for taking part in this study</b> <sup>3</sup> .	
I know how to contact the research team if I need to.	
I agree to take part in this research study, having been fully informed of the <b>risks, benefits, and alternatives set out in full in the information leaflet</b> I have been provided.	
[I agree to be contacted by researchers by [email/phone <sup>4</sup> ] as part of this research study] <sup>5</sup> . <i>Email:</i> <i>Phone:</i>	
<b>Data processing</b>	<b>Initial</b>
I agree to allow personal information about me to be shared within the research team for the purpose of health research, as described in the Information leaflet <sup>6</sup> .	
I understand that there are <b>no direct benefits to me</b> from participating in this study. I understand that I <b>have the right to obtain a copy of my personal data as well as supplementary information</b> .	
I understand that I <b>can stop taking part in this study</b> at any time before data anonymisation without giving a reason, and this will not affect my participation in health research.	
I consent that my anonymised data may be used in future studies, but only if approved by the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.	

-----  
Participant Name (Block Capitals)

Participant Signature

Date

<sup>3</sup> Amend as appropriate.

<sup>4</sup> Please include the appropriate relevant details.

<sup>5</sup> Please delete as appropriate.

<sup>6</sup> This section of the consent should be amended in accordance with the information leaflet to detail those third parties that data will be shared with.

**To be completed by the Principal Investigator or nominee.**

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

1. Researcher name: Asil Sadeq

Title and qualifications: Ms., PhD student in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin.

Signature

***2 copies to be made: 1 for the participant, 1 for research records.***

### **Appendix 3.6:** Invitation email

Dear x,

I hope this email finds you well.

My name is Asil Sadeq, a PhD student in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin. The research team members and I (Prof. Cristin Ryan, Assoc. Prof. Tamasine Grime) are interested in healthcare and medicines management for older people residing in Ireland's nursing homes (NHs).

**We are contacting you to invite you to take part in a research study and kindly forward this email to other nurses, doctors and pharmacist that provide their services to nursing home older people:**

This study aims to explore the medicines management process (MMP) in the Irish NH by understanding the work systems involved and exploring key stakeholders' views of how these work systems ensure safe and effective medicines management. We also aim to explore the impact that COVID-19 has had on the MMP and identify opportunities to improve the MMP in Irish NHs.

We really appreciate your busy schedule and all the work you provide. Nevertheless, you are a key member involved in the MMP in the Irish NH setting, and we would like to learn from your experiences. If you decide to take part, you will be invited to **one virtual 30-60 minutes interview** through MS Teams at a time of your convenience. Prior to this interview, we request that the enclosed consent form (attached) be signed and sent back on this email.

We have included a detailed information sheet (attached below) to explain the study. Within the information sheet, you will find an eligibility checklist to self-assess your participation in this study. Please do not hesitate to contact us on the following contact details for any further information or concerns:

**Asil Sadeq (main)**

PhD student- [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)

Prof. Cristin Ryan

Supervisor- [cristin.ryan@tcd.ie](mailto:cristin.ryan@tcd.ie)

Assoc. Prof. Tamasine Grimes

Supervisor- [tagrimes@tcd.ie](mailto:tagrimes@tcd.ie)

Thank you.

Looking forward to hearing from you.

Kind regards,

Asil Sadeq.

On behalf of the research team members at the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin.

**Appendix 3.7:** Invitation poster

## Research study

*Work system analysis to explore the medicines management process in the nursing home setting in Ireland: A qualitative study using the Systems Engineering Initiative for Patient Safety model*

**-CALL FOR PARTICIPANTS-**

Healthcare professionals (physicians, GPs, pharmacists and nurses) who contribute to any aspects of MMP in NHs in Ireland are invited to take part in a research study from Trinity College Dublin, on the **Medicines management process provided to older people residing in the nursing home setting.**



**30-60 minutes**



**Virtual interview**



**Aim: to explore your experience of the medicines management process provided to older people in nursing homes in Ireland.**



**Trinity College Dublin**  
Coláiste na Tríonóide, Baile Átha Cliath  
The University of Dublin

**If interested, please contact us directly on the email ([sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)) for participation and/or further information on the study.**

## Appendix 3.8: NHI agreement

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Nursing Homes Ireland  
2051 Castle Drive, Citywest,  
Dublin 24, D24 K299.  
t. (01) 469 9800 | e. info@nhilie | nhilie

9<sup>th</sup> June 2022

Asil Sadiq  
University of Dublin, Trinity College,

**Re: Work system analysis to explore the medicines management process in the nursing home setting in Ireland: a qualitative study using the Systems Engineering Initiative for Patient Safety model.**

Dear Asil,

I wish to confirm that NHI are engaged with the above research and consent to sharing information in relation to the research with NHI members to assist in recruitment for various phases of the work and to share information throughout and after the event.

If you have any queries about this please don't hesitate to get in touch.

Yours sincerely,

A handwritten signature in black ink that reads 'Deirdre Shanagher'.

**Deirdre Shanagher**  
**Strategic Clinical Nurse Expert with Regulatory Compliance.**

## Appendix 3.9: PSI agreement



7<sup>th</sup> June 2022

Dr. Tamasine Grimes,  
Associate Professor of Pharmacy,  
Panoz Institute,  
Trinity College Dublin,  
Dublin 2

Dear Professor Grimes,

**Re: Work system analysis to explore the medicines management process in the nursing home setting in Ireland: Protocol for a qualitative study using the Systems Engineering Initiative for a Patient Safety model.**

Before releasing the data you have requested, the Pharmaceutical Society of Ireland (PSI) requires confirmation that it will be used only for the specified purpose for which we have agreed to provide it.

In accepting data from the PSI, which is being provided to your student, Asil Sadeq, for the purposes of distributing the above survey, in accordance with the terms of the PSI's data protection statement, Trinity College Dublin agrees to be liable for any breaches of the Data Protection Act 2018 and the General Data Protection Regulation (GDPR), in relation to the data, once you have received it.

The PSI requires confirmation from you that the data will be securely maintained for the period necessary to achieve the specified purpose for which it is being provided to you, following which the data will be securely destroyed, and will not be copied, scanned electronically, or passed by any other means or in any other format to another party, or used for a purpose, other than the specified purpose for which it is being given to you.

This letter must be signed and returned to the PSI before the requested data can be released.

---

I agree to:

1. Use the data given to me by the PSI for the specified purpose only;
2. Securely maintain the data given to me by the PSI for the period necessary to achieve the specified purpose;
3. Send emails to PSI registrants only via the bcc option, or similar email address concealing facility so as not to reveal others' personal data;
4. Securely destroy the data given to me by the PSI, and not copy, or scan it, or pass it to another party, by any means, or in any format;
5. Accept liability for any breaches of the Data Protection Act 2018 and the General Data Protection Regulation (GDPR), in relation to the data given to me by the PSI once I have received the data.

Teach CCÉ, Sráid na bhFíiníní, Baile Átha Cliath 2, D02 TD72, Éire. PSI House, Fenian Street, Dublin 2, D02 TD72, Ireland.  
T. + 353 1 218 4000 | E. + 353 1 283 7678 | info@psi.ie | www.psi.ie

6. Ensure that the statement in bold below, will appear prominently in any correspondence I send, using contact details I have been provided by the PSI.

**Please note, your contact information has been provided by the Pharmaceutical Society of Ireland (PSI) in accordance with the terms of the PSI's Data Protection Statement. Undertakings have been provided to the PSI on usage, confidentiality, security, and deletion of your details in compliance with the Data Protection Act 2018 and the General Data Protection Regulation (GDPR).**

Name (In block letters) Tamasine Grimes

Organisation (In block letters) Trinity College Dublin, School of Pharmacy and Pharmaceutical Sciences

Signature:  Date: 09.06.2022

### **Appendix 3.10:** Email to pharmacists

Dear x,

We are contacting you to invite you and/or members of your network to **take part** in a research study that aims to explore the medicines management process (MMP) in the Irish NH setting. Healthcare professionals who contribute to any aspects of MMP in NHs in Ireland are eligible to take part (pharmacists, GPs, and nurses); Your profession has been identified as a key stakeholder in this process in the Irish NH setting, and we would like to learn from your experiences in this area.

#### ***What is involved with taking part?***

Participants will be invited to sign an **electronic consent form** (attached), and to **conduct a one virtual 30-60 minutes interview** at a time of your convenience. We have included a detailed information sheet to explain the study. All disseminated results of this study will be completely anonymised. Within the information sheet, prospective participants will find an eligibility checklist to self-assess their eligibility to participate in this study.

#### ***Who is doing this research?***

This research study is a part of a PhD project, under the supervision of Prof. Cristin Ryan and Assoc. Prof. Tamasine Grime, who are interested in healthcare and medicines management for older people residing in nursing homes (NHs) in Ireland.

Please note, your contact information has been provided by the Pharmaceutical Society of Ireland (PSI) in accordance with the terms of the PSI's Data Protection Statement. Undertakings have been provided to the PSI on usage, confidentiality, security, and deletion of your details in compliance with the Data Protection Act 2018 and the General Data Protection Regulation (GDPR).

Please note that a research ethics approval for this study has been granted from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee (reference number: 2021-01-01).

Prospective participants who would like to know more or who would like to participate should contact us directly by emailing: [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)

If you could share this email with members within your organisation/network who you feel may be eligible to participate, we would appreciate it.

Additional contact details:

Assoc. Prof. Tamasine Grime- Supervisor: [tagrimes@tcd.ie](mailto:tagrimes@tcd.ie)

Prof. Cristin Ryan- Supervisor: [cristin.ryan@tcd.ie](mailto:cristin.ryan@tcd.ie)

Thank you.

Yours sincerely,

Asil Sadeq.

On behalf of the research team members at the School of Pharmacy and Pharmaceutical Sciences,  
Trinity College Dublin.



### **Appendix 3.11:** Invitation email

Dear Nursing home x manager/person in charge

My name is Asil Sadeq. I am- a PhD student in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, under the supervision of Professor Cristin Ryan and Associate Professor Tamasine Grimes.

We are currently conducting a research study on the medicines management process provided to older persons residing in the Irish nursing homes. This project aims to understand the overall process and identify opportunities to improve it. We will collect data by interview by phone or on MS Teams. We are recruiting to 1) nursing home residents (age>65 years old) who has been residing for at least two years in a nursing home in Ireland and have the capacity to provide an informed consent; 2) family members/representatives (age>18) of nursing homes residents.

We are emailing you to kindly invite you to share the information with eligible residents/ family members in your nursing home. We have attached, the participant information sheet and consent form, which can be shared with prospective participants. We can also, with your permission, post copies to your nursing home to distribute to potentially eligible participants. The participant information leaflet provides our contact details (email, phone number and post address).

We have also attached a copy of an invitation poster and invite you to distribute the poster to potential participants in your nursing home.

We appreciate your support with recruiting participants to this study. The opinion of older nursing residents is very valuable to this research and will aid in improving the medicines management process in nursing homes in Ireland.

Please do not hesitate to contact me if you have any questions or concerns.


Thank you.

Kind regards,

Asil Sadeq,

On behalf of the research team from the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin.

**Appendix 3.12:** Invitation poster


 Trinity College Dublin  
Coláiste na Tríonóide, Baile Átha Cliath  
The University of Dublin

**Invitation to participate in a research study on  
the medicines management process**



Have you been living in a nursing within the last 2  
years?  
Are you of age 65 years or older?  
Can you provide an informed consent?

**OR**



Are you a family member of a nursing home  
resident of age 65 years or older?  
Are you over 18 years old?

We would like to chat with you about your experience. If  
interested, please contact the research team on  
**Email: [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie) or Phone: 01 896 2943**  
For further information and participation

**Appendix 3.13:** Email to interviewed healthcare professionals

Dear x,

I hope you are well.

Many thanks for participating in the study and your valuable input that helped us with our research study to improve the medicines management process in Ireland.

We have extended the study and we are looking to interview nursing home residents that are over 65 years old and can provide an informed consent.

The interview process is going to be the same, I am (myself) going to interview potential participants virtually on MS teams and the questions are on their opinion and involvement in managing their medicines.

I kindly ask you to support recruiting one or two residents who might be interested in participating in the study. I have attached an invitation poster and information sheet (please find attachments) that you can kindly distribute to eligible residents?

I am well trained and have a special designed interview guide that suits older nursing home residents. I am also flexible to do the interviews anytime at their convenience.

If not, could you advise me on a way that I can reach nursing home residents for recruiting? I would really appreciate it.

Many thanks in advance!

Looking forward to hearing from you.

Kind regards,  
Asil

**Appendix 3.14:** Nursing Home Ireland email

NHI are collaborating on a research project: Work system analysis to explore the medicines management process in the nursing home setting in Ireland: A qualitative study using the Systems Engineering Initiative for Patient Safety model. Please click here to access an [information sheet](#) and here for an [invitation poster](#) to participate in this research.

Please consider sharing this with 1) residents in your nursing home (age>65) and ability to provide an informed consent; and 2) family members/representatives (age>18) of nursing home residents of age more than 65 years old.

Please contact Ms. Asil Sadeq on the email ([sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)) or phone (01 086 2943) for further information on the study of if you wish to participate.

**Appendix 3.15:** Email to family members

Dear x

My name is Asil Sadeq, a PhD Student in the school of pharmacy in TCD. I am getting in contact with you regarding participating in a research project on your involvement in managing medicines for your loved one in the nursing home.

Your participation involves 1 virtual interview for 30-60 on Ms teams at the time of your convenience. Please find participant information document attached and consent form attached.

Please let me know when does it suit for an interview?

Many thanks for agreeing to participate in the project. You're a valuable member of your loved one's care process and we value the information given by you.

Please let me know if you have any questions.

I look forward to hearing from you.

Kind regards,  
Asil

**Appendix 3.16:** Email to NH group

Dear x

It would be of great appreciation if you could support the recruitment by reaching out to DONs in the NHs through circulating the invitation poster and participants information leaflet of the **Carechoice group**- Please find them attached.

We understand the challenges in recruiting NH residents and families, and we would really value your support with that.

Please let me know if you can help and/or have any questions.

Thanks a million,

Kind regards,  
Asil

**Appendix 3.17:** Participant information sheet

PART 1- for NH residents

**Name of Study: Work system analysis to explore the medicines management process in the nursing home setting in Ireland**

<b>Site</b>	<b>Trinity College Dublin</b>
<b>Principal Investigator(s) and Co-Investigator(s) (insert names, titles and contact details)</b>	<b>1. Asil Sadeq, PhD student in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin. Email: sadeqa@tcd.ie 2. Associate Professor, Tamasine Grimes, MSc, PhD, Trinity College Dublin. Email: tagrimes@tcd.ie</b>
<b>Study Organiser/ Sponsor (if applicable)</b>	<b>Trinity College Dublin</b>
<b>Data Controllers</b>	<b>Trinity College Dublin</b>
<b>Data Protection Officer</b>	<b>Data Protection Officer Secretary's Office Trinity College Dublin Dublin 2</b>

➤ **You are being invited to take part in a research study that is**

being undertaken by a PhD student (Asil Sadeq) in Trinity College Dublin.

- Before you decide whether or not you wish to take part, please read this information sheet carefully.
- Feel free to ask the PhD student Asil Sadeq on the email (sadeqa@tcd.ie) or phone (01 896 2943) if you have any questions or concerns.
- Don't feel rushed or under pressure to make a quick decision.
- You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.
- You may wish to discuss it with your family, friends or GP.

This leaflet has five main parts:

**Part 1 – The Study**

**Part 2 – Data Protection**

**Part 3 – Costs, Funding and Approval**

**Part 4 – Future Research**

**Part 5 – Further Information**



## **Part 1 – The Study**

### **Why is this study being done?**

**We are doing this study to understand the way medicines are managed for you in the facility. We would like to understand whether you are involved, what you think works well and what you think could be done better or differently.**

**We want to share knowledge about what makes this management of medicines safer and better.**

**The medicines management process is a process that includes the entire way medicines are selected, prescribed, reviewed, dispensed, administered and monitored for you.**

### **Why have I been invited to take part?**

- You are being invited because you are an older adult residing for more than two years in a nursing home in Ireland.**
- We intend to recruit 5 nursing home residents.**

### **Do I have to take part? Can I withdraw?**

- You do not have to take part in this study; it is entirely voluntary.
- You can change your mind and withdraw at any time before we anonymise your data
- If you decide to withdraw, it will not affect your current or future medical care.
- You do not have to give a reason for not taking parting or withdrawing.
- If you wish to withdraw, email Asil Sadeq (Email: [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)) or phone Asil Sadeq on (01 896 2943), who will be able to organise this for you.
- All your identifiable data records will be destroyed if you withdraw.

#### What happens if I change my mind?

- You can change your mind at any time by contacting Asil Sadeq at [email: [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)] or phone 01 896 2943.
- If you choose not to continue to take part, this will not affect your future medical care.
- If you wish, you can ask that your data stored that haven't been anonymised to be destroyed.
- If you request this, we will destroy all data still in our possession that hasn't been anonymised.
- We will no longer use or share your data for research from this point onwards.

### **How will the study be carried out?**

- The study involves an interview with the PhD student.
- The interview will be carried out either on the phone or by video call using Microsoft Teams
- Telephone interviews will be audio recorded through MS teams.
- The interview will take place at the time of your convenience and will last around 30- 60 minutes.

### **What will happen to me if I decide to take part?**

- If you decide to participate in this study, you will be asked to sign a consent form and send it back to us, either by email or by post. If you are returning it by email, the address is as follows: ([sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)) or
- You may also return your consent form by post- for the attention of Asil Sadeq, School of Pharmacy and Pharmaceutical Sciences, Panoz institute, Trinity College Dublin), postcode: D02 VF25
- After we receive the signed consent, we will contact you to arrange a day and time to have the interview with you.
- The interview will be conducted with by Asil Sadeq.
- At start of the interview, we will ask you for your permission to record the interview and we let you know when the recording starts.
- You will be asked questions about your experience and involvement in the medicines management process provided to

**you in your nursing home and identify opportunities to improve it.**

### **What will happen to my Data?**

**The interview will be audio recorded using MS Teams. The recording will be transcribed automatically where it will be fully anonymised where any and all personal information that you provide will be completely removed.**

- **All personal identifiers will be removed when the interview recording is transcribed; There will be no way from this point forward to connect an interview to a named participant.**

- **We may use quotes from interview to help us illustrate or explain a point when we write our report. All quotes will be anonymised and not traceable to any individual person or organization.**

- **All hard copies and electronic computerised data throughout the study will be stored securely in Trinity College Dublin.**

- **All data will be stored until the end of the study. After this time, it will permanently be deleted.**

- **Access to the data will be limited to the research team: PhD student (Asil Sadeq), academic supervisors (Assoc. Prof. Tamasine Grimes).**

### **Are there any benefits to taking part in this research?**

- Taking part in this study will not directly benefit you. However, your participation in this study will help contribute to improving the medicines management process in nursing homes in the Republic of Ireland.

**Are there any risks to me or others if I take part?**

- There is a risk that a connection to your identity could be made. However, great care will be taken to reduce this risk, and the risk to you of a breach of confidentiality is considered very low.

**Will I be told the outcome of the study?**

- The study results will be reported in medical/scientific journals and disclosed at medical/scientific conferences and in the thesis dissertation. No information which reveals your identity will be disclosed.

## **Part 2 – Data Protection**

**What information about me (personal data) will be used as part of this study?**

**We will use the personal contact details you have provided to us to arrange the interview with you.**

**What will happen to my personal data?**

**We will only process your personal data as is necessary for this research study.**

**Your personal and contact details will be held safely and securely.**

**The audio recording and the transcript of your interview will be stored safely and securely.**

**Who will access and use my personal data as part of this study?**

**Only Asil Sadeq (the PhD student) and the supervisor Associate Professor Tamazine Grimes will have access to your personal data.**

**Your personal data will not leave Ireland or the EU. Only anonymised data will be reported in medical/scientific journals and disclosed at medical/scientific conferences and in the thesis dissertation.**

**Will my personal data be kept confidential? How will my data be kept safe?**

- **Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe:**
- **Your contact details and consent form will be stored safely and securely with access restricted to Asil Sadeq and the research supervisor. After the interview and within 28 days, the interview transcript will be anonymised and all identifying information will be deleted. The audio recording will be deleted after 28 days.**
- **A data protection risk assessment was undertaken on this study and it identified that this research study poses a low risk in personal data processing.**
- **The research team members have completed the required training on data protection law and practice.**
- **The results of the study will be reported in medical/scientific journals and disclosed at medical/scientific conferences and thesis dissertations. No information which reveals your identity will be disclosed.**

**What is the lawful basis to use my personal data?**

**By law,<sup>7</sup> we can use your personal information for scientific research<sup>8</sup> (in the public interest<sup>9</sup>). We will also ask for your explicit consent to use your data as a requirement of the Irish Health**

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<sup>7</sup> The European General Data Protection Regulation (GDPR)

<sup>8</sup> Article 9(2) (j)

<sup>9</sup> Article 6(1)(e)

## **Research Regulations.**

<b>What are my rights?</b>
----------------------------

**You have the right to:**

- **Access your data and receive a copy of it.**
- **Restrict or object to the processing of your data.**
- **Object to any further processing of the information we hold about you.**
- **Have inaccurate information about you corrected or deleted.**
- **Request the deletion of your data.**

**By law, you can exercise the above rights in relation to your personal data unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting the PhD student Asil Sadeq on email: [Sadeqa@tcd.ie](mailto:Sadeqa@tcd.ie) , or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: [dataprotection@tcd.ie](mailto:dataprotection@tcd.ie). Website: [www.tcd.ie/privacy](http://www.tcd.ie/privacy).**



### **Part 3 – Costs, Funding and Approval**

**Has this study been approved by a research ethics committee?**

**Yes, this study has been approved by the Faculty of Health Sciences Research Ethics Committee (ethicscommittee@tcd.ie)**

**[Approval date: INSERT DATE AND REFERENCE NUMBER].**

**Who is organising and funding this study? Will the results be used for commercial purposes?**

**Asil Sadeq is organising this research study to obtain an academic qualification. This research is not being funded by any organization. The results will not be used for commercial purposes.**

**Is there any payment for taking part? Will it cost me anything if I agree to take part?**

**There is no payment for undertaking in the study and it will not cost you anything to take part.**

### **Part 4 – Future Research**

**Will my personal data be used in future studies?**

- The anonymised data may be used in future studies.

## Part 5 – Further Information

### Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- **Researcher:**

**Name: Asil Sadeq**

**Email: sadeqa@tcd.ie**

**Phone: 01 896 2943**

- **Principal investigator:**

**Name: Tamasine Grimes**

**Email: tagrimes@tcd.ie**

**Phone: +353 1 896 2805**

- **Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: [www.tcd.ie/privacy](http://www.tcd.ie/privacy).**

**Under GDPR, if you are not satisfied with how your data is being processed, you have the right to complain with the Office of the**

**Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: [www.dataprotection.ie](http://www.dataprotection.ie).**

**Will I be contacted again?**

**If you would like to participate in this study, you will be asked to sign the consent form. We will then contact you to arrange an interview time at your convenience.**

PART 2- for family members

**Name of Study: Work system analysis to explore the medicines management process in the nursing home setting in Ireland**

<b>Site</b>	<b>Trinity College Dublin</b>
<b>Principal Investigator(s) and Co-Investigator(s)</b>  (Insert names, titles and contact details)	<b>1. Asil Sadeq, PhD student in the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin.</b>  Email: sadeqa@tcd.ie  <b>2. Associate Professor, Tamasine Grimes, MSc, PhD, Trinity College Dublin.</b>  Email: tagrimes@tcd.ie
<b>Study Organiser/ Sponsor (if applicable)</b>	<b>Trinity College Dublin</b>
<b>Data Controllers</b>	<b>Trinity College Dublin</b>
<b>Data Protection Officer</b>	<b>Data Protection Officer</b>  <b>Secretary's Office</b>  <b>Trinity College Dublin</b>  <b>Dublin 2</b>

➤ You are being invited to take part in a research study that is being undertaken by a PhD student (Asil Sadeq) in Trinity College

**Dublin.**

- **Before you decide whether or not you wish to take part, please read this information sheet carefully.**
- **Feel free to ask the PhD student Asil Sadeq on the email (sadeqa@tcd.ie) or phone (01 896 2943) if you have any questions or concerns.**
- **Don't feel rushed or under pressure to make a quick decision.**
- **You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.**
- **You may wish to discuss it with your family, friends or GP.**

**This leaflet has five main parts:**

**Part 1 – The Study**

**Part 2 – Data Protection**

**Part 3 – Costs, Funding and Approval**

**Part 4 – Future Research**

**Part 5 – Further Information**

## **Part 1 – The Study**

### **Why is this study being done?**

**We are doing this study to understand the way medicines are managed for your relative in the nursing home. We would like to understand whether you are involved, what you think works well and what you think could be done better or differently.**

**We want to share knowledge about what makes this management of medicines safer and better.**

**The medicines management process is a process that includes the entire way medicines are selected, prescribed, reviewed, dispensed, administered and monitored for you.**

### **Why have I been invited to take part?**

- You are being invited because you are a family member of an older adult residing for more than two years in a nursing home in Ireland.**
- We intend to recruit 5 family members or representatives of nursing home resident.**

## **Do I have to take part? Can I withdraw?**

- You do not have to take part in this study; it is entirely voluntary.
- You can change your mind and withdraw at any time before we anonymise your data
- If you decide to withdraw, it will not affect your current or future medical care.
- You do not have to give a reason for not taking parting or withdrawing.
- If you wish to withdraw, email Asil Sadeq (Email: [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)) or phone Asil Sadeq on (01 896 2943), who will be able to organise this for you.
- All your identifiable data records will be destroyed if you withdraw.

### **What happens if I change my mind?**

- You can change your mind at any time by contacting Asil Sadeq at [email: [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)] or phone 01 896 2943.
- If you choose not to continue to take part, this will not affect your future medical care.

- If you wish, you can ask that your data stored that haven't been anonymised to be destroyed.
- If you request this, we will destroy all data still in our possession that hasn't been anonymised.
- We will no longer use or share your data for research from this point onwards.

### How will the study be carried out?

- The study involves an interview with the PhD student.
- The interview will be carried out either on the phone or by video call using Microsoft Teams
- Telephone interviews will be audio recorded through MS teams.
- The interview will take place at the time of your convenience and will last around 30- 60 minutes.

### What will happen to me if I decide to take part?

- If you decide to participate in this study, you will be asked to sign a consent form and send it back to us, either by email or by post. If you are returning it by email, the address is as follows: ([sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)) or
- You may also return your consent form by post- for the



attention of Asil Sadeq, School of Pharmacy and Pharmaceutical Sciences, Panoz institute, Trinity College Dublin), postcode: D02 VF25

- After we receive the signed consent, we will contact you to arrange a day and time to have the interview with you.
- The interview will be conducted with by Asil Sadeq.
- At start of the interview, we will ask you for your permission to record the interview and we let you know when the recording starts.
- You will be asked questions about your experience and involvement in the medicines management process provided to your family member residing in a nursing home and identify opportunities to improve it.

**What will happen to my Data?**

The interview will be audio recorded using MS Teams. The recording will be transcribed automatically where any and all personal information that your provide will removed.

- All personal identifiers will be removed when the interview recording is transcribed; There will be no way from this point forward to connect an interview to a named participant.
- We may use quotes from interview to help us illustrate or explain a point when we write our report. All quotes will be anonymised and not traceable to any individual person or organization.

- All hard copies and electronic computerised data throughout the study will be stored securely in Trinity College Dublin.
- All data will be stored until the end of the study. After this time, it will permanently be deleted.
- Access to the data will be limited to the research team: PhD student (Asil Sadeq), academic supervisors (Assoc. Prof. Tamasine Grimes).

**Are there any benefits to taking part in this research?**

- Taking part in this study will not directly benefit you. However, your participation in this study will help contribute to improving the medicines management process in nursing homes in the Republic of Ireland.

**Are there any risks to me or others if I take part?**

- There is a risk that a connection to your identity could be made. However, great care will be taken to reduce this risk, and the risk to you of a breach of confidentiality is considered very low.

**Will I be told the outcome of the study?**

- **The study results will be reported in medical/scientific journals and disclosed at medical/scientific conferences and in the thesis dissertation. No information which reveals your identity will be disclosed.**

## **Part 2 – Data Protection**

**What information about me (personal data) will be used as part of this study?**

**We will use the personal contact details you have provided to us to arrange the interview with you.**

**What will happen to my personal data?**

**We will only process your personal data as is necessary for this research study.**

**Your personal and contact details will be held safely and securely.**

**The audio recording and the transcript of your interview will be stored safely and securely.**

**Who will access and use my personal data as part of this study?**

**Only Asil Sadeq (the PhD student) and the supervisor Associate Professor Tamasine Grimes will have access to your personal data.**

**Your personal data will not leave Ireland or the EU. Only anonymised data will be reported in medical/scientific journals and disclosed at medical/scientific conferences and in the thesis dissertation.**

**Will my personal data be kept confidential? How will my data be kept safe?**

- **Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe:**
- **Your contact details and consent form will be stored safely and securely with access restricted to Asil Sadeq and the research supervisor. After the interview and within 28 days, the interview transcript will be anonymised and all identifying information will be deleted. The audio recording will be deleted after 28 days.**
- **A data protection risk assessment was undertaken on this study and it identified that this research study poses a low risk in personal data processing.**
- **The research team members have completed the required training on data protection law and practice.**
- **The results of the study will be reported in medical/scientific journals and disclosed at medical/scientific conferences and thesis dissertations. No information which reveals your identity will be disclosed.**

## What is the lawful basis to use my personal data?

By law,<sup>10</sup> we can use your personal information for scientific research<sup>11</sup> (in the public interest<sup>12</sup>). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations.

## What are my rights?

You have the right to:

- Access your data and receive a copy of it.
- Restrict or object to the processing of your data.
- Object to any further processing of the information we hold about you.
- Have inaccurate information about you corrected or deleted.
- Request the deletion of your data.

By law, you can exercise the above rights in relation to your personal data unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting the PhD student Asil Sadeq on email: [Sadeqa@tcd.ie](mailto:Sadeqa@tcd.ie), or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: [dataprotection@tcd.ie](mailto:dataprotection@tcd.ie). Website: [www.tcd.ie/privacy](http://www.tcd.ie/privacy).

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<sup>10</sup> The European General Data Protection Regulation (GDPR)

<sup>11</sup> Article 9(2) (j)

<sup>12</sup> (Article 6(1)(e))

### **Part 3 – Costs, Funding and Approval**

**Has this study been approved by a research ethics committee?**

**Yes, this study has been approved by the Faculty of Health Sciences Research Ethics Committee (ethicscommittee@tcd.ie)**

**[Approval date: INSERT DATE AND REFERENCE NUMBER].**

**Who is organising and funding this study? Will the results be used for commercial purposes?**

**Asil Sadeq is organising this research study to obtain an academic qualification. This research is not being funded by any organization. The results will not be used for commercial purposes.**

**Is there any payment for taking part? Will it cost me anything if I agree to take part?**

**There is no payment for undertaking in the study and it will not cost you anything to take part.**

### **Part 4 – Future Research**

**Will my personal data be used in future studies?**

- The anonymised data may be used in future studies.

## Part 5 – Further Information

**Who should I contact for information or complaints?**

**If you have any concerns or questions, you can contact:**

- **Researcher:**

**Name: Asil Sadeq**

**Email: [sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)**

**Phone: 01 896 2943**

- **Principal investigator:**

**Name: Tamasine Grimes**

**Email: [tagrimes@tcd.ie](mailto:tagrimes@tcd.ie)**

**Phone: +353 1 896 2805**

- **Data Protection Officer, Trinity College Dublin: Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: [dataprotection@tcd.ie](mailto:dataprotection@tcd.ie). Website: [www.tcd.ie/privacy](http://www.tcd.ie/privacy).**

**Under GDPR, if you are not satisfied with how your data is being processed, you have the right to complain with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: [www.dataprotection.ie](http://www.dataprotection.ie).**



**Will I be contacted again?**

**If you would like to participate in this study, you will be asked to sign the consent form. We will then contact you to arrange an interview time at your convenience.**

**Appendix 3.18:** Consent form



**Trinity College Dublin**  
Coláiste na Tríonóide, Baile Átha Cliath  
The University of Dublin

**STUDY NAME:** Work system analysis to explore the medicines management process in the nursing home setting in Ireland.

**Identification Number for study:** 220501

**Consent Form**

**There are 2 sections in this form.**

**Section 1 has a statement and asks you to initial if you agree.**

**Please feel free to ask questions if there is something you do not understand.**

**Section 2 asks for your consent. Please select either yes or no to indicate your choice.**

**The end of this form is for the researchers to complete.**

<b>General Understanding</b>	<b>Initial</b>
I confirm I have read and understood the <b>Information Leaflet</b> for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	
I understand that this study <b>is entirely voluntary, and if I decide that I do not want to take part, I can stop taking part in this study at any time before the anonymisation stage without giving a reason.</b>	
I understand that I <b>will not be paid for taking part in this study</b> <sup>13</sup> .	
I know how to contact the research team if I need to.	

<b>Consent</b>	<b>Select Yes/No</b>
I agree to take part in this research study having been fully informed of the <b>risks and benefits</b> which are set out in full in the information leaflet which I have been provided with.	<b>Yes No</b> <input type="checkbox"/> <input type="checkbox"/>
I agree to the use of my <b>personal data</b> by the research team for the research study as described in the information leaflet.	<b>Yes No</b> <input type="checkbox"/> <input type="checkbox"/>
<b>Future use of information</b>	<b>Initial</b>
I give permission for my <b>anonymised</b> information to be stored for possible <b>future research related</b> to the current study on the topic of medicines management provided to residents in nursing homes <b>without further consent</b> being required but only if the research is approved by a Research Ethics Committee.	

-----  
Participant Name (Block Capitals)

Participant Signature

Date

To be completed by the Principal Investigator or nominee:

I, the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.

I have given a copy of the information leaflet and consent form to the participant with contacts of the study team

Researcher name

Title and qualifications

Signature

Date

|        |        |

2 copies to be made: 1 for patient and 1 for PI

### **Appendix 3.19:** Topic guides

#### PART 1- PIC/nurse

Describe each stage of the MMP in your organization (prompting SEIPS 3.0 components along the way

SEIPS components	Interview component	Process
Persons	Who is involved in different stages of MMP? Is there an MDT? and if so, Who is involved in the MDT? Describe the residents'/ family members involvement in MMP? Special skills?	Medicines management process (MMP)  Admission (Pre-admission, admission, transfer to hospital, re-admission);
Tasks	MMP stages tasks? Medication safety? COVID related new tasks and practices	Prescribing;  Ordering;  Delivery;  Storage;
Tools and technologies	Tools/ technologies used at each stage of MMP Guidelines/criteria? Communication between nursing home and pharmacy/GP practice/ hospital? Medication record keeping? COVID related new tools and technologies used? Communication between off-site and onsite staff during COVID? Sources of information	Medication review;  Preparation;  Administration;  Monitoring.
Physical environment	Describe physical environment of your NH- distance from accommodation to work or work to NH (off-site healthcare professionals), dispensing, delivery, storage, temperature, lighting, others? Covid related physical factors? Drug administration rounds- environment?	
Organizational conditions	Training of staff? Does each resident have a prescriber, or it is one physicians care for all residents in your NH? Is your NH contracted with GP practice or hospital physicians? Describe MDT meetings in your NH? Describe offsite carers? Are you contracted with a pharmacy? Are orders verified? What happens if the order is not verified? What happens if there are discrepancies in medicines delivered and medication plan? Process of medication plan modification? Error management process? COVID related protocols? COVID- pandemic new training and skills?	
External conditions	Describe the medication related audit and inspection in your NH? Describe the local standard/ guidelines follow?	

	Describe insurance companies? COVID new protocols and standards?	
--	---	--

Additional comments?

PART 2- HCPs

SEIPS component	Interview points
Persons	Demographic information, qualification, duration on involvement in MMP
Tasks	Which of the MMP stages are you involved? Talk about your tasks in these MMP stages Challenges: workload, long shift, time pressure, complexity, others? Improvement suggestions? COVID related challenges? New practices/tasks during COVID
Tools and Technologies	What tools/technologies do you use in your MMP tasks and its importance Mutual tools between you and other HCPs? Challenges with these tools/technologies Solutions suggestions Are there new tools/technologies used during COVID?
Physical environment	Describe the physical environment- noise, light, temperature, travel distance, breaks, equipment Challenges in the physical environment that affects MMPs tasks efficiency Solution suggestions? COVID and impact on physical environment factors?
Organizational conditions	Describe conditions in your organization- coordination system, staffing, delays in tasks, peer-support, rewards, cultural factors Communication between you and other HCPs- team work and collaboration. Training to ensure efficiency and competence? Challenges? Suggestions to improvements in the organizational conditions. What COVID changed in the conditions of your organizations- new protocols?
External environment	Describe the external environment- regulators, local standards, insurance, HSE, HIQA? Facilitation of MMP? Challenges to your role in MMP? Improvement suggestions? COVID related new practices from external environment- international COVID restrictions

Additional comments?

PART 3- NH residents

((Questions may vary from one participant to another, and some may not be asked all questions))

Hello, my name is Asil Sadeq, and I am a PhD student at Trinity College Dublin.

Thank you again for agreeing to participate in this interview.

I am going to ask you some questions about the medicines/tablets for your loved one. There are no right or wrong answers, so please feel free to say what you think.

If at any time you are not sure about what I am asking, please feel free to ask me to explain or repeat the question.

I will record the interview and type up the recording later, but anything you say will be completely anonymised.

Are you happy to proceed?

(START RECORDING)

-How long have you been in the facility?

-Are you involved in managing your medicines/tablets?

*(If yes)* can you describe your involvement 'prompt questions will be asked to facilitate the conversation)

*(If no)* 'prompt questions will be asked to facilitate conversation'

Prompt questions:

\*When you first came here, were you involved or asked about your medicines and/or medical history?

➤ (If yes)

*Can you describe your involvement?*

*Who was there with you?*

➤ (If no)

*Do you know who did they ask?*

*Did you feel like this was helpful?*

\*Do you know if you have the same doctor or pharmacy from before you come here or were they changed?

\*Do you know what are your tablets used for?

\*Who does your tablets?

*(If they mention healthcare professionals)*

\*Do you know your doctor or pharmacist now?

\*Do you talk to your carers about how medicines should be given to you? Example: how you prefer to take them, what form, what times?

➤ (If yes)

*Can you talk about this?*

*How do you talk to them? Example: over the phone or face-to-face? (T&T)*

*Does this work well for you?*

- (If no) do you feel like you shouldn't? and why?

\*If you felt like you needed a medicine, would you be able to get it here from someone?

\*Do you think decisions about medicines or timings of drug rounds are made with your best interest or to suit routines and timings here?

\*Do you know when staff are reviewing your medicines?

- (If yes) can you talk about this?
- (If no) would you prefer to be informed or do you trust their decision?

Now after you take your medicines-

\*Do you know if the medicine is working or not working with you?

- (If yes) how do you know?

\*Do you feel you can talk to your carers if your medicines are not working or you felt any discomfort?

- (If yes) who do you talk to?
- (If no) why do you feel like you shouldn't?

\*Are there any challenges here? Is there anything about your surroundings that affect your involvement, example: noise interrupting you and you get distracted?

\*How could it be done better or what would you change to make it better?

COVID-related questions:

\*Do you know what was happening in last 2 years?

-what the experience was? Or were there any changes to all what we spoke it about?

-How were you talking to your carers?

-Did the people who take of you change?

-Did social impact your health? Example: you felt more anxious or depressed and you ended you taking medications for this?

-Have you discussed this with your carers?

- (If yes) can you talk about this
- (If no) why did you feel like you shouldn't?

#### Part 4- Family members

((Questions may vary from one participant to another, and some may not be asked all questions))

Hello, my name is Asil Sadeq, and I am a PhD student at Trinity College Dublin.

Thank you again for agreeing to participate in this interview.

I am going to ask you some questions about the medicines/tablets for your loved one. There are no right or wrong answers, so please feel free to say what you think.

If at any time you are not sure about what I am asking, please feel free to ask me to explain or repeat the question.

I will record the interview and type up the recording later, but anything you say will be completely anonymised.

Are you happy to proceed?

(START RECORDING)

-Are you the next of kin or the person the nursing home gets in contact with regarding your loved one?

- Who is involved with managing medicines for your loved one?

Prompts: nurses? Doctors? Pharmacist?

Prompts: are you involved?

\*Can you tell me more about your involvement? What do you do? (Prompt questions will be asked to facilitate conversation)

#### **Prompt questions:**

\*When your loved one entered the nursing home, were you involved or asked about their medicines?

➤ (If yes)

*\*Can you tell me more about this?*

*Prompts: What were you asked? What information was gathered? How was it gathered?  
Who was there with you?*

*\*Were you allowed to share information about how they like things to be done in terms of medicines?*

*Prompts: choice of medicines? How are medicines given?*

*\*Did you feel that this was helpful for your loved one?*

*\*Was your loved one present?*

*Prompts: was your loved one involved? How was your loved one involved? What information was gathered from them? How was it gathered?*



- (If no)
  - \*Would you like to be involved?
  - \*Were there any challenges from the nursing home regarding your involvement or your loved one involved in managing medicines?

\*Do you think your loved one can access the medicine you think they need?

\*Do you know your loved one's healthcare professionals and meet with them?

- (If yes)
  - Can you talk about this?
  - Prompts: how often do you talk or meet? and how are information shared between you (example: face-to-face, phone, email)?

- (If no) Are there any challenges to communicating with your loved one's healthcare professional carers?

\*Are there anything from your surroundings that affect your involvement?

Example: travel time, no involvement, interrupting noise that distract you from talking to them about your loved ones medicine?

\*Do you know if there are times when your loved one has missed a dose?

- (If yes)
  - are you informed when this happens?
  - Can you talk about what happens?
- (If no)
  - would you prefer to be informed?
  - Can you talk about this?

\*When is a decision made about your loved one's medicines- do you trust this decision is in their best interest?

- (If yes) can you talk about this?
- (If no)
  - can you tell me why not?
  - In your opinion, are there any other interest?
  - Prompts: Example: staff time, convenience to suit routine or timing?

\*Can you tell me who handles the delivery of medicines from the pharmacy to the NH? (If they say pharmacy or nurse): are you and your loved one happy with the delivery and times of delivery?

- (If they say they do it themselves) can you tell me why did you choose to deliver?
  - Prompts: challenges about timings of delivery or medicines delivered?

Now after your loved one takes their medicine:

\*Do you know if the medicine is working for them or not?

- (If yes) can you tell me how you know?

\*Can you tell me what happens when you notice something is not right with your loved one or when you think a medicine is not working appropriately for them? (TASK)

Prompt questions:

- Who do you talk to?
- *what happens after?*
- *Would you like the procedure here to be done anything differently?*
- (If they don't do that)  
*why do you feel you shouldn't?*  
*what are the challenges? Are the challenges from the NH staff or the doctors?*

\*Do you know when the doctors or staff reviewing/discussing medicines for your loved one?

- (If yes)  
*can you talk about this?*  
*Are you involved in the discussion?*  
*Are you notified when there are interactions of medicines?*
- (If not) *would you prefer to be involved/notified and perhaps attend a discussion or do you trust and accept their decision?*

\*How important do you think your overall involvement with managing your loved ones' medicines?

\*Are there any rules from the nursing home that positively and negatively impact your involvement?

\*How could it be done better?

COVID-related questions:

\*Can you describe your involvement with managing your loved ones' medicines during the pandemic?

\*Was your involvement in managing your loved ones' medicines more or less than at other times?

- (If more) *can you talk about this?*
- (If less) *challenges? Were the challenges because of covid restrictions? Or were there other reasons?*

\*Did visiting restrictions impact your ability to monitor your loved one's symptoms or bad effects from medicines?

- (If yes) *tell me more about this?*

\*How did you communicate with your loved ones' healthcare professional carers during covid about managing their medicines?

Was there more communication than before covid or was it less?

\*Did using technologies such as zoom or teams help better communicate with your loved ones healthcare professional carers during covid times?

- Do you think you will still use it after now with easing restrictions of covid?

GP contract/resident own GP

These are all my questions.

Is there anything about managing your loved one's medicines/ tablets that you feel is important but was not covered or asked in this interview?

Thank you for your time

(STOP RECORDING)

**Appendix 3.20:** MMP photo shared with participants during the interview



## Appendix 3.21 Ethical approvals

PART 1- Level I ethical approval from the School of Pharmacy and Pharmaceutical Sciences, Research Ethics Committee, TCD



Coláiste na Tríonóide, Baile Átha Cliath  
Trinity College Dublin

Ollscoil Átha Cliath | The University of Dublin

Asil Sadeq,  
School of Pharmacy and Pharmaceutical Sciences,  
Trinity College,  
Dublin 2.

Ref. 2021-01-01 (A01)

28 March 2022

Dear Asil,

**Re: Work system analysis to explore the medicines management process in the nursing home setting in Ireland: Protocol for a qualitative study using the Systems Engineering Initiative for Patient Safety model**

I am happy to confirm that your recent application for amendment of the above project's approval (methodology) has been approved.

You are reminded that any further significant deviation from the research description in the application requires approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee before implementation.

Your attention is drawn to the reporting requirements outlined on the Committee's website ([http://pharmacy.tcd.ie/research/SoPPS\\_REC.php](http://pharmacy.tcd.ie/research/SoPPS_REC.php)), in particular the need for:

- An immediate report in writing (by email to [pharmacy.ethics@tcd.ie](mailto:pharmacy.ethics@tcd.ie)) of any serious or unexpected adverse events on participants, or unforeseen events that might affect the benefits/risks ratio as outlined in the application.
- Annual reports (report form on the Committee's website).
- An end of project report (report form on the Committee's website).

The newly updated record for this study has been designated 2021-01-01 (A01), indicating it incorporates one approved amendment. Please quote this reference number in any further correspondence.

Yours sincerely,

Sheila Ryder,  
Chairperson,  
School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.

**Sheila Ryder**  
Chairperson  
Research Ethics Committee  
School of Pharmacy and Pharmaceutical Sciences  
Panoz Building, East End 4/5,  
Trinity College,  
Dublin 2, Ireland.  
Tel. +353 1 896 2786  
E-mail [pharmacy.ethics@tcd.ie](mailto:pharmacy.ethics@tcd.ie)  
[http://pharmacy.tcd.ie/research/SoPPS\\_REC.php](http://pharmacy.tcd.ie/research/SoPPS_REC.php)

**Síle Ní Mharcaigh**  
Cathairleach  
Coiste um Eitic Thaighde  
Scoil na Cógaisíochta agus na nEolaíochtaí Cógaisíochta  
Foirgneamh Panoz, An Taobh Thoir 4/5,  
Coláiste na Tríonóide,  
Baile Átha Cliath 2, Éire.  
Tel. +353 1 896 2786  
R-phost [pharmacy.ethics@tcd.ie](mailto:pharmacy.ethics@tcd.ie)  
[http://pharmacy.tcd.ie/research/SoPPS\\_REC.php](http://pharmacy.tcd.ie/research/SoPPS_REC.php)

PART 2- Level II Ethical approval from the Faculty of Health Sciences, Research Ethics Committee, TCD



Coláiste na Tríonóide, Baile Átha Cliath  
Trinity College Dublin  
Ollscoil Átha Cliath | The University of Dublin

Asil Sadeq,  
The School of Pharmacy & Pharmaceutical Sciences,  
Panoz Institute, Trinity College Dublin,  
The University of Dublin, Dublin 2  
Ireland  
D02PN40

14th October 2022

**Ref:** 220501  
**Title of Study:** Work system analysis to explore the medicines management process in the nursing home setting in Ireland: Protocol for a qualitative study using the Systems Engineering Initiative for Patient Safety model.

Dear Asil,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in October 2022. We are pleased to inform you that the above project has ethical approval to proceed.

This study has been ethically approved. We would advise you to seek review and comments on your DPIA from the DPO if required prior to study commencement'

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,

A handwritten signature in black ink that reads "Jacintha O'Sullivan".

Prof. Jacintha O'Sullivan  
Chairperson  
Faculty Research Ethics Committee

**Appendix 3.22:** Data Protection Officer approval letter



**Trinity College Dublin**  
Coláiste na Tríonóide, Baile Átha Cliath  
The University of Dublin

06<sup>th</sup> August 2022

Study Title: Work system analysis to explore the medicines management process in the nursing home setting in Ireland: Protocol for a qualitative study using the Systems Engineering Initiative for Patient Safety model

Dear Asil

The Data Protection Office has reviewed the Data Protection Impact Assessment ('DPIA') and supporting documentation in respect of this research study and provided feedback as part of the review process. Upon review of the information consequently provided I am satisfied that the intended processing of personal data for the purposes of this study as described therein is in compliance with data protection legislation, specifically the EU General Data Protection Regulation 2016 (GDPR), Data Protection Acts 1988-2018 and Health Research Regulations 2018.

Please note that the completion of a DPIA is not a one-time exercise, but a continual process. If at any stage there are changes to the processing envisaged by this assessment please contact me.

Be advised that the Trinity College Data Protection Office may carry out a review to assess if the processing is being performed in accordance with the information provided.

I wish you the very best of luck with your research.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Eustace', written over a horizontal line.

**John Eustace**

Data Protection Officer  
Secretary's Office  
Trinity College Dublin  
Dublin 2, Ireland

**Appendix 3.23:** Withdrawal form



Trinity College Dublin  
Coláiste na Tríonóide, Baile Átha Cliath  
The University of Dublin

<p><b>STUDY NAME: Work system analysis of safe and effective medicines management process in nursing homes in Ireland</b></p> <p><b>Centre ID:</b></p> <p><b>Identification Number for study:</b></p>
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<b>General</b>
I confirm that I wish to <b>withdraw</b> from this study.
I understand that all my <b>identifiable data (prior to data anonymisation)</b> will be permanently deleted and destroyed.

PARTICIPANT NAME (BLOCK CAPITALS):

DATE:

SIGNATURE:

1 COPY FOR PARTICIPANT- 1 COPY FOR RESEARCH RECORDS.



Private & Confidential

Asil Sadeq  
[sadeqa@tcd.ie](mailto:sadeqa@tcd.ie)

28 December 2022

Our Ref. FOIR 117 022

**Re: – FOI Request Search and Retrieval Estimation**

Dear Ms Sadeq,

I refer to your recent FOI request received on 13 December 2022, which requested the following:

I would like to access the electronic inspection reports for Nursing homes for inspections undertaken in 2019.

**1. Search and Retrieval Fees**

The FOI Act requires the charging of search and retrieval fees in certain circumstances, such as where the level of work involved in searching for and retrieving records for a FOI request is estimated to take more than 5 hours. The rules on fees are contained within [Section 27 of the FOI Act](#).

After careful consideration and consultations, it has been estimated that the **total time required to search for and retrieve records is approximately 45 hours**. The prescribed amount chargeable for each such hour is €20.00 resulting in a fee that is in excess of the overall ceiling limit, which currently stands at €700. On that basis, I am proposing to refuse to process your request unless it can be refined so that the estimated search and retrieval cost falls below the overall ceiling limit.

If, following our discussions, you agree to refine your request so that the estimated search and retrieval charges are less than the overall ceiling limit of €700, you will be required to pay a deposit of 50% of the fee. Where the cost of search and retrieval is greater than €500 but less than €700, a maximum charge of €500 applies.

**2. Offer of assistance**

I would be happy to assist you refine your request so that it no longer results in fees or the level of fees is reduced below the ceiling limit of €700. Your request involves a large number

**Head Office:**  
Unit 1301, City Gate, Mahon,  
Cork, Ireland.  
Tel: +353 (0) 21 240 9300  
Fax: +353 (0) 21 240 9600

**Dublin Regional Office:**  
George's Court, George's Lane,  
Dublin 7, Ireland  
Tel: +353 (0) 1 814 7400  
Fax: +353 (0) 1 814 7499

e-mail: [info@hiqa.ie](mailto:info@hiqa.ie) [www.hiqa.ie](http://www.hiqa.ie)

of records. If you would like to specify the reports from specific nursing homes, we would be happy to provide the reports.

If you chose to refine your request, the actual search and retrieval work to be carried out will not commence until any deposit for fees has been paid. No deposit should be paid until the text of the refined request has been agreed and relevant deposit/fees have been calculated.

The final cost of processing your request will be based on the actual amount of work undertaken in relation to records released to you. Incorporated in this final charge will be the cost of any copying of records at the prescribed rate. Should the final amount be less than the deposit which you have paid you will be refunded the excess.

You should also note that this letter suspends the time limit for a final decision on your request for access to the records. The time limit will recommence if and when your request is refined so that the estimated search and retrieval fee is less than the limit at which fees are paid or when the relevant deposit is paid.

### **3. Appeal**

A separate course is open to you is to appeal the decision to impose estimated fees above. This appeal can be made in writing to the HIQA FOI Office via [foi@hiqa.ie](mailto:foi@hiqa.ie)

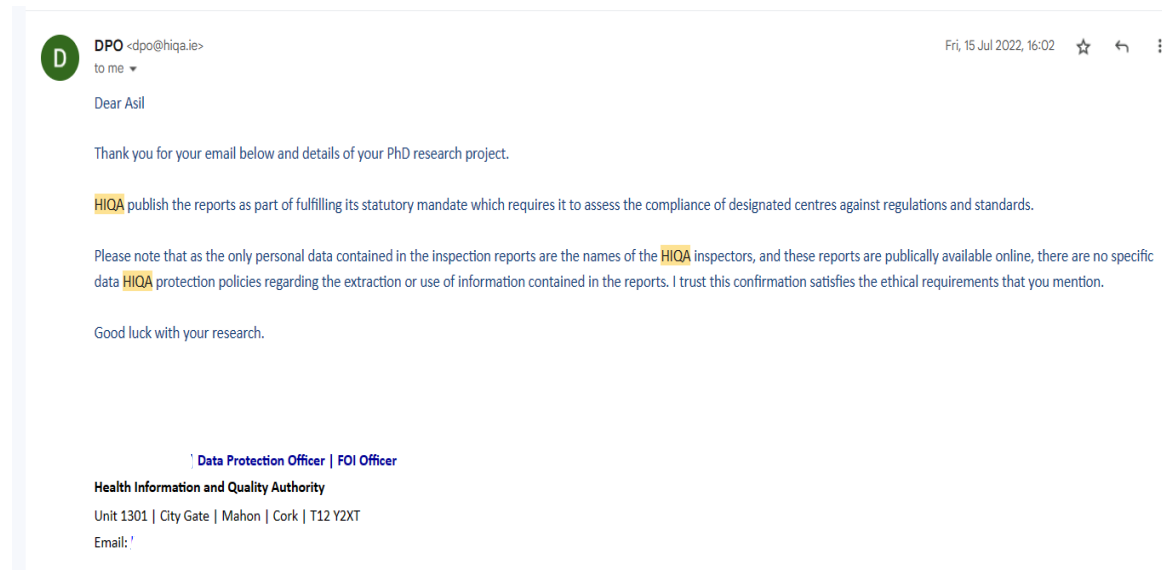
In that event, you would normally have four weeks from receipt of this notification in which to make the appeal. We will, however, allow the appeal to be made late in certain circumstances. It would assist greatly, if in your letter of appeal you refer to this letter and stated the reasons for your appeal.

If you have any queries in relation to your FOI request please feel free to contact me at [foi@hiqa.ie](mailto:foi@hiqa.ie) or 085 8050586.

Yours sincerely,

Sean Lynch  
Freedom of Information Administrator

## Appendix 4.2: Personal communications between the PhD candidate and HIQA's Data Protection Officer



**Appendix 4.3:** Association between Regulation 29 reporting and NH characteristics

	2019 (n=93)		2020 (n=51)		2021 (n=86)		2022 (n=60)	
NH characteristics	Regulation 29 Reported	Regulation 29 not reported	Regulation 29 Reported	Regulation 29 not reported	Regulation 29 Reported	Regulation 29 not reported	Regulation 29 Reported	Regulation 29 not reported
<b>NH size <i>N</i> (%)</b>								
-Big	51 (60.7)	33 (39.3)	21 (45.7)	25 (54.3)	23 (29.5)	55 (70.5)	21 (37.5%)	35 (62.5)
-Small	5 (50)	5 (50)	2 (40%)	3 (60%)	2 (28.6)	5 (71.4)	2 (50)	2 (50)
<b>Geographic class <i>N</i> (%)</b>								
-Rural	46 (62.2)	28 (37.8)	18 (47.4)	20 (52.6)	20 (30.3)	46 (69.7)	19 (42.2)	26 (57.8)
-Urban	10 (50)	10 (50)	5 (38.5)	8 (61.5)	5 (26.3)	14 (73.7)	4 (26.7)	11 (73.3)
<b>Ownership type <i>N</i> (%)</b>								
-Private	45 (56.3)	35 (43.8)	22 (45.8)	26 (54.2)	23 (31.1)	51 (68.9)	20 (40)	30 (60)
-Public	11 (78.6)	3 (21.4)	1 (33.3)	2 (66.7)	2 (18.2)	9 (81.8)	3 (30)	7 (70)
<b>Inspection type <i>N</i> (%)</b>								
-Announced	20 (71.4)	8 (28.6)	11 (52.4)	10 (47.6)	0 (0)	1 (100)	2 (100)	0 (0)
-Unannounced	36 (54.5)	30 (45.5)	12 (40)	18 (60)	25 (29.8)	59 (70.2)	21 (36.2)	37 (63.8)

NH: nursing home

**Appendix 4.4:** Association between Regulation 29 compliance and NH characteristics

	2019 (n=56)			2020 (n=23)			2021 (n=25)			2022 (n=23)		
NH characteristics	C	SC	NC	C	SC	NC	C	SC	NC	C	SC	NC
<b>NH size <i>N</i> (%)</b>												
-Big	37 (72.5)	10 (19.6)	4 (7.8)	13 (61.9)	5 (23.8)	3 (14.3)	16 (69.6)	3 (13)	4 (17.4)	12 (57.1)	7 (33.3)	2 (9.5)
-Small	3 (60)	1 (20)	1 (20)	1 (50)	1 (50)	0 (0)	1 (50)	1 (50)	0	1 (50)	1 (50)	0 (0)
<b>Geographic class <i>N</i> (%)</b>												
-Rural	32 (69.6)	9 (19.6)	5 (10.9)	10 (55.6)	5 (27.8)	3 (16.7)	15 (75)	3 (15)	2 (10)	10 (52.6)	7 (36.8)	2 (10.5)
-Urban	8 (80)	2 (20)	0 (0)	4 (80)	1 (20)	0 (0)	2 (40)	1 (20)	2 (40)	3 (75)	1 (25)	0 (0)
<b>Ownership type <i>N</i> (%)</b>												
-Private	33 (73.3)	8 (17.8)	4 (8.9)	13 (59.1)	6 (27.3)	3 (13.6)	15 (65.2)	4 (17.4)	4 (17.4)	11 (55)	7 (35)	2 (10)
-Public	7 (63.6)	3 (27.3)	1 (9.1)	1 (100)	0 (0)	0 (0)	2 (100)	0 (0)	0 (0)	2 (66.7)	1 (33.3)	0 (0)
<b>Inspection type <i>N</i> (%)</b>												
-Announced	15 (75)	5 (25)	0 (0)	8 (72.7)	3 (27.3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (100)	0 (0)
-Unannounced	25 (69.4)	6 (16.7)	5 (13.9)	6 (50)	3 (25)	3 (25)	19 (22.4)	4 (4.7)	5 (5.9)	13 (61.9)	6 (28.6)	2 (9.5)

*NH:* Nursing home; *C:* Compliant; *SC:* Substantially compliant; *NC:* Not compliant