THE INTRODUCTION OF HOME HAEMODIALYSIS IN THE MALTESE ISLANDS: A NEEDS ANALYSIS

Matthias Azzopardi

A dissertation presented to the Faculty of Health Sciences in part-fulfilment of the requirements for the Degree in Master of Science in Health Systems Management and Leadership at the University of Malta

Supervised by Prof. Sandra C. Buttigieg M.D.(Melit.), M.Sc.(Pub.Hlth.), M.B.A.(Exec.)(Melit.), Ph.D.(Aston), F.F.P.H.(UK), M.M.C.F.D

October 2025

M.Sc. in Health Systems Management and Leadership

The Introduction of Home Haemodialysis in the Maltese Islands

A Needs Analysis

Abstract

Chronic kidney disease is a major public health issue, with end-stage kidney disease patients requiring renal replacement therapy. In Malta, haemodialysis is exclusively hospital-based, creating pressures on bed capacity, accessibility and staffing. Home haemodialysis (HHD) may offer improved health outcomes and quality of life while relieving strain on the healthcare system, however, its feasibility and desirability in small island states remain largely unexplored. This study seeks to answer the question: To what extent is home haemodialysis feasible and desirable in a small island state within the European Union?

The research, guided by an interpretivist approach, employed a qualitative case-study design. Semi-structured interviews and focus groups with stakeholders were conducted, and the findings were analysed using established frameworks, to provide a multidimensional, person-centred understanding of feasibility and desirability.

The analysis revealed five key themes: quality of life and independence, safety and support, training and education, infrastructure and logistics, and sustainability and strategy. Data triangulation across stakeholder groups revealed perceived benefits and concerns, identifying barriers and facilitators.

The results indicate that stakeholders perceive home haemodialysis as both feasible and desirable, particularly for its potential to improve quality of life, autonomy, and system efficiency. However, concerns were raised regarding training requirements, psychosocial support, and infrastructural capacity. The study concludes that successful implementation in Malta will depend on careful planning, sustained investment, and supportive policy frameworks.

This dissertation contributes to the knowledge base on the introduction of person-centred dialysis care in small island states within the European Union, and its findings may serve as a basis for similar settings.

Dedication

To my fiancée, Jacqueline, my source of strength, patience, encouragement, and unwavering support throughout this journey. You have been my anchor and my greatest inspiration.

To my family, who from a young age instilled in me a love of learning and the drive to pursue knowledge.

And to all those living with kidney disease, whose courage, perseverance, and spirit in the face of challenges are profoundly motivating. You are a true testament to resilience and real heroes.

Acknowledgements

I would like to express my sincere gratitude to all those who have contributed to the successful completion of this dissertation.

Foremost, I extend my deepest appreciation to my tutor, Professor Sandra Buttigieg, for her continual guidance, invaluable support, and thoughtful feedback throughout the course of this study. Her expertise and mentorship have been instrumental in shaping this research.

I would also like to express my sincere thanks to all the members of the Department of Health Systems Management and Leadership, Faculty of Health Sciences, University of Malta, for their academic support and for fostering a learning environment that encouraged both critical inquiry and professional growth. I am also most grateful to Ms Norah Abela Briffa for her continual support and prompt assistance, which proved indispensable at various stages of the project.

Special thanks are due to Mr Reuben Formosa and Ms Charmaine Formosa, who not only acted as intermediaries but also offered constant encouragement, support, and valuable advice. I would also like to thank Mr Damian Baldacchino, a friend and colleague, for his helpful insights, which enriched the development of this dissertation.

My heartfelt thanks go to my family for their unconditional support and belief in my capabilities. In particular, I wish to acknowledge my fiancée, Jacqueline Eleonora Ek, for her remarkable patience, encouragement, and steadfast support throughout this academic journey.

I am also sincerely grateful to all members of staff of the Renal Unit and the Nephrology Division at Mater Dei Hospital, Malta, for their cooperation and assistance during the research process.

Finally, I extend my appreciation to all the participants of the study, without whom this research would not have been possible. Their willingness to contribute is genuinely appreciated and valued.

Table of Contents

Abbreviations

AI	Artificial Intelligence
CASP	Critical Appraisal Skills Programme
CEO	Chief Executive Officer
CKD	Chronic Kidney Disease
CORR	Canadian Organ Replacement Register
DPO	Data Protection Officer
ERN	European Reference Network
ERA	European Renal Association
ESKD	End-Stage Kidney Disease
EU	European Union
FREC	Faculty Research Ethics Committee
GBD	The Global Burden of Disease
GDPR	General Data Protection Regulation
HD	Haemodialysis
HHD	Home Haemodialysis
ICHD	In-centre Haemodialysis
IT	Information Technology
LMIC	Low- and Middle-Income Countries
MeSH	Medical Subject Headings
PD	Peritoneal Dialysis
PICOC	Population, Intervention, Comparator, Outcome, Context
PPIE	Patient and Public Involvement and Engagement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QOL	Quality of Life
RRT	Renal Replacement Therapy
UREC	University Research Ethics Committee

List of Tables

List of Figures

Chapter 1: Introduction

1.1 Background of the Study

1.1.1 Overview of Chronic Kidney Disease (CKD) and Renal Replacement Therapy (RRT)

Globally, healthcare systems are facing increasing pressures due to ageing populations and the rising incidence of non-communicable diseases (Ibraheem et al., 2025). Chronic Kidney Disease (CKD) is a significant public health challenge worldwide, affecting millions of individuals and exerting considerable pressure on healthcare systems. According to The Global Burden of Disease Collaboration (2020), CKD is among the leading causes of mortality, with prevalence rates continuing to rise due to risk factors such as diabetes, hypertension, and ageing populations. CKD is defined as a progressive loss in kidney function over time, with patients requiring renal replacement therapy (RRT) in advanced stages to sustain life (Levey & Coresh, 2012). RRT includes both haemodialysis and peritoneal dialysis, with haemodialysis being the more common modality. Haemodialysis typically takes place in a hospital or clinic setting, however there is a growing recognition of home-based therapy.

Home haemodialysis (HHD) offers an alternative opportunity for better flexibility, quality of life (QOL), and clinical outcomes, including fluid and blood pressure control (Rocco et al., 2015). HHD offers considerable advantages to patients, their caregivers, healthcare workers and hospital administrators (Bieber et al., 2021). HHD provides a solution to some of the challenges posed by End-Stage Kidney Disease (ESKD) by decentralising care, reducing hospital congestion, and enabling patients to receive treatment in the comfort of their homes (Walker et al., 2016). From a theoretical

perspective, HHD can be examined through the lens of Maslow's Hierarchy of Needs (Maslow, 1943). This suggests that human motivation follows a structured order, from physiological and safety needs to higher-level psychological, esteem and self-actualisation needs. Meeting these needs is crucial for patients to adapt to new treatment modalities such as HHD. Patients with CKD often have multiple comorbidities, requiring frequent hospital visits and specialist follow-ups. HHD allows them to adapt treatment to their physiological and safety needs. Christensen (2018) highlights the significance of systematically identifying performance and infrastructure gaps in order to ensure effective healthcare delivery.

HHD has been associated with better clinical outcomes, including improved fluid management, blood pressure control (Kraus et al., 2007), and reduced cardiovascular complications (Chan et al., 2015). Studies suggest that HHD reduces staffing, transportation, and infrastructure costs (Beby et al., 2016), potentially making it more cost-effective than in-centre haemodialysis (ICHD). The COVID-19 pandemic emphasised the importance of home-based care, which minimises patient exposure to infectious environments (Stern et al., 2020).

Despite these benefits, HHD remains underutilised in many regions, including Malta, where a centralised system of in-centre (hospital) haemodialysis (ICHD) predominates. By investing in HHD, health systems can free acute care spaces currently occupied by chronic patients, while also promoting improved clinical outcomes (Marshall et al., 2021). This positively impacts service providers by improving cost efficiencies, addressing workforce demands and nurturing environmental sustainability (European Renal Association [ERA], 2023). Person-

centred care principles emphasise the importance of adapting healthcare services to individual needs, preferences, and values (Tomaselli et al., 2020). In light of this, implementing HHD in Malta requires a deep understanding of stakeholder perspectives and a needs analysis that considers clinical, logistical, and psychological factors.

HHD is not without its challenges, and numerous variables need to be considered. These include patient training and education, infrastructure, equipment, medical support and safety, which need to be factored in (Schreiber et al., 2021). These needs may act as facilitators or barriers to the implementation of HD and can be categorised as subjective (patient-reported) and objective (externally observed) (Brindley, 1989); or felt (patients' and caregivers' necessities) and perceived needs (identified by the clinicians and policymakers) (Berwick, 1989). Facilitators must be in place and barriers overcome in order to ensure patient acceptance and system feasibility.

Implementing a new service such as HHD requires robust policy frameworks, infrastructure support, and patient education programs. Understanding the specific needs and barriers in the Maltese Islands is the first step in optimising service delivery and sustainability of healthcare reforms.

1.2 Statement of the Research Problem

The rising global prevalence of chronic kidney disease has increased the demand for renal replacement therapy (Morita et al., 2019). Bello et al. (2022) estimate that approximately four million people undergo dialysis, with haemodialysis comprising about 89% of this. According to the Renal Unit database (Malta & Gozo), 253 patients receive haemodialysis, while 88 undergo peritoneal dialysis. Spatial constraints due

to an ageing population, medical advancements, and staff shortages may lead to under-dialysis, increasing morbidity and mortality (Sever et al., 2021). HHD presents a viable alternative (Marshall et al., 2021).

Malta's healthcare system is dependent on a centralised, hospital-based dialysis (Baldacchino et al., 2019). The Renal Unit at Mater Dei Hospital has been reported to operate at or near full capacity, raising concerns about access, delays and sustainability (Calleja, 2019). Geographical limitations further impact patients living in remote areas, requiring frequent and costly travel for treatment. Dialysis places heavy demands on hospital resources (especially human resources), often leading to staff shortages.

HHD implementation in Malta faces structural and policy-related challenges, which can be analysed using the Donabedian Model of Healthcare Quality (Donabedian, 1966). This evaluates healthcare services based on three domains: structure (availability of resources and infrastructure), process (quality of care delivery and staff training), and outcomes (patient health and system-wide efficiencies). Applying the Donabedian model to HHD will identify key barriers and facilitators to its adoption.

HHD offers patients more autonomy and flexibility and improves psychological well-being (Antoun et al., 2023). It would reduce pressure on the central healthcare system and allows resources to be redirected elsewhere (Vanholder et al., 2017). Stakeholder readiness must be taken into consideration. Patients, caregivers, and healthcare providers must be engaged in the transition; therefore, a systematic evaluation of acceptance and feasibility is required (Sidani et al., 2009).

Introducing HHD in Malta requires evaluating stakeholder acceptance, infrastructure, resources, and technological support. A needs analysis assessing the feasibility and desirability of this service can help identify these factors.

1.3 Research Question and Objectives

The introduction of HHD is expected to be a cost-effective strategy that increases dialysis capacity while reducing staff workload. This study examines the perspectives of key stakeholders (i.e. those providing formal and informal care, receivers of care and management) to evaluate the feasibility and desirability of HHD, including benefits and barriers to its implementation. Healthcare providers, patients, and caregivers are mainly concerned with making HHD safe, affordable, and practical, ensuring users are well-supported, homes are adequately equipped, and everyone involved understands their roles (Khan et al., 2022). The research intends to provide stakeholder insights into the extent to which HHD may potentially enhance the quality of life and management of renal dialysis patients, improve patient outcomes, as well as assist in optimising operational efficiency of dialysis units within the Maltese healthcare system while also addressing the needs of those involved.

Person-centred care is a method of caring that prioritises the needs, preferences, and values of patients. It is an adaptive and respectful approach that empowers patients by involving them in the decision-making process about their treatment plans. This approach is an evolution of the foundational idea of patient-centred care, which recognises each patient as a unique individual (Tomaselli et al., 2020). Formalising person-centred care into policy documents may be a driver for reaching higher quality standards and safer health care (Tomaselli et al., 2020). A triangulated approach is

used to integrate qualitative insights from stakeholders with system-level assessments of infrastructure and policy (Yin, 2018).

The research seeks to answer the question: To what extent is home haemodialysis feasible and desirable in a small island state within the European Union?

Feasibility refers to the practical achievability of implementing a new service and takes into consideration factors such as resources, infrastructure, workforce capacity, cost-effectiveness, and operational sustainability (Bowen et al., 2009). Desirability relates to the extent to which the service is valued by stakeholders based on perceived benefits, acceptability, and alignment with their needs (May et al., 2018).

1.4 Study PICOC Framework

To structure the research, the Population, Intervention, Comparison, Outcomes, and Context (PICOC) framework (Table 1.1) is utilised in this study to provide a systematic approach to defining the study's scope and research parameters (Grant, 1994).

Table 1.1 - Study PICOC

Population	Patients with end-stage kidney disease (ESKD) in the Maltese Islands, with diverse support structures, who fall within predetermined inclusion criteria for recruitment of the study. Caregivers, healthcare personnel, management, and policymakers. Healthcare workers will include renal nurses, physicians, and technicians.
Intervention	Evaluation of stakeholders' perspectives and readiness for the introduction of HHD
Comparison	Between the current renal replacement therapy and the proposed HHD service Between the Maltese context and international counterparts Across socio-economic strata in Malta and Gozo
Outcomes	Stakeholder perspectives, expectations, and readiness for the transition to HHD measured using domains derived from the theoretical framework
Context	Renal replacement therapy service provided within the Maltese Islands, i.e., a small island state within the EU

This study aims to explore the perspectives of stakeholders regarding the feasibility and expectations of HHD in a small island state within the European Union. Using needs analysis, it systematically analyses two key principles of operations management: feasibility and desirability. Feasibility focuses on identifying practical solutions achievable within existing constraints and resources, aligning with the recognition that operations management decisions are conditioned by factors such as available capacity, system predictability, and business objectives (Wild, 1983). Desirability examines what should be accomplished in line with stakeholders' needs

and values, reflecting the broader call within responsible health innovation to engage stakeholders and align innovations with societal, ethical, and system-level priorities (Rivard & Lehoux, 2020). Using a needs analysis enables a structured investigation of both dimensions, addressing practical aspects as well as the ethical and social implications.

The objectives of the study are:

1. To explore the needs, readiness, and expectations of key stakeholders and identify what they consider feasible and desirable in the implementation of HHD.

2. To investigate, through triangulation of data sources, the extent to which stakeholders perceive the potential benefits, challenges, barriers and facilitators of HHD, and assess its feasibility from the standpoint of those responsible for implementation.

1.5 Significance of the Study

This study explores the links between health systems leadership and management, person-centred care, and health policy. The research addresses the gap in the knowledge base concerning the introduction of HHD in small island states, where healthcare accessibility and resource constraints present unique challenges. It does so by seeking practical solutions that can enhance dialysis accessibility. Recognising the intricate nature of the research problem, it makes use of both qualitative data and triangulation of that data to facilitate a well-rounded analysis to address this.

This research is intended to contribute to the body of knowledge on the feasibility and desirability of adopting HHD by examining how a small European Member State

with a population of approximately 550,000, characterised by distinctive infrastructure, geography, and culture, perceives the potential introduction of HHD therapy. This exploratory study may serve as a basis for more in-depth studies prior to the adaptation of the service in Malta and other countries of similar size and healthcare systems.

1.5.1 Contribution to Theoretical Knowledge

By integrating Maslow's Hierarchy of Needs, Christensen's Needs Analysis Framework, and the Donabedian Model of Healthcare Quality, this study provides a multi-faceted approach to understanding the introduction of HHD. Triangulating qualitative data with system-level assessments, ensures a comprehensive evaluation of HHD feasibility.

Classifying needs into objective and subjective (Brindley, 1989) and felt and perceived categories (Berwick, 1989) will enhance the understanding of how different stakeholders view the potential implementation of HHD. This contextualised research will contribute to broader discussions on how person-centred care can be effectively implemented in resource-constrained healthcare systems.

1.5.2 Implications for Healthcare Policy and Practice

The findings from this study seek to inform health policy decisions, workforce planning, and strategic healthcare investments within Malta and other similar small healthcare systems by evaluating operational feasibility, providing a policy roadmap for sustainable HHD integration and offering recommendations for training programs, addressing the workforce and caregiver support necessary for implementation.

This study aligns with global healthcare trends which promote decentralised, patient-centred, and cost-effective care (Rosengren et al., 2023). Successful implementation of HHD would enhance patient autonomy, reduce hospital congestion, and improve health outcomes, in line with EU objectives on healthcare sustainability (Pirhonen, 2020; European Parliament & Council of the European Union, 2021).

This study adopts a qualitative case study design based on interviews and focus groups; while offering rich, context-specific insights, the approach is limited by its reliance on self-reported perceptions rather than quantitative measures of cost or clinical outcomes.

1.6 Overview of the Structure of the Thesis

This thesis is organised into six chapters, each addressing a distinct but interrelated component of the research.

Chapter 1: Introduction provides the background to the study, states the research problem, and presents the research questions and objectives. It outlines the PICOC framework and explains the significance of the study in terms of theoretical contributions and implications for healthcare policy and practice.

Chapter 2: Literature Review critically evaluates existing literature on HHD, assessing its benefits, challenges, and stakeholder perspectives. The chapter explores theoretical underpinnings determining the conceptual framework that guides the study.

Chapter 3: Methodology describes the philosophical foundation, research design, and methodological approach. It sets out the data collection methods, sampling

strategy, analytical techniques, and ethical considerations, before concluding with a summary of the rationale for these choices.

Chapter 4: Results presents the findings derived from interviews and focus groups. The analysis is structured around five themes: quality of life and independence, safety and support, training and education, infrastructure and logistics, and sustainability, strategy and innovation. Stakeholder perspectives are compared across groups to highlight areas of convergence and divergence.

Chapter 5: Discussion interprets the findings in relation to the reviewed literature and theoretical frameworks. It considers the feasibility and desirability of HHD, identifies facilitators and barriers to its implementation, and explores policy, workforce, and economic implications. The chapter also reflects on the strengths and limitations of the study.

Chapter 6: Conclusions and Recommendations summarises the key findings and provides recommendations for policy, practice, and further research. It highlights the contributions of the study to knowledge, theory, and practice, and situates the findings within both the Maltese context and the wider international setting.

Together, these chapters provide a coherent and comprehensive examination of the feasibility and desirability of introducing home haemodialysis within a small European island state.

Chapter 2: Literature Review

2.1 Introduction

The literature review is a fundamental component of the research study, providing the researcher with an understanding of the existing knowledge, theories, and studies on the topic being investigated. The primary objective of the review is to review scholarly articles, books, and other relevant literature to gather, analyse, and critically assess the available data to contextualise the research and provide insights into the key factors influencing the introduction of home haemodialysis (HHD) in the Maltese Islands from a stakeholder perspective.

2.1.1 Scope and Objectives of Literature Review

This chapter will focus on literature examining the feasibility, desirability, and potential impact of implementing HHD in small island states like Malta. Specifically, the review will explore how stakeholder perspectives, including those of patients, healthcare providers, policymakers, and caregivers, affect the adoption and integration of HHD within the healthcare system. Additionally, the chapter will consider the implications of HHD on quality of life, patient outcomes, and overall healthcare system efficiency.

This literature review aims to:

- Assess the clinical, economic, and psychosocial impacts of HHD.
- Evaluate stakeholder perspectives, including patients, caregivers, healthcare professionals, and policymakers.
- Identify key barriers to and facilitators for HHD adoption in Malta.

- Explore global best practices in HHD and assess their applicability to Malta's healthcare system.

The literature review focuses on the following:

1. Home Haemodialysis and End-Stage Kidney Disease (ESKD) – An overview of HHD, its benefits, challenges, and its role in managing end-stage kidney disease (CKD).
2. Stakeholder Perspectives on Home Haemodialysis – Exploration of attitudes, perceptions, and concerns of various stakeholders, including patients, healthcare professionals, and policymakers.
3. Feasibility and Desirability of Home Haemodialysis – Discussion of the practical, logistical, and infrastructural considerations for implementing HHD in Malta, a small island state with unique healthcare system constraints.
4. Quality of Life and Patient Outcomes in Home Haemodialysis – Assessment of how HHD impacts patients' quality of life, mental well-being, and clinical outcomes compared to in-centre dialysis.
5. Home Haemodialysis in Small Countries – Examination of existing models and case studies of HHD implementation in other small countries to draw lessons applicable to Malta.
6. Healthcare System Implications and Policy Considerations – Discussion of the broader implications of HHD on the Maltese healthcare system, including cost-effectiveness, workforce training, and sustainability.

2.2 Literature Search

The literature review used elements of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) framework (Figure 2.1) to ensure a rigorous

selection and analysis of sources. A structured search strategy was implemented across PubMed, Scopus, Embase and Google Scholar databases, guided by predefined inclusion and exclusion criteria. Following an initial screening of titles and abstracts, full-text evaluations were conducted to assess relevance. PRISMA principles were applied to ensure reliability and reproducibility.

A systematic search strategy (Figure 2.1) using keywords and Boolean operators was employed. Only peer-reviewed articles published in English within the past ten years were included. With regard to relevance and design, studies were selected for their examination of feasibility, desirability, quality of life, clinical and economic outcomes, and stakeholder perspectives, particularly within small countries or resource-limited contexts, to ensure applicability to the Maltese healthcare setting. Both qualitative and quantitative designs were included, to combine clinical evidence with experiential and contextual insights.

The primary search terms included the following keywords and MeSH Terms:

- Home Haemodialysis
- End-Stage Kidney Disease or Chronic Kidney Disease
- Stakeholder Perspectives
- Needs Analysis
- Feasibility and Desirability
- Quality of Life
- Patient Outcomes
- Healthcare systems in small nation states (with a focus on Malta)

A critical review of the selected literature was then carried out, and articles were categorised based on their relevance to the research objectives. This review provides a comprehensive understanding of the challenges and benefits of introducing HHD in the Maltese Islands, helping to inform the study's findings and recommendations.

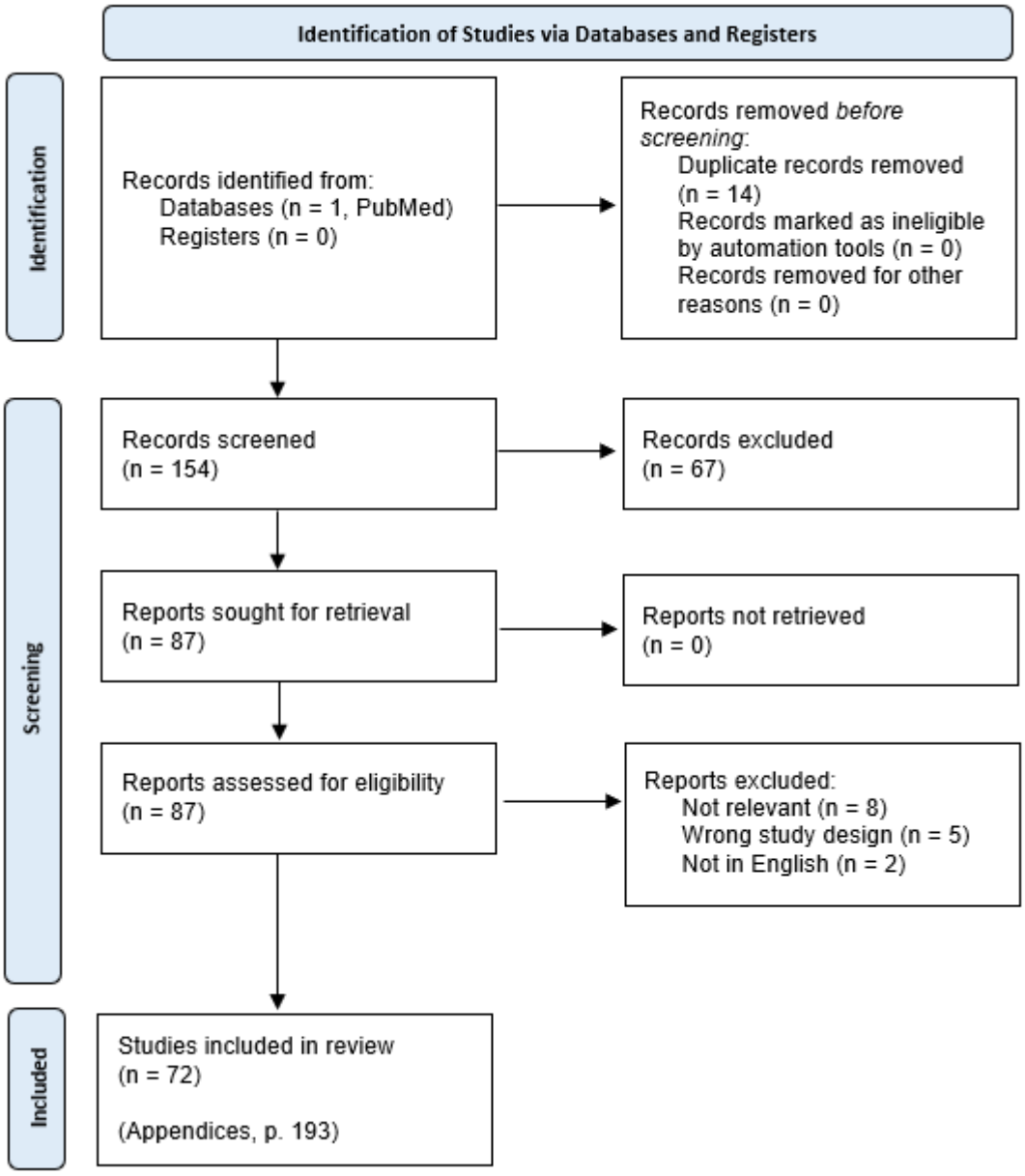

Figure 2.1 - PRISMA 2020 Flow Diagram (Page et al., 2021) for Study Selection

Table 2.1 - Inclusion and Exclusion Criteria for Literature Search

Category	Inclusion Criteria	Exclusion Criteria
Publication Type	Peer-reviewed journal articles	Non-peer-reviewed sources
Language	English	Non-English Publications
Timeframe	Published within the last 10 years	Studies published >10 years ago
Study Design	Both qualitative and quantitative studies (including mixed methods)	Studies with unclear on non-empirical methodology

Table 2.1 summarises the predefined inclusion and exclusion criteria applied in the literature search. These criteria ensured relevance, quality, and applicability of the reviewed studies to the Maltese context.

2.3 Home Haemodialysis: Benefits and Challenges

Chronic kidney disease (CKD) is a growing global public health concern, with a significant proportion of patients progressing to end-stage kidney disease (ESKD), requiring renal replacement therapy (RRT) (Karkar et al., 2015). Haemodialysis (HD) remains the most common form of RRT and is usually provided in hospital settings or satellite dialysis centres. However, HHD has gained increasing attention due to its clinical, economic, and quality-of-life benefits (Lavoie-Cardinal et al., 2021).

Small island states, including Malta, face unique healthcare challenges, including workforce shortages, geographical limitations, and resource constraints, which affect the provision of dialysis services. HHD presents an opportunity to reduce these pressures, yet its adoption remains limited due to stakeholder concerns, infrastructure barriers, and policy gaps (Thomas-Hawkins et al., 2022).

This literature review explores stakeholder perspectives on HHD implementation. Drawing upon international experience, it identifies the key facilitators and barriers.

2.3.1 Benefits

HHD has been associated with a range of clinical, physiological, and social benefits, which have led to its increasing advocacy among nephrologists and policymakers (Díaz-Buxó et al., 2015).

2.3.1.1 Clinical Benefits

Research indicates that HHD may be associated with improved clinical outcomes compared to in-centre haemodialysis (ICHD). The ability to undergo frequent and prolonged dialysis sessions at home leads to better blood pressure control (Kraus et al., 2007), reduced left ventricular hypertrophy (Friesen et al., 2015; Susantitaphong et al., 2012), and improved management of anaemia (Poon et al., 2015). Furthermore, frequent and extended dialysis improves toxin clearance and fluid management (Rodenberger, 2008; Karkar et al., 2015) and may result in lower hospital admission rates (Tennankore et al., 2021).

Studies show that patients who switch to HHD may report increased energy levels, reduced post-dialysis fatigue, and better overall well-being (Pérez-Alba et al., 2020). Individualised dialysis therapy contributes to an improved quality of life (Gedney &

Kalantar-Zadeh, 2018). From a cardiovascular perspective, more frequent dialysis sessions reduce the accumulation of uraemic toxins and improve cardiac function, decreasing the incidence of dialysis-induced hypotension and associated cardiac events (Chan et al., 2015). This is particularly relevant given that cardiovascular disease remains a leading cause of mortality among dialysis patients. Furthermore, patients undergoing intensive HHD have been found to experience improved biochemical outcomes and reduced antihypertensive medication use (Cherukuri et al., 2018).

Other studies note that the evidence base remains limited. Randomised trials are modest in number, while non-randomised studies are heterogeneous in design and prone to bias. Reviews indicate that home modalities provide outcomes and quality of life broadly comparable to in-centre dialysis (Quinn & Lam, 2023), with HHD showing possible associations with reduced cardiovascular risk, fewer hospitalisations, and quicker recovery. However, these findings rest on low-certainty evidence, and cost-effectiveness compared with in-centre haemodialysis remains uncertain (Cheetham et al., 2024).

2.3.1.2 Quality of Life

HHD improves autonomy and overall quality of life by allowing patients to dialyse at their convenience, significantly reducing travel and waiting times (Stewart et al., 2024). The flexibility in scheduling treatments allows patients to maintain employment, engage in social activities, and undergo personalised treatment regimens (Thomas-Hawkins et al., 2022). Additionally, improved sleep patterns and

reduced post-dialysis fatigue contribute to a better daily living experience (Wong, 2019; Weinhandl, 2021).

2.3.1.3 Cost Benefits

Economic evaluations suggest that HHD can be a cost-effective alternative to ICHD. While the initial setup costs for home dialysis infrastructure, including dialysis machines and water treatment systems, are significant, long-term savings are made through reduced hospital visits, lower medication requirements, and decreased transportation expenses (Weinhandl, 2021). Additionally, healthcare systems benefit from decreased pressure on dialysis centres and reduced demand for in-hospital dialysis slots (Thomas-Hawkins et al., 2022).

2.3.1.4 Development of Training Programmes

The successful implementation of HHD relies on the patient's suitability, which includes having adequate cognitive ability, manual dexterity, and support at home. To ensure patient safety and effective treatment, it is necessary to have structured assessment and training programmes before starting the HHD process. These will empower patients and their caregivers, equipping them with appropriate knowledge and skills and improving treatment adherence (Karkar et al., 2015; Stewart et al., 2024).

2.3.2 Challenges in Implementing HHD

Despite its benefits, the implementation of HHD is hindered by several challenges, including training demands, psychosocial concerns, financial constraints, and healthcare system limitations.

2.3.2.1 Training and Competency Requirements

Unlike in-centre haemodialysis (ICHD), which is managed by healthcare professionals, HHD requires patients to take responsibility for their treatment (Pérez-Alba et al., 2020). Research indicates that many patients feel unprepared for this responsibility, leading to increased reluctance to transition to home-based care. Structured education programmes and continuous remote support are essential for ensuring patient confidence (Power & Ashby, 2014; Hejazi et al., 2021). Caregivers also require adequate training to assist with dialysis sessions, highlighting the need for standardised training (Díaz-Buxó et al., 2015).

2.3.2.2 Psychosocial Factors and Patient Concerns

Patients would be used to healthcare workers setting up their cannulas in preparation for their in-centre haemodialysis sessions, and when considering HHD, they often express concerns related to self-cannulation (inserting a needle into one's own fistula), infection risk, and dialysis-handling complications (Power & Ashby, 2014; Thomas-Hawkins et al., 2022). Social isolation is another key issue, as patients lose the opportunity to interact with nurses, doctors and other dialysis patients at the dialysis centre (Eilers, 2018). The psychological burden associated with managing dialysis independently may lead to increased stress, anxiety, and non-adherence. Both patient and caregivers often experience emotional exhaustion and burnout due to the added responsibility of assisting with dialysis (Farzi et al., 2019; Hejazi et al., 2021), leading to increased stress levels within households. To mitigate these issues, psychosocial support services and respite care programmes should be integrated into HHD support systems (Bennett et al., 2015).

2.3.2.3 Economic and Logistical Barriers

HHD requires substantial financial investment, including costs associated with home dialysis machines, water treatment systems, and necessary home modifications. In healthcare systems where reimbursement schemes for home dialysis are limited, these expenses can be unaffordable for patients (Desbiens et al., 2024b). In addition to initial setup costs, ongoing expenses such as electricity, water consumption, and medical supplies further contribute to the financial burden on patients (Pérez-Alba et al., 2020; Lavoie-Cardinal et al., 2021).

Smaller nations and remote areas face supply chain constraints that impact the availability of dialysis equipment, consumables, and technical support services (Díaz-Buxó et al., 2015). Furthermore, workforce shortages, including nephrologists and dialysis-trained nurses, limit the capacity of healthcare systems to provide adequate home-based support (François et al., 2015).

2.3.2.4 Policy and Regulation

Policy plays an important role in determining HHD feasibility. Many existing healthcare policies favour ICHD, resulting in barriers that hinder the expansion of HHD programmes (Thomas-Hawkins et al., 2022; Desbiens et al., 2024b). Countries that have implemented structured financial incentives and transitional care programmes have demonstrated higher HHD adoption rates (Pérez-Alba et al., 2020; Lavoie-Cardinal et al., 2021). In regions where formalised policy frameworks for HHD are lacking, reforms are required to enhance accessibility, sustainability, and patient uptake (Power & Ashby, 2014; Karkar et al., 2015).

These findings highlight the clinical and psychosocial aspects of HHD, helping to address objective 1 on stakeholder needs and readiness, and providing a basis for assessing feasibility and desirability in line with the research question.

2.4 Stakeholder Perspectives on Home Haemodialysis

2.4.1 Patient and Caregiver Perspectives

Patients often prefer HHD due to its flexibility, improved health outcomes, and potential for better quality of life. However, self-management responsibilities, emergency preparedness, and social isolation remain significant barriers to widespread adoption (Power & Ashby, 2014; Thomas-Hawkins et al., 2022).

For caregivers, the improved clinical outcomes, autonomy gained, and reduced need for transportation and hospital appointments are seen as advantageous; however, the transition to HHD can be stressful (Hejazi et al., 2021). The increased responsibility for assisting with dialysis can contribute to burnout (Díaz-Buxó et al., 2015), emphasising the need for support services, including respite, counselling, and financial assistance to mitigate the psychological and economic strain (Desbiens et al., 2024b).

2.4.2 Healthcare Professional Perspectives

Research indicates that healthcare workers have reservations about prescribing HHD. While they recognise the clinical benefits of HHD, they expressed concerns about patient adherence, the need for training, and the availability of resources. (Pérez-Alba et al., 2020). Ensuring that healthcare providers receive adequate training in patient

education and remote monitoring is fundamental to promote HHD as a viable alternative to in-centre dialysis (François et al., 2015).

Workforce shortages in trained nursing staff pose additional challenges in supporting HHD programmes, particularly in small island healthcare systems with limited access to specialised care (Díaz-Buxó et al., 2015). Patients, caregivers and healthcare professionals are often concerned about complications that may arise during haemodialysis, including hypotension, infection, needle dislodgement, access clotting or fluid overload. Expanding telemedicine support and integrating remote patient monitoring technologies can facilitate improved HHD management and alleviate these concerns (Desbiens et al., 2024b).

2.4.3 Administrative Perspectives

Healthcare administrators must balance between costs and person-centred care, ensuring that sufficient resources are allocated for HHD training, equipment procurement, and necessary modifications to homes (Power & Ashby, 2014). Reimbursement models prioritising in-centre dialysis over home-based alternatives create financial disincentives, limiting HHD accessibility (Desbiens et al., 2024b). Addressing these barriers requires targeted policy interventions (Thomas-Hawkins et al., 2022) such as financial incentives for home dialysis uptake and subsidies for necessary equipment and utilities (Hager et al., 2019; Manns et al., 2019).

Efficient supply chains are critical for timely delivery of consumables, especially in isolated areas where equipment delays can disrupt treatment (Díaz-Buxó et al., 2015). Establishing dedicated HHD support teams can mitigate these challenges and improve operational efficiency (Morita et al., 2019).

By capturing patient, caregiver, and professional viewpoints, this literature supports objective 2 on stakeholder perceptions of HHD's benefits, barriers, and facilitators, and provides a bridge between the theoretical discussion and the data collected.

2.5 Analytical Review of the Literature

2.5.1 Critical Appraisal

To assess the quality of the studies reviewed, the Critical Appraisal Skills Programme (CASP) framework was applied, focusing on study design, sample size, data collection methods, and relevance to HHD research.

2.5.2 Study Design and Methodology

The studies reviewed utilised diverse research methodologies, ranging from randomised controlled trials (RCTs) (Palmer et al., 2014) to qualitative (Pérez-Alba et al., 2020) and mixed-methods approaches (Hanson et al., 2017; Reddy et al., 2024).

RCTs provide empirical evidence on HHD effectiveness, particularly concerning clinical outcomes and patient adherence and are instrumental in evaluating the impact of different dialysis modalities. However, randomised comparisons of HHD and PD with in-centre HD are difficult to carry out and the results are limited (Palmer et al., 2014; Quinn & Lam, 2023). Few RCTs directly compare home and in-centre haemodialysis, with most randomised data comparing treatment frequency. The 2024 Cochrane review rates certainty as low, and so comparative effectiveness remains uncertain (Cheetham et al., 2024).

Observational and retrospective studies also contributed valuable insights, particularly regarding long-term treatment adherence (François et al., 2015) and

survival rates among HHD patients, however, these were often limited by selection bias and confounding variables, necessitating further controlled trials to strengthen the evidence base (Pérez-Alba et al., 2020).

Qualitative research has provided an essential perspective on patient and caregiver experiences, uncovering barriers to HHD adoption such as training difficulties, financial concerns, and the psychological burden of self-administering dialysis (Power & Ashby, 2014). These studies highlighted the role of healthcare workers in decision-making (Walker et al., 2017), suggesting that structured education and remote support systems can enhance HHD uptake.

Mixed-methods approaches have been particularly useful in combining quantitative clinical data with qualitative patient experiences, leading to a more comprehensive understanding of HHD challenges and facilitators (Díaz-Buxó et al., 2015). These methodologies bridge the gap between clinical outcomes and real-world patient experiences, allowing for more person-centred policy recommendations (Pérez-Alba et al., 2020).

2.5.3 Sample Size and Generalisability

Sample sizes varied considerably across studies. Large-scale registry analyses, such as the study by Desbiens et al. (2024a), which found that overall survival was better for patients transitioning from peritoneal dialysis to haemodialysis when compared to incident haemodialysis patients, included 874 patients (from a total of 63,327 individuals on the Canadian Organ Replacement Register(CORR)) and examined diverse populations and demographic groups. However, despite their strengths,

large-scale studies may not capture nuanced patient experiences that qualitative research can provide.

Smaller qualitative studies, such as those conducted by Pérez-Alba et al. (2020), François et al. (2015) and those referenced by Díaz-Buxó et al. (2015), while offering in-depth patient and caregiver narratives, often lacked the statistical power required to extrapolate findings across wider populations, limiting their generalisability beyond the specific patient cohorts examined (Power & Ashby, 2014). Selection biases in qualitative research methodologies may impact the reliability of findings, necessitating complementary quantitative research (Pérez-Alba et al., 2020).

Perl et al. (2023) note that most research comes from high-income healthcare settings. Future research should examine larger samples to enhance external validity and ensure diversity in demographics and socioeconomic backgrounds. Expanding research to include more Low- and Middle-income countries (LMIC) will be essential in assessing the feasibility of HHD across varied healthcare infrastructures (Tomori et al., 2024).

2.5.4 Data Collection Methods

Data collection methods included patient-reported outcomes, interviews, clinical data, and remote assessment tools. Digital health technologies, including telemedicine, were integrated into study designs (Díaz-Buxó et al., 2015; Pérez-Alba et al., 2020). Studies relying on self-reported data are subject to recall and response biases, highlighting the need for objective clinical measurements in future investigations (François et al., 2015).

2.5.5 Relevance to Research Question

The reviewed literature addresses the key aspects of HHD, including patient perspectives, clinical outcomes, and the role of digital health. There remains a significant gap in administrative and policy analyses, limiting the understanding of HHD implementation (Power & Ashby, 2014).

Table 2.2 summarises the main findings from the key sources in the literature:

Table 2.2 – Key Literature Findings, Methodologies and Identified Gaps

Study	Country	Methodology	Stakeholders Engaged	Key Findings	Theoretical Foundation	Identified Gaps
Pérez-Alba et al. (2020)	Spain	Case Series / Pilot study (Clinical Outcomes)	Nephrologists, HHD Patients	Telemedicine-support HHD is feasible and may improve patient engagement	HHD may enhance patient autonomy and QoL, however evidence remains anecdotal	Need for broader studies on economic feasibility and clinical outcomes
Power & Ashby (2014)	United Kingdom	Narrative Review	HHD Patients, HCWs, Policymakers discussed	Patients prefer HHD but face barriers in training and support	No explicit theoretical model, person-centred care principles	Insufficient policy recommendations
Díaz-Buxó et al. (2015)	USA	Clinical Review (Home Dialysis Dosage)	Nephrologists, Patients undergoing HHD, Dialysis equipment manufacturers	Provides prescription guidance for HHD and notes potential benefits	Emphasis on individualised patient care, optimisation of dialysis therapy	Further validation required across diverse populations

Desbiens et al. (2024a)	Canada	Retrospective Observational Cohort / Registry-based Analysis (CORR)	Patients undergoing PD & HHD, Nephrologists, Nurses, Carers	Structured HHD programmes result in better survival but have similar hospitalisation risk	Person-centred care principles, integrated home dialysis model, Multidisciplinary approach	Limited evaluation of caregiver burden, generalisability outside Canada uncertain
François et al. (2015)	France	Mixed-methods (Healthcare Provider Perspectives)	Nephrologists, Dialysis nurses, Healthcare administrators	Healthcare professionals acknowledge benefits but highlight resource constraints	Healthcare provider perspectives, resource allocation and workforce training	Need for standardised HHD workforce training
Huang et al. (2019)	Canada	Multicentre, pilot, RCT (Cannulation Techniques)	HHD patients, Nephrologists, Dialysis nurses, Clinical researchers	Buttonhole cannulation does not reduce pain or complications	Feasibility, training, patient welfare, complications	Long-term impact on patient comfort remains unclear

Dubin & Rubinsky (2019)	USA	Digital Decision Support Tools	Patients with advanced CKD, Health educators	Modality decision tools enhance patient confidence in choosing HHD	Digital health framework, patient education, shared decision making, digital health and IT	Need for clinical workflow integration
Scarpioni et al. (2021)	Italy	Qualitative (Patient & Provider Views)	HHD Patients, Nephrologists, Dialysis Nurses	Social isolation and financial constraints hinder HHD uptake	Identification of barriers to HHD uptake	Common barriers are social isolation, financial constraints and caregiver burnout
Pungchompoo et al. (2016)	Thailand	Mixed-methods (Telehealth Feasibility)	Patients undergoing HD, Dialysis nurses, Caregivers	Telehealth increases accessibility, especially for elderly patients	Holistic care, framework for telehealth	Sustainability of remote monitoring needs assessment

Tennankore et al. (2021)	Canada	Prospective Cohort Study / Registry-based analysis (CORR)	HHD & PD Patients, Clinicians indirectly	Integrated home dialysis models improve clinical outcomes	HHD models to improve patient outcomes	Lack of long-term cost-effectiveness analysis
Usvyat et al. (2018)	USA	Retrospective Quantitative Analysis (Technology Integration)	HHD Patients, Clinicians indirectly	Telehealth interventions may improve adherence and effects on complications remain exploratory	Technological integration (including AI) to improve HHD outcomes	Limited research on AI-driven monitoring

Evidence indicates that HHD may offer clinical benefits, especially with frequent or intensive dialysis sessions. However, as highlighted by the recent Cochrane review (Cheetham et al., 2024), these advantages are supported mainly by low-certainty evidence from observational studies and small cohorts rather than large RCTs. The reported benefits, while encouraging, should be interpreted with caution given the limitations of the current evidence base.

2.5.6 Identified Gaps in Literature

1. Administrative and Policy Analysis: Most studies focus on clinical and patient-oriented perspectives, with limited discussion on healthcare policies, funding models, and regulatory barriers (Power & Ashby, 2014; Desbiens et al., 2024a).
2. Longitudinal Studies: Few studies have assessed the long-term clinical and economic impacts of HHD, particularly in terms of cost-effectiveness compared with in-centre haemodialysis (Pérez-Alba et al., 2020).
3. Caregiver Support: While patient experiences are well-documented, there is insufficient research on caregiver burden and strategies to mitigate emotional and financial stress (François et al., 2015; Desbiens et al., 2024a).
4. Diversity: The current literature focuses on high-income healthcare settings, necessitating research in low-resource and geographically isolated regions (Díaz-Buxó et al., 2015; Pérez-Alba et al., 2020).

Addressing these gaps is necessary for comprehensively understanding the impact of introducing and implementing HHD in a small EU island state like Malta. This insight will help shape effective policies and support systems to ensure HHD's long-term sustainability and accessibility.

Analysing methodological approaches and gaps in the literature justifies the study's chosen methodology in Chapter 3 and ensures alignment with the research aim.

2.6 Theoretical Framework

A theoretical framework serves as the foundation for understanding the key variables, relationships, and theories that support a research study. It provides a structured approach by which the research problem is examined, guiding the collection, analysis and interpretation of data. In this research, to explore the feasibility and desirability of implementing HHD in Malta, the theoretical framework integrates established models that explain patient adaptation, healthcare service quality, and stakeholder needs.

This theoretical framework serves as the analytical foundation for the study. It is grounded in three theories: *Maslow's Hierarchy of Needs* (1943), *Christensen's Needs Analysis Framework* (2018), and the *Donabedian Model of Healthcare Quality* (1966). The integration of these models provides a comprehensive understanding of stakeholder interests and enables a systematic evaluation of needs to enhance the delivery of healthcare services.

2.6.1 Theories Supporting the Study

2.6.1.1 Maslow's Hierarchy of Needs

Maslow's Hierarchy of Needs (1943) offers a framework for understanding how HHD addresses patient needs and the required conditions for implementing it successfully (Figure 2.2). Maslow's theory systemically analyses the factors influencing patient acceptance of the treatment. It posits that human needs are organised in a hierarchy,

starting with basic physiological and safety needs, followed by social, esteem and self-actualisation needs.

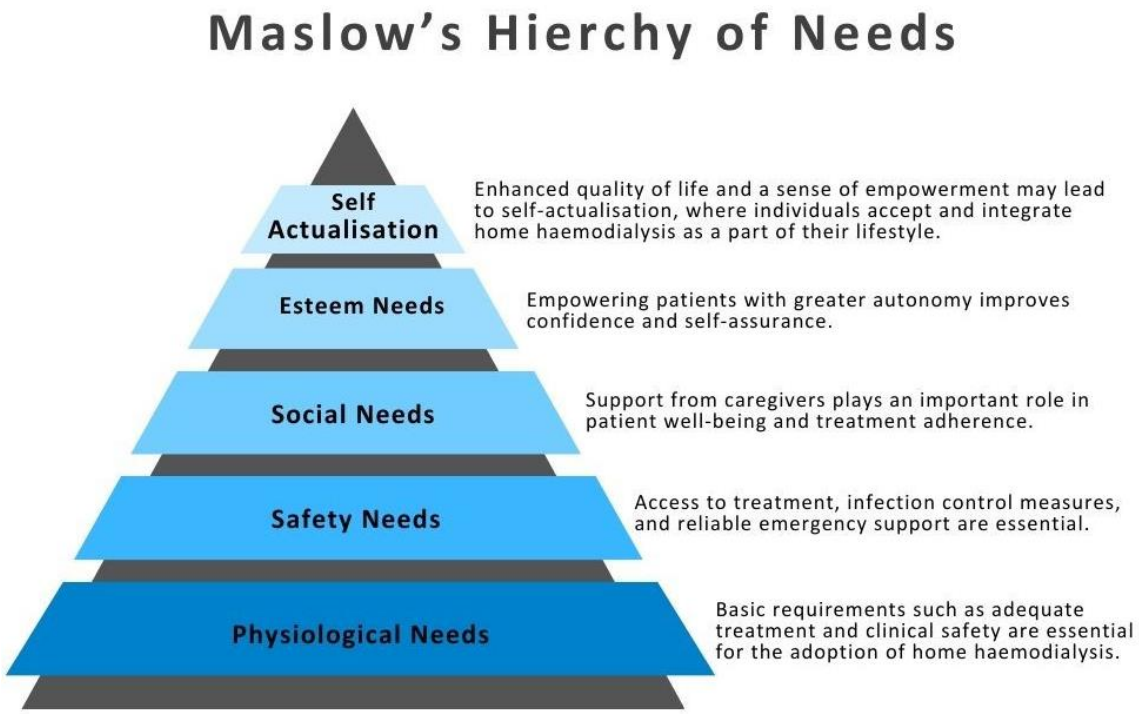

Figure 2.2 - Maslow's Hierarchy of Needs (Maslow, 1943), adapted for HHD

2.6.1.2 Christensen's Needs Analysis Framework

Christensen's (2018) framework (Figure 2.3) systematically identifies performance and infrastructure gaps that affect the adoption of healthcare innovations. This model is particularly relevant in understanding the factors influencing HHD implementation in Malta, where systemic challenges such as resource allocation, training availability, and policy must be addressed. This framework assesses readiness for HHD as a new service in Malta and identifies the necessary interventions to bridge existing gaps.

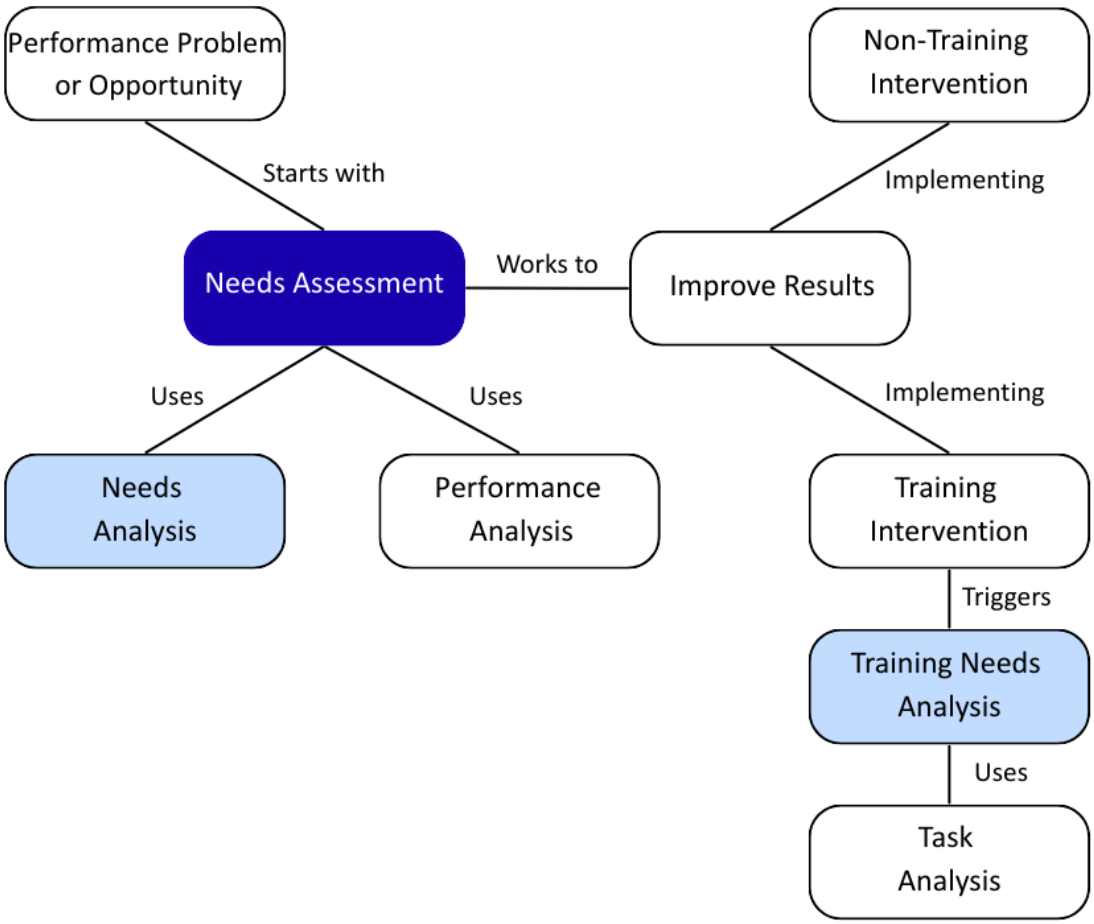

Figure 2.3 - Needs Analysis & Assessment Concept Map (Christensen, 2018)

Table 2.3 - Christensen's Needs Analysis Framework, Adapted for HHD

Objective Needs	Infrastructure, medical equipment, and healthcare professional support required for HHD implementation.
Subjective Needs	Patient perceptions of HHD benefits, fears, and attitudes toward home-based care.
Felt Needs	The extent to which patients and caregivers perceive HHD as a desirable alternative to in-centre dialysis.
Perceived Needs	Policymakers and administrators' understanding of HHD's potential benefits and challenges.

2.6.1.3 Donabedian Model of Quality

The Donabedian Model (1966) provides a framework for assessing healthcare service quality by examining three essential components: structure, process, and outcomes. This study applies the model (Figure 2.4) to evaluate the feasibility of introducing HHD in the Maltese Islands and examines the required structural and procedural elements to achieve optimal patient outcomes.

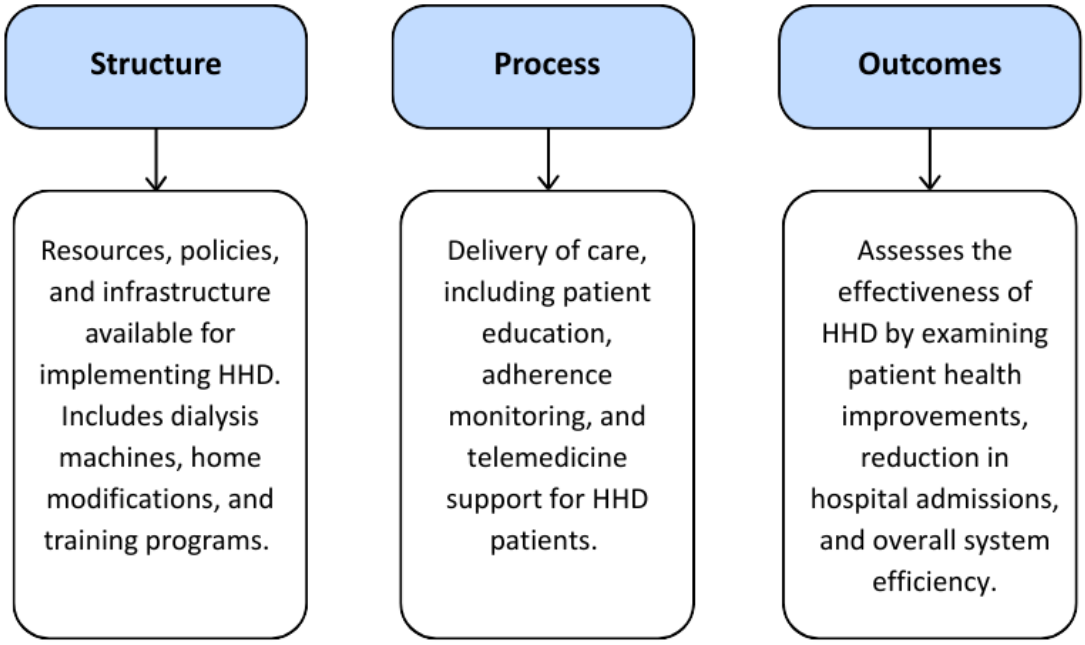

Figure 2.4 - Donabedian Model of Healthcare Quality, Adapted for HHD

2.6.1.4 Integrating the Theories into the Research Framework

The interplay between Maslow's Hierarchy of Needs, Christensen's Needs Analysis Framework, and the Donabedian Model creates a holistic approach to understanding HHD implementation.

The framework ensures that:

1. Patient needs are addressed – by applying Maslow's theory, the study assesses the psychological and physiological factors influencing patient acceptance of HHD.

2. Systemic barriers and facilitators are identified – Christensen's framework helps evaluate the gaps that may hinder or promote HHD adoption.
3. Healthcare Quality is measured – the Donabedian Model provides a structured way to assess service effectiveness and patient outcomes.

By integrating these models, the study ensures a comprehensive needs analysis for introducing HHD in Malta. This approach enhances the validity of the research and offers valuable insights for policymakers, healthcare providers, and patients considering HHD as a sustainable healthcare solution. Table 2.4 links the findings from the literature review to three key frameworks, showing how the studies relate to patient needs, goals, and healthcare quality.

Table 2.4 - Linking Theoretical Frameworks to the Reviewed Study Findings

Study	Maslow's Hierarchy	Christensen's Framework	Donabedian Model
Pérez-Alba et al. (2020)	Esteem, self-actualisation (independence, QoL)	HHD as disruptive adaptation	Structure: equipment; Process: remote monitoring; Outcome: improvement and feasibility
Power & Ashby (2014)	Safety, belonging (training/support barriers)	Functional & emotional jobs (support in training, preference)	Structure: home, training; Process: self-care, shared-decisions; Outcome: satisfaction, autonomy
Díaz-Buxó et al. (2015)	Physiological needs (adequate dialysis)	Incremental innovation with dose-adjustments, frequent schedules	Structure: prescription frameworks; Process: more frequent and longer sessions; Outcome: QoL and survival benefits
Desbiens et al. (2024a)	Safety, esteem (reduced admissions, better adherence)	Functional job (reduce hospitalisations)	Structure: dialysis frameworks; Process: integrated model for transition;

			Outcome: survival benefit, hospitalisation
François et al. (2015)	Safety, belonging (patient)	Organisational adaptation	Structure: workforce availability; Process: resources and training; Outcome: QoL, overcoming barriers
Huang et al. (2019)	Safety (risk management)	Incremental process	Structure: access devices, protocols; Process: cannulation (buttonhole vs stepladder); Outcome: pain, complications, infection
Dubin & Rubinsky (2019)	Esteem, self-actualisation (informed decisions)	Functional & emotional jobs (confidence in decision-making)	Structure: online platform; Process: interactive education; Outcome: improved knowledge, confidence
Scarpioni et al. (2021)	Belonging, safety (isolation, financial constraints)	Emotional job (reduce isolation, financial strain)	Structure: support, facilities; Process: provider-assisted dialysis;

			Outcome: barriers, feasibility, increased uptake
Pungchompoo et al. (2016)	Safety, esteem (accessibility for elderly)	Functional job (access care remotely)	Structure: telehealth infrastructure; Process: remote monitoring; Outcome: improved access
Tennankore et al. (2012)	Esteem, safety (improved outcomes)	Functional job (optimise transition model)	Structure: transplant registry, nocturnal HHD availability; Process: frequent HHD; Outcome: improved clinical outcomes, fewer hospitalisations
Usvyat et al. (2018)	Safety, esteem (adherence, fewer complications)	Functional job (monitoring); emotional (peace of mind)	Structure: telehealth system (Nx2me); Process: remote monitoring; Outcome: better adherence, fewer complications

2.6.2 Conceptual Framework

A conceptual framework provides a structured representation of the key concepts, variables, and their relationships within a research study. This framework serves as the foundation for understanding the factors influencing the implementation of HHD in Malta by integrating patient perspectives, healthcare system components, and stakeholder considerations.

2.6.2.1 Key Constructs and Their Relationships

The conceptual framework (Figure 2.5) for this study is structured around three major domains: person-centric factors, healthcare system factors, and policy and stakeholder engagement. These domains interact to influence the feasibility and desirability of HHD in Malta.

- Patient-Centric Factors – these factors pertain to the experiences, perceptions, and psychological considerations of patients undergoing dialysis. This domain is primarily guided by Maslow's Hierarchy of Needs.
- Healthcare System Factors – these factors examine the readiness, structure, and quality of healthcare services in supporting HHD adoption. The Donabedian Model of Healthcare Quality informs this domain, which includes:
    - Infrastructure and Resources – the availability of dialysis equipment, home modifications, and necessary support structures.
    - Healthcare Workforce Readiness – training, knowledge, and willingness of healthcare professionals to support HHD patients.
    - Process of Care Delivery – including patient training programmes, telemedicine support, and monitoring mechanisms for HHD patients.

    - Health Outcomes – clinical benefits, reduction in hospital visits, and potential for improved survival rates associated with HHD compared to in-centre dialysis.
    - Cost-Effectiveness – economic viability of HHD implementation, including financial implications for both patients and healthcare institutions.
- Stakeholder and Policymaker Engagement – stakeholder perspectives, including those of patients, caregivers, healthcare professionals, and policymakers, influence HHD adoption. Christensen's Needs Analysis Framework is central to this domain, which includes stakeholder perceptions, regulatory and policy frameworks, and barriers and facilitators to adopting the service.

The studies from the reviewed literature involved a range of stakeholders, including patients undergoing dialysis, nephrologists, dialysis nurses, and healthcare administrators. In line with Patient and Public Involvement and Engagement (PPIE) trends, patients were central to most investigations (Walker et al., 2015), reflecting a person-centred approach to exploring their experiences, preferences, and clinical outcomes (Power & Ashby, 2014; Scarpioni et al., 2021). While some studies employed qualitative methods to capture detailed narratives (Power & Ashby, 2014; Pungchompoo et al., 2016), others included patients primarily as subjects in quantitative research (Díaz-Buxó et al., 2015; Usvyat et al., 2018). Nephrologists and dialysis nurses featured prominently across studies, underlining their key role in clinical oversight and modality selection (Walker et al., 2017). Healthcare administrators and policymakers were less consistently represented but were integral to discussions on workforce capacity and care integration (Manns et al., 2019; Hager

et al., 2019). Caregivers, however, were noticeably underrepresented, appearing in only a limited number of studies (Walker et al., 2016), limiting the understanding of social and systemic factors influencing HHD uptake and sustainability.

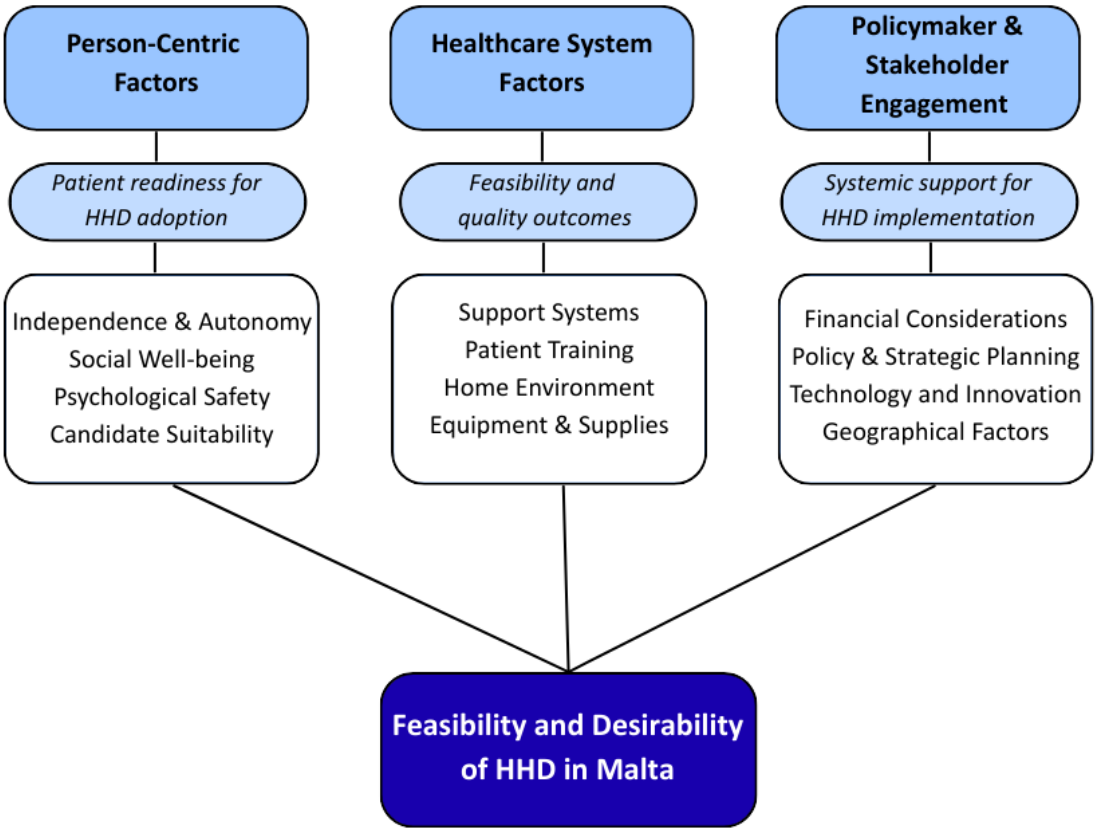

Figure 2.5 - Conceptual Framework for the Introduction of HHD in Malta

The three domains interact dynamically, where patient motivation, healthcare quality, and policy decisions collectively shape the feasibility and desirability of HHD in Malta.

Integrating Maslow's Hierarchy, Christensen's Needs Analysis Framework, and the Donabedian Model provides a structured framework for the research, guiding the analysis of feasibility and desirability and ensuring the objectives are addressed systematically, as discussed in Chapter 5.

Chapter 3: Methodology

3.1 Research Design and Approach

The research design is a qualitative needs analysis case study guided by interpretivism. It is driven by the aim of informing healthcare innovation in Malta and structured to gather qualitative evidence from those impacted by Home Haemodialysis (HHD) implementation. This design allows the researcher to remain flexible (e.g., adapting interview strategies or adding participants as new themes emerge) without compromising the depth required to make the findings meaningful for policy and practice (Berger & Luckmann, 2011).

3.1.1 Philosophical Foundation

This study makes use of an interpretivist approach, focusing on three areas: ontology (i.e., the nature of reality), epistemology (i.e., how knowledge is created), and axiology (i.e., the influence of values on research). Interpretivism seeks to understand the subjective meanings people give to their experiences (Saunders et al., 2023). It views reality as constructed through human interpretation, interaction, language, and culture, and aims to explore these meanings in depth (Bryman, 2015).

Ontologically, interpretivism takes a relativist view, recognising multiple socially constructed realities rather than a single objective truth (Guba & Lincoln, 1994). In healthcare, for example, the experience of HHD is influenced not only by clinical results but also by patients' personal histories, beliefs, and circumstances.

Epistemologically, knowledge is seen as co-created by researchers and participants and is not detached from the research process (Creswell & Cresswell, 2023).

Engagement with participants is required and qualitative methods are used to identify their perspectives (Saunders et al., 2023). The researcher acts as an empathetic interpreter, recognising that findings are shaped by the interaction between themselves and participants (Denzin, 2001).

Axiologically, interpretivism acknowledges that research is value-laden, and that these values influence the study (Guba & Lincoln, 1994). This research seeks to understand patients' perspectives of HHD in order to identify individual needs, producing rich, context-specific insights rather than universal solutions (Walker et al., 2015).

The interpretivist approach suits this study because it values the perspectives of those directly involved, accepts multiple interpretations, and generates knowledge grounded in lived experience.

3.1.2 Researcher Positionality

Qualitative researchers are encouraged to adopt strategies that minimise bias and enhance trustworthiness. Approaches such as reflexive journaling, peer debriefing, member checking, and triangulation are widely recognised as means of ensuring rigour in qualitative research (McLeod, 2024; Olmos-Vega et al., 2022; Saber, 2024; Turner & Jenkins, 2023).

In this study, the researcher acknowledged the potential for bias arising from their position as an insider researcher and nephrology specialist. To mitigate this, a reflexive journal was maintained throughout the study to track how personal perspectives might influence data collection and interpretation. Peer debriefing with colleagues was employed to challenge emerging themes and introduce alternative

viewpoints. Member checking allowed participants to review and confirm the accuracy of transcripts and interpretations, while triangulation across interviews and notes ensured that conclusions were supported by multiple sources of evidence.

3.1.3 Research Approach

The study employs a qualitative case study approach to carry out an in-depth, multifaceted exploration of the complex issue of introducing HHD within its real-life context (Crowe et al., 2011). The "case" in this research is the Maltese Islands' renal care system and its readiness for HHD – a fixed system within which various stakeholders interact. A qualitative case study is well-suited because it allows the integration of multiple data sources and perspectives to build a rich picture of the phenomenon (Crowe et al., 2011). In this study, multiple stakeholders (patients, nurses, doctors, technicians, administrators, and policymakers) were included as different data units within the single case of Malta's healthcare setting. This design aligns the notion by Yin (2018) of an embedded single-case study, wherein sub-units (stakeholder groups) provide insight into the overarching case (the national adoption of HHD).

The rationale for a case study was also driven by the exploratory and context-dependent nature of the research question *("To what extent is home haemodialysis feasible and desirable in a small island state within the European Union?").* Case studies are instrumental when asking *"how"* and *"why"* questions about a set of events over which the researcher has little control (Crowe et al., 2011). The case study approach enables the examination of feasibility (the practical requirements,

resources, and constraints in the local context) and desirability (the preferences, attitudes, and concerns of those involved) together.

By gathering data from multiple stakeholder groups, the study could triangulate perspectives (patients vs. providers vs. decision-makers) to achieve a comprehensive understanding. This design increases the study's practical relevance: insights are grounded in the real-world environment of a small island state, capturing nuances that purely quantitative or broad cross-country studies might miss. This approach acknowledges that the feasibility of HHD involves clinical, logistical, and policy dimensions - hence the necessity of input from patients, healthcare workers and administrators.

The use of only qualitative methods to explore stakeholder perspectives limits the study's ability to assess aspects of feasibility (such as cost, staffing, and resource requirements), which would require quantitative data beyond the scope of this research.

This study design supports objective 1 by exploring stakeholder needs and expectations and objective 2 by examining perceived benefits and barriers, while aligning with the overarching research question on feasibility and desirability.

3.2 Data Collection Methods

Interviews and focus group discussions were used as data collection methods to gather insights into stakeholders' perceptions and experiences. The discussions were semi-structured and guided by predefined questions, allowing for a natural flow of conversation with opportunities to probe for further details. This approach provided

the benefits of both structured comparability and open-ended discovery (Kallio et al., 2016). The interviewer utilised an interview guide (Appendices, pp. 228-237) to ensure key topics, such as knowledge of HHD, perceived benefits and challenges, and support needs, were consistently covered. Flexibility was maintained to explore unique insights from different stakeholder groups. Interviews typically lasted between 30 and 60 minutes and, with participant consent, were audio-recorded to ensure accuracy in later analysis.

3.2.1 In-Depth Interviews

In qualitative research, one-on-one interviews are widely recognised as a means of enabling participants to share personal experiences and opinions without external influence. This format is particularly valuable when addressing sensitive health-related issues, as it provides privacy and allows participants to discuss concerns openly (Jamshed, 2014). Open-ended questions are commonly used to encourage narrative responses, while active listening and probing techniques, such as follow-up questions, help clarify meaning and explore emerging themes in greater depth (DiCicco-Bloom & Crabtree, 2006).

In this study, one-on-one interviews were conducted with patients, healthcare workers, and policymakers. The individual interview format was especially beneficial for patients, as it allowed them to discuss concerns such as home treatment fears or caregiving burdens in a private setting. Open-ended questions encouraged participants to narrate their experiences in their own words, and the researcher applied active listening and probing techniques to clarify responses and examine issues in greater detail.

3.2.2 Focus Groups

Focus groups are a well-established qualitative method used to generate data through participant interaction. They allow individuals to exchange ideas, compare experiences, and consider alternative perspectives, making them useful for identifying both consensus and divergence within groups (Krueger & Casey, 2015). The moderator's role is to guide discussion using a semi-structured approach, encouraging participants to respond to one another rather than solely to the researcher, thereby producing richer insights. Audio recording and transcription are commonly employed to capture the full content of the discussions for later analysis.

In this research, focus group discussions were conducted with homogenous groups of participants, including dialysis unit nurses, general practitioners, and patients attending twilight sessions. The researcher acted as moderator, using a semi-structured guide to facilitate conversation and encourage interaction among participants. This approach allowed participants to reflect on each other's comments and provided insight into collective views. With consent, all focus groups were audio-recorded to ensure accuracy during subsequent analysis.

3.2.3 Interview Guides and Information Sheets

The development of interview guides in qualitative research is generally informed by research objectives and existing literature. Guides are intended to ensure that key themes are addressed while allowing flexibility for participants to elaborate (Kallio et al., 2016). Best practice recommends phrasing questions in clear, open-ended language to avoid leading responses and to promote narrative detail. Information sheets and consent procedures are also essential ethical components, as they provide

participants with clear explanations of the study, outline voluntary participation, and ensure informed decision-making (Turner, 2014).

In this study, the interview guides were designed around the study's objectives and drew on established research in home dialysis. Questions were organised to cover domains such as knowledge of HHD, perceived benefits and challenges, and required support. The guides were reviewed by academic experts, including the thesis supervisor and an external nephrologist, to enhance content validity. A pilot interview was also conducted with a non-participant dialysis patient, leading to refinements such as simplifying medical terminology and adjusting question order. Prior to data collection, all participants received detailed information sheets outlining the study's aims, procedures, and ethical safeguards. Consent was obtained in writing, including explicit permission for audio recording. Anonymity was maintained through pseudonyms (e.g., P1, P2), and participants were reminded of their right to withdraw at any stage.

Interviews with patients covered personal issues; if a participant displayed distress or hesitation, the interviewer offered to pause or skip a question, adhering to the principle of *"do no harm"* (Orb et al., 2001). In focus groups, the moderator ensured balanced participation and respectful dialogue, particularly when differing opinions emerged. Using both interviews and focus groups captures a wide range of perspectives, addressing both objectives by uncovering individual needs and readiness, while exploring collective views on feasibility and desirability.

3.3 Sampling Strategy

Purposive sampling is a widely used strategy in qualitative research because it enables the recruitment of participants who can provide information-rich insights into the research topic (Palinkas et al., 2015; Smith, 2024). Unlike random sampling, which seeks representativeness across a general population, purposive sampling identifies individuals who hold relevant knowledge and experience, making it especially suitable for studies examining complex healthcare issues. This approach is particularly valuable when engaging diverse stakeholder groups whose perspectives contribute to a comprehensive understanding of a phenomenon.

In this research, purposive sampling was applied to recruit participants from key stakeholder categories directly involved in or affected by HHD in Malta. Inclusion criteria focused on five groups: patients receiving dialysis care, renal unit nurses and technicians, nephrologists, healthcare administrators, and health policymakers. Each group was selected to ensure that perspectives on the feasibility and desirability of HHD were captured from clinical, managerial, and policy angles.

To incorporate caregiver perspectives ethically, anonymised surveys were distributed to avoid collecting identifiable information. In some cases, patients invited family members to contribute voluntarily during interviews through a patient-mediated consent process. Healthcare professionals were also interviewed and provided reflections on issues commonly raised by caregivers, adding further depth to the dataset.

Table 3.1 summarises the sampling approaches applied to each group.

Table 3.1 - Sampling Methods

Stakeholder Group	Sampling Methods	Application and Rationale
Dialysis Patients	*Purposive, Maximum Variation, Snowball*	Included adult patients with end-stage kidney disease on in-centre haemodialysis in Malta. Used criterion-based purposive selection (diagnosis and treatment modality) and maximum variation to capture diversity in age, gender, treatment duration, and home circumstances. Initial patient contacts were made via an intermediary; snowball sampling was also utilised, as participating patients recommended others who met the criteria (Palinkas et al., 2015; Smith, 2024).
Renal Nurses & Technicians	*Purposive, Maximum Variation, Expert*	Selected nursing staff and dialysis technicians from the main hospital's renal unit. Purposive criteria included at least one year of experience in dialysis care. Maximum variation sampling was applied to include a mix of roles and experience levels. Additionally, expert sampling was used by recruiting nurses recognised as knowledgeable about dialysis innovations (Etikan, 2016; Smith, 2024).
Nephrologists & Family Medicine Specialists	*Purposive, Expert*	Identified the small group of renal physicians and family medicine specialists in Malta's public health system. All doctors were considered experts due to their specialised

		qualifications and knowledge (Robinson, 2014).
Healthcare Administrators	*Purposive, Expert, Snowball*	Targeted health administrators involved in renal services or health system planning. Expert sampling was used in selecting decision-makers with oversight of dialysis programs. Snowball sampling was employed to reach additional relevant officials (Smith, 2024).
Policymakers	*Purposive, Expert*	Included officials at the national health policy level. Given Malta's size, few policymakers deal with renal or chronic disease services. Snowball sampling was used to reach additional relevant experts (Smith, 2024).

The above strategies reflect a combined purposive sampling approach, where multiple techniques were used to cover the stakeholder views in a comprehensive manner. Maximum variation sampling was important to capture the heterogeneity of experiences and opinions (Palinkas et al., 2015; Smith, 2024). By intentionally including a wide range of participant characteristics (different patient backgrounds and various professional roles, Table 2), the study could identify common themes across diverse groups as well as determine unique perspectives. This strengthens the transferability of findings – if a theme emerges consistently among such varied participants, it suggests a robust finding relevant to the broader population of stakeholders (Smith, 2024). Conversely, maximum variation also allowed the

detection of any outlier views (for example, if only a young patient with small children at home is optimistic about HHD while others are not).

Expert sampling was used to ensure that the data included highly informed voices on technical and policy matters (Etikan, 2016; Smith, 2024). For example, the input of a charge nurse or the director of nursing and midwifery provided information on institutional feasibility (budget, training programs) that patients or frontline staff might not fully know. By interviewing these experts, the study gained insights into system-level facilitators or barriers to HHD adoption that are essential for a complete needs analysis. Obtaining managerial and policymaker perspectives is important to understand organisational priorities, but risks introducing a elite bias towards administrative viewpoints. To mitigate this, the perspectives of end-users (healthcare workers and patients) were considered, providing insights into the practical implications of policy decisions.

Snowball sampling was effective in the small-country setting where professional networks are closely knit. After initial purposive recruitment (often starting with well-known contacts in the renal unit), the researcher asked participants (especially those in administrative or policy roles) to suggest other stakeholders who meet the criteria or who might offer a different viewpoint. This referral method helped reach individuals who were otherwise not immediately accessible to the researcher. For instance, a senior nurse mentioned a particular patient who had previously inquired about home dialysis – this patient was then invited to participate, enriching the patient sample. Snowball sampling is known to be effective for accessing “hard-to-reach” populations or busy experts by leveraging recommendations (Noy, 2008;

Smith, 2024). Ethical considerations were strictly upheld; participants were never pressured to divulge names, and those referred were contacted with the referrer's permission to ensure privacy.

Theoretical sampling was employed to guide the sampling and questioning process by iteratively adjusting who was interviewed (and what was asked) in order to fully represent the important concepts that were coming to light (Smith, 2024). Based on the emerging findings, participants with relevant experiences, such as nurses, patients and carers, were purposefully recruited. Early interviews identified key issues, and as the study progressed, interview questions were refined to focus on these themes.

For example, after interviewing a policymaker and administrator, *"the involvement of healthcare workers and general practitioners within the community"* surfaced as a key theme for feasibility. To explore this theoretically, an additional focus group session was arranged with a group of family medicine specialists working in the community (who had not been sampled initially) to discuss training needs in-depth – an application of theoretical sampling to fill an analytical gap based on emerging findings (Coyne, 1997; Smith, 2024). Similarly, when practice nurse interviews highlighted *"logistical implications"* as important, the researcher ensured that a question on logistics was asked to subsequently interviewed patients and clinicians. The sampling process continued until data saturation was reached within each stakeholder category – when new interviews no longer yielded novel insights but rather reiterated similar points. At that stage, recruitment was concluded.

The use of focus groups provided a setting to explore shared and contrasting perspectives through group interaction by identifying contextual insights, common concerns, and differing views (Farnsworth & Boon, 2010). The facilitator actively managed the group to ensure balanced participation, supporting and encouraging all members to contribute and addressing dominant voices when necessary. This approach ensured that a broad range of perspectives was captured, enhancing the credibility of the findings.

Saturation was determined when no new themes or insights emerged from the data and similar views were consistently expressed across participant groups. As interviews progressed, recurring topics, such as safety and the need for adequate training and support, began to appear regularly. Once these themes were repeatedly identified across different stakeholder groups and further data collection no longer added new information, saturation was considered to have been reached.

Subjects were contacted through two intermediaries, who facilitated the recruitment process and ensured that initial introductions were made in an ethical and structured manner.

Table 3.2 - Summary of Participants Interviewed

Category	Participants	Count
Patients & Caregivers	Haemodialysis patients (including home and in-centre)	5
	Peritoneal dialysis patients	3
	Patients nearing End-Stage Kidney Disease	1
	Focus group with dialysis patients	3
	Caregivers	3
Healthcare Workers	Specialist nurses (home dialysis, charge nurses)	5
	Biomedical technician & Operations Manager	1
	Nephrologists (consultant and trainee)	2
	General practitioners (focus group)	3
Policy & Administration	Senior hospital administrators and policymakers	3
Total		**25**

Due to Malta's small population and healthcare system, the sample size of 25 participants was considered appropriate to capture a broad range of stakeholder perspectives. While the study aimed for maximal variation within this context, future research could benefit from a larger sample from across other small states to obtain more comprehensive data.

Using various sampling techniques ensured diverse stakeholder representation, aligning directly with the study's objectives.

3.4 Data Analysis Techniques

The interview and focus group data were analysed using thematic analysis to identify patterns. All audio recordings were transcribed verbatim and the transcripts were cross-checked against the original recordings to ensure accuracy. Thematic analysis was conducted in a systematic manner following the iterative steps outlined by Braun & Clarke (2006). Initially, the researcher familiarised himself thoroughly with the content by reading the raw data multiple times while making preliminary notes. During this phase significant phrases, emotional tones, and emerging meanings were taken note of.

Next, an open coding process was undertaken. Using *NVivo* 12 software (QSR International) to assist with the analysis, the researcher coded segments of text that appeared meaningful to the research questions. A code in this context represents a label signifying a concept within the data. The coding process was primarily inductive, with codes generated from participants' own words and concepts rather than being imposed a priori, though it was also informed by the interview guide topics. For example, when a patient stated, *"I'd feel safer with a nurse around than doing it alone,"* that segment was coded under a concept such as *"safety concerns".* Another excerpt, such as *"home dialysis would save me the trip to hospital,"* was coded as *"convenience/independence".* Initially, several granular codes were created, as each meaningful unit of text was tagged. *NVivo* software was instrumental in this stage, allowing the researcher to highlight a quote and assign it to a node (a container for coded data in *NVivo*), thereby keeping all codes organised in a single repository (Woolf & Silver, 2017). This enabled the researcher to manage the substantial volume

of data efficiently and retrieve all excerpts associated with a given code for further analysis.

Related codes were then clustered into categories. The researcher examined the initial codes to identify higher-level patterns. For example, codes such as *"safety concerns," "self-sufficiency,"* and *"schedule flexibility"* all aligned with a broader category of *"Independence and Autonomy"*. *NVivo* facilitated this thematic clustering by organising the codes into a hierarchy (overarching themes and categories). Some codes were merged, while others were split if they encompassed distinct ideas (Wong, 2008). The researcher continuously moved between the raw data and the developing code structure, following Braun & Clarke's (2006) recommendation to review and refine themes by assessing whether the coded extracts meaningfully cohere and ensuring distinctiveness between themes (Smith, 2024). For instance, an initial theme labelled *"Infrastructure,"* which included codes on water supply and space for equipment, was later expanded into *"Infrastructure and Logistics"* to incorporate sub-themes such as home modifications, consumable supply logistics, and geographical factors.

Memo-writing was employed to track the development of themes, and memos were linked to nodes to document decisions regarding code definitions or how a participant's statement exemplified a theme (Wong, 2008). Once a stable set of themes was established, each was defined and named.

Thematic analysis enabled the researcher to move from raw descriptive data to an interpretive understanding of patterns. For instance, the analysis did not merely observe that some patients favoured HHD while others expressed fear, but also noted

that perceived self-efficacy and trust in medical support were important determinants of whether participants viewed HHD positively or negatively. Thus, the thematic structure provided a coherent and structured means of addressing the research questions.

NVivo software played a significant role in managing the data throughout the analysis process. All transcripts were imported into the program, enabling the researcher to query the data efficiently, such as searching for keywords across all interviews or using matrix coding queries to examine theme intersections across stakeholder groups to enhance analytical depth and ensure that interpretations were firmly grounded in the data (Wong, 2008). It is important to note that *NVivo* was only used as a research tool. The software assisted by systematically organising, searching, and cross-referencing the qualitative data, enabling the researcher to efficiently identify and explore connections between themes. All coding decisions, theme development, and interpretations were made by the researcher. As Woolf & Silver (2017) highlight, qualitative analysis software facilitates data organisation but does not replace the analyst's role in identifying meaningful patterns.

To enhance the validity of the findings, the study incorporated triangulation on two levels: data source triangulation and method triangulation. Data source triangulation was built into the research design, as data were collected from diverse stakeholder groups (patients, caregivers, healthcare workers and administrators). This enabled cross-checking of findings; for example, if patients expressed concerns about emergency management at home and healthcare professionals independently raised the same issue, it provided convergent evidence backing the *"Safety and Support"*

theme. Patton (1999) notes that using multiple data sources makes qualitative research more credible by corroborating findings from different viewpoints. Areas where stakeholder views diverged were also taken into account and factored into the analysis. For example, administrators perceived HHD as cost-saving, whereas patients expressed concerns about personal expenses.

To increase the robustness of the findings, a comparison of both methodologies (dual-method triangulation) was used by combining interviews and focus groups (Carter et al., 2014). Interviews provided personal insights, while focus groups revealed group dynamics and consensus-building. For example, while some nurses expressed concerns about increased workload during interviews, this issue also featured in group discussions, confirming it as a widely shared concern.

To further ensure analytic rigour, member checking and peer debriefing strategies were utilised. For member checking, a summary of the findings was shared with a small subset of participants (one from each stakeholder group) to review and provide feedback. Peer debriefing sessions with the research supervisor and colleagues provided external validation of the thematic structure, ensuring that the data supported the conclusions.

To ensure the quality and rigour of the study, established criteria of trustworthiness in qualitative research were applied. Following the framework proposed by Lincoln and Guba (1985), the study addressed credibility, transferability, dependability, and confirmability through a range of strategies. These measures strengthened the reliability of the findings and enhanced confidence in their interpretation. Table 3.3 summarises how each criterion was met in this research.

Table 3.3 - Rigour and Reliability in Qualitative Research

Traditional	Trustworthiness	Methods for Meeting Trustworthiness Criteria
Internal Validity	Credibility	Data triangulation was carried out by collecting perspectives from patients, caregivers, healthcare professionals, administrators, and policymakers through interviews and focus groups. Method triangulation included qualitative interviews, document analysis, and service statistics. Member checking was carried out by providing participants with summaries of their transcripts for confirmation.
External Validity	Transferability	A detailed description of Malta's healthcare context, dialysis services, and stakeholder experiences was provided to allow comparisons with similar small-island or resource-limited settings.
Reliability	Dependability	A consistent semi-structured approach was used for all interviews and focus groups.
Objectivity	Confirmability	Reflexive journaling and peer debriefing helped reduce bias. All interviews and focus groups were transcribed within 24 hours.

Thematic analysis supports the research aim by identifying and triangulating patterns across stakeholder groups, ensuring findings are systematically linked to the feasibility and desirability criteria.

3.5 Ethical Considerations

The study adhered to strict ethical protocols, aligning with the University of Malta's guidelines and general research ethics standards. Ethical approval was granted by the Faculty Research Ethics Committee, ensuring compliance with informed consent (Appendices, pp. 208-215, 238-255), confidentiality and legal regulations such as the General Data Protection Regulation (GDPR).

3.5.1 Informed Consent

All participants received an information letter outlining the study's aims and procedures. They were given ample time to review the information sheet before providing written consent. The voluntary nature of participation was emphasised, allowing individuals to withdraw without consequence. Two intermediaries were employed to select and contact participants and care was taken to prevent coercion when approaching patients and members of staff. Participants were also required to consent explicitly to recorded interviews.

3.5.2 Privacy and Confidentiality

Due to the sensitivity of the topics discussed, anonymity was prioritised. Participants were assigned pseudonyms (e.g., Patient 1, Nurse 2), which were used across transcripts and field notes. Any identifying details in interviews were omitted or generalised. The key linking real identities to codes was securely stored separately

from the research data. Digital files were encrypted and password-protected, while hard copies were stored in a locked cabinet accessible only to the researcher and supervisor. In line with GDPR, personal data were pseudonymised to prevent identification without access to a separate key (European Data Protection Supervisor, 2021).

3.5.3 Data Security and Storage

Strict data protection measures were implemented. Audio recordings were transferred to a secure drive and promptly deleted from recording devices. Coded transcripts and *NVivo* data were stored under password protection, avoiding cloud storage. Research data will be retained for two years in anonymised form. Only the researcher handled raw data, while the supervisor accessed anonymised versions for additional confidentiality.

3.5.4 Participant Wellbeing

The study recognised that discussing chronic illness could cause distress for patients and staff. Participants were given the option to skip questions or withdraw anytime, and the researcher monitored for any signs of distress, offering breaks if needed. Support resources, like counselling services, were available, though no one reported needing them.

For staff and administrators, confidentiality was also fundamental to ensure open discussions. Assurances were made that managers would not access recordings, and interviews were held privately.

3.5.5 Fairness and Respect

Stakeholders were treated as equals, and at the end of each session, participants were given an opportunity to clarify or add insights. Many requested to know how the research would be used, and they were informed that findings would contribute to a thesis and stakeholder report. Where requested, an executive summary of results was offered post-study completion.

3.5.6 General Data Protection Regulation (GDPR) Compliance

GDPR principles of data minimisation (collecting only necessary information), purpose limitation (using data solely for research), and security were upheld. Participants were made aware of their rights, including access to their data, correcting errors, and the option to withdraw until data analysis was complete. Although no one withdrew, the option supported participant autonomy.

3.6 Generalisability

Although the study focuses on Malta's healthcare system, the findings may be transferable to other small states or similar health systems. Malta's close collaboration with European counterparts, including its participation in European Reference Networks (ERNs), supports its relevance beyond the national context and the broader applicability of the research.

3.7 Strengths and Limitations of the Methodology

As with any research design, the chosen methodological approach carried both strengths and limitations that shaped the scope and interpretation of the findings.

This study employed a qualitative case study design, which was well suited to exploring the feasibility and desirability of HHD in Malta. The inclusion of multiple stakeholder groups enabled a broad range of perspectives and enhanced the credibility of the results. Using both interviews and focus groups provided complementary insights by combining individual experiences with group discussions. Anchoring the analysis in established theoretical frameworks further strengthened the interpretation and ensured a structured approach.

The approach also presented certain limitations. As a single case study, the findings may not be easily generalised beyond Malta or similar small island states. The cross-sectional design captured views at a single point in time, prior to the implementation of HHD, so results reflected expectations rather than lived experiences. The exclusive use of qualitative methods restricted the ability to measure cost-effectiveness or long-term outcomes, which would require quantitative or mixed-methods approaches. In addition, the relatively small sample size limited the breadth of perspectives, and responses may have been influenced by factors such as social desirability bias, despite measures taken to reduce this.

Overall, the methodological approach enabled a rich, context-specific understanding of stakeholder perspectives, while its limitations highlighted the need for further research using larger samples, longitudinal designs, and complementary quantitative methods as discussed in further detail in Chapters 5 and 6.

3.8 Summary of Methodology

This study employed a qualitative case study approach to explore the feasibility and desirability of HHD in Malta. Interviews and focus groups with patients, healthcare workers, and policymakers provided varied insights, which were analysed thematically to identify key concerns and benefits. The results, presented in the next chapter, reflect the diverse views captured through this method and provide a comprehensive understanding of what would be needed to introduce HHD successfully.

The methodological choices in this chapter align with the study's objectives and ensure that the data collected provide robust evidence to address the research question: to what extent is home haemodialysis feasible and desirable in a small EU island state?

Chapter 4: Results

4.1 Introduction

This chapter presents the findings of the study, addressing the research question: To what extent is home haemodialysis (HHD) feasible and desirable in a small island state within the European Union? The results are organised to reflect the study's objectives, beginning with an exploration of the needs, readiness, and expectations of key stakeholders, followed by an examination of their perceived benefits and challenges of HHD. Areas of alignment and divergence among stakeholder perspectives are highlighted, with particular attention to factors influencing viability and acceptability.

These findings are structured around the themes identified through thematic analysis of interview and focus group data. Comparisons between stakeholder groups highlight the perceived benefits and challenges that may influence the feasibility and desirability of HHD. These findings form the basis for the discussion in Chapter 5, where they are examined in relation to the literature and theoretical framework.

4.1.1 Study Participants

The participants were chosen from diverse backgrounds to ensure a comprehensive exploration of the subject being studied, in which expert opinions were triangulated with first-hand patient experiences. Each participant was assigned a unique code ('P' followed by a number) for pseudonymity. Table 4.1 presents an overview of the participants' roles, assigned codes, numbers, and years of experience.

Table 4.1 - Participant Roles and Demographics

Role	Participant Codes	Number	Experience
Nurses	P1–P5	5	10–38 years
Technician	P6	1	25 years
Doctors	P7–P11	5	8–19 years
Administrators	P12–P14	3	4–10 years
Patients	P15–P22	8	1–27 years
Caregivers	P23–P25	3	Not specified

4.2 Thematic Analysis

Using Braun & Clarke's (2006) thematic analysis approach, the transcripts were coded and grouped into categories and themes. The five main themes emerged from qualitative data analysis, reflecting key issues raised across stakeholder groups in relation to HHD.

- Theme 1: Quality of Life and Independence
- Theme 2: Safety and Support
- Theme 3: Training and Education
- Theme 4: Infrastructure and Logistics
- Theme 5: Sustainability, Strategy and Innovation

Figure 4.1 demonstrates the main themes and their corresponding subcategories that emerged from the thematic analysis.

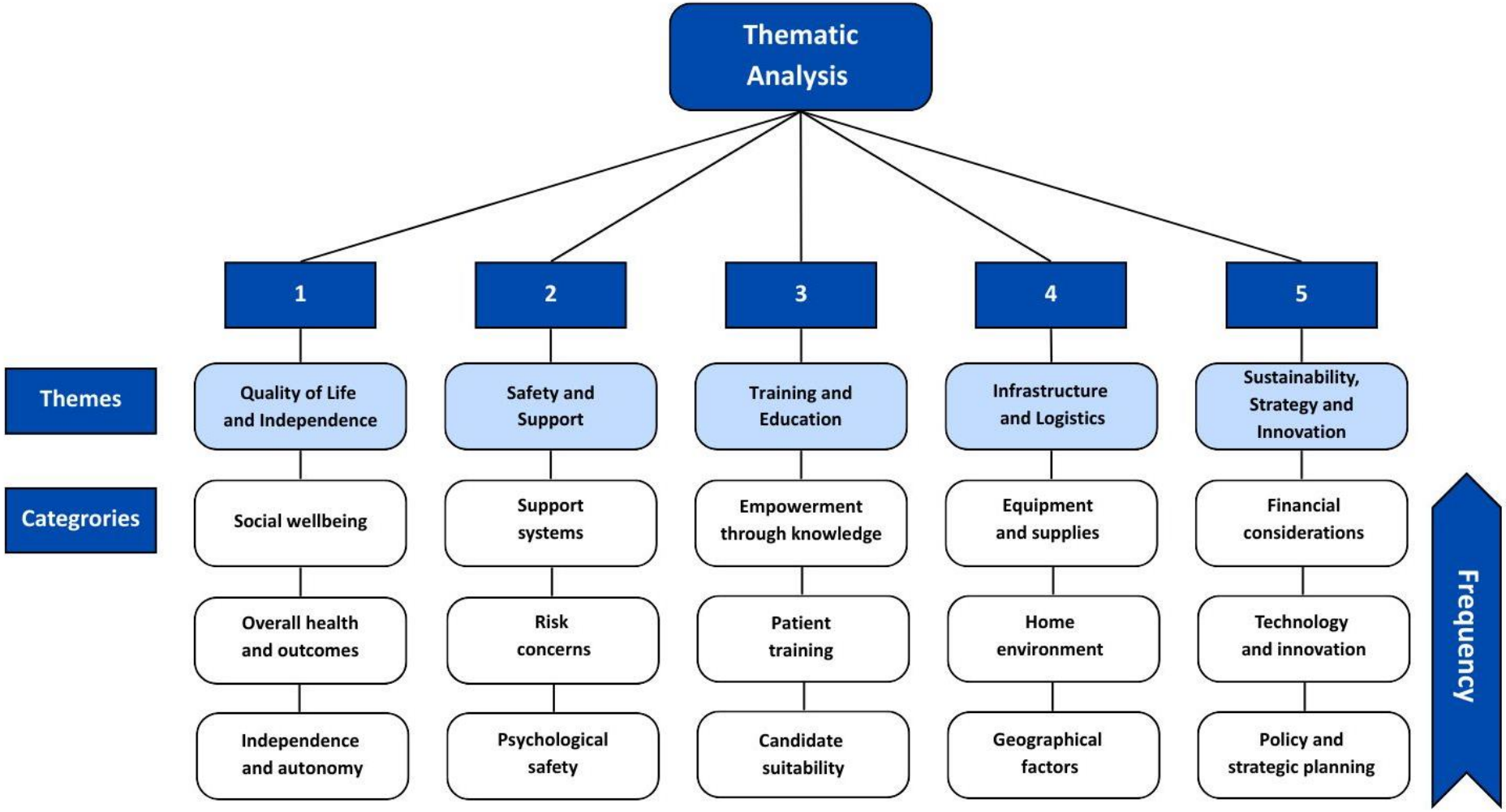

Figure 4.1 – All Themes and Categories Identified by Thematic Analysis

4.2.1 Quality of Life and Independence

One of the most frequently cited advantages of HHD was its potential to improve patients' quality of life (QOL) by increasing autonomy and flexibility. As one patient described, *"It would result in better quality of life … it's almost like living a normal life again"* (P19). Healthcare workers similarly noted that HHD allows patients *"to dialyse on their own at their own convenience and in the comfort of their home"* (P1). Patients and clinicians highlighted that home therapy would reduce the burden of frequent visits, allowing individuals to maintain employment, participate in social activities, and feel less constrained by dialysis schedules. Opinions on the social dimension of dialysis were mixed. Some patients expressed concern about missing the company of in-centre dialysis, while others preferred home-based treatment with a good support network.

Table 4.2 presents an overview of Theme 1, *Quality of Life and Independence*, outlining the key categories, codes, and participant quotes that demonstrate the impact of HHD on autonomy, social well-being, and health outcomes.

Table 4.2 - Theme 1 - Quality of Life and Independence

Theme 1: Quality of Life and Independence		
Category	**Code**	**Quote**
Independence and Autonomy Patients' ability to manage their dialysis on their own terms,	**Self-sufficiency** Ability to manage dialysis without reliance on direct clinical assistance	*"The main advantage of home haemodialysis would be to regain my independence"* (P4)

maintaining control over treatment and lifestyle		
	Convenience / Independence Flexibility to integrate treatment into personal lifestyle and preferences	*"Patients can regain control of their time … undergo treatment in the comfort of their own home"* (P13) *"No patient should be forced to take up home haemodialysis"* (P4)
	Schedule Flexibility Freedom to arrange dialysis sessions at convenient times	*"They'll have more flexibility to live their lives around dialysis rather than the other way around"* (P5)
Social Well-being How HHD impacts social connections and emotional support networks	**Social Dimension** Opportunities for social interaction and emotional support during in-centre dialysis sessions	*"Being at home may also help with mental health, avoiding the stress of hospital settings"* (P9) *"I like coming to the renal unit! I work from home coming here gives me a social and therapeutic aspect"* (P13)
	Travel & Appointments Time and energy spent related to travelling to	*"I had to stop working because the travel to and from dialysis was just too*

	dialysis facilities and clinic appointments	*much with the hospital transport schedule"* (P5)
Overall Health and Outcomes Medical outcomes from doing HHD as opposed to in-centre HD	**Health Outcomes** Medical condition from regular dialysis	"Patients report feeling generally healthier and more able to do daily activities." (P13)
	Complications & Hospital Admissions Reduced incidence of adverse events and need for hospital care	*"Clinically, we've seen patients on home haemodialysis have better fluid control and fewer hospital admissions"* (P1)

Social Well-being was the most frequently mentioned category within Theme 1, followed closely by *Overall Health and Outcomes*, while *Independence and Autonomy* was discussed less often but still featured prominently in participants' accounts.

Figure 4.2 illustrates the frequency with which each category was mentioned, showing their relative prominence in the data.

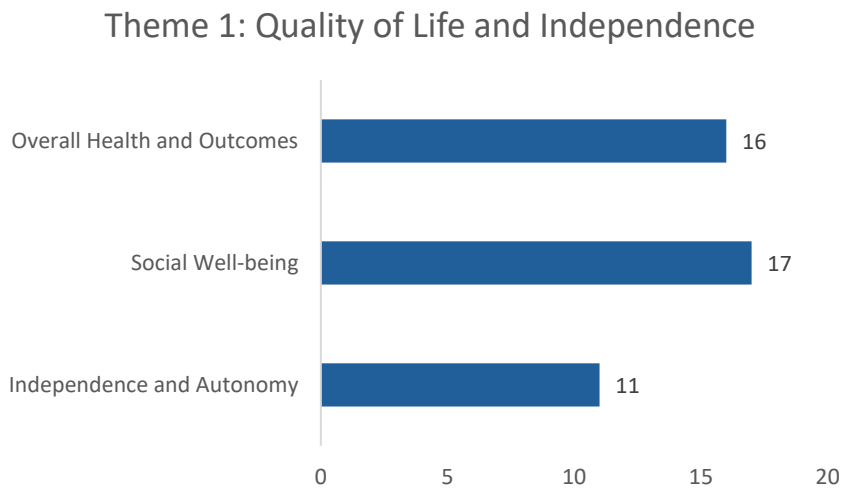

Figure 4.2 – Theme 1: Quality of Life and Independence, Category Frequency

This theme addresses objective 1 by highlighting needs and expectations for autonomy, while also linking to objective 2 by showing that Quality of Life improvements are important perceptions of desirability.

4.2.2 Safety and Support

Many patients expressed concerns about the safety of self-managing dialysis without professional supervision. Fear and the need for support emerged as a dominant theme. One patient stated, *"Needling a fistula is not an easy job!"* (P16). Many participants acknowledged that while HHD requires confidence in self-care, not all patients feel equipped for that responsibility.

Some patients described their fear of handling medical emergencies alone. *"During dialysis, things can change quickly… blood pressure drops, dizziness, or worse… At home you'd have to manage it yourself, and that's a big risk,"* (P15) one patient explained. Healthcare professionals emphasised the need for reliable support systems to address these concerns. One nurse remarked, "*Full support would be required 24/7"* (P3). Patients would need immediate access to on-call nurses or

technicians in case of complications, caregivers wanted to be present during dialysis sessions to provide assistance, while healthcare workers acknowledged that additional support could ease the transition for new patients.

Table 4.3 outlines the categories, codes, and quotes relating to Theme 2, *Safety and Support*, highlighting the concerns and psychological factors determining the stakeholders' perceptions on HHD safety.

Table 4.3 - Theme 2 - Safety and Support

Theme 2: Safety and Support		
Category	**Code**	**Quote**
Support Systems Mechanisms in place to assist patients in safely managing treatment at home	**24/7 Patient Support** Continuous access to medical assistance at any time	*"a 24-hour on-call system for patient support is needed … patients need to know that someone is available 24/7 if they run into problems"* (P1)
	Remote Monitoring Ongoing oversight of treatment through technology	*"It's reassuring for patients to know someone is keeping an eye on them even though they're at home"* (P14)
	Emergency Protocols Clear procedures for responding to urgent complications	*"A strong backup system is essential. Without it, patients will lose confidence in the program"* (P6)

Risk Concerns Potential issues that may happen when undergoing HHD	**Self-care Difficulty** Challenges in independently performing dialysis tasks	*"Some patients struggle with the idea of doing it all themselves, it can be overwhelming at first"* (P1)
	Caregiver Presence Need for a trained partner to assist with treatment and monitor patient	*“Family involvement is crucial in Malta. Decisions are often made collectively”* (P2)
	Safety Concerns Concerns about the risks of treatment without direct medical supervision	*"I worry about something going wrong when I’m alone"* (P5)
Psychological Safety Emotional and mental readiness to perform dialysis	**Fear of the Unknown** Anxiety about new or unfamiliar treatment	*“A main obstacle to uptake is the fear of the unknown”* (P1)
	Fear of Causing Harm Concern about making errors that could impact	*“Some patients or families may not feel comfortable with this responsibility”* (P11)

	health and treatment efficacy	*"No matter how much training I get, I don't see myself doing it"* (P21)

Figure 4.3 shows that *Support Systems* was the most frequently discussed category within Theme 2, showing that having support available is perceived as the most important factor for safe HHD. *Risk Concerns* and *Psychological Safety* were mentioned less often but still represented a substantial portion of participants' feedback.

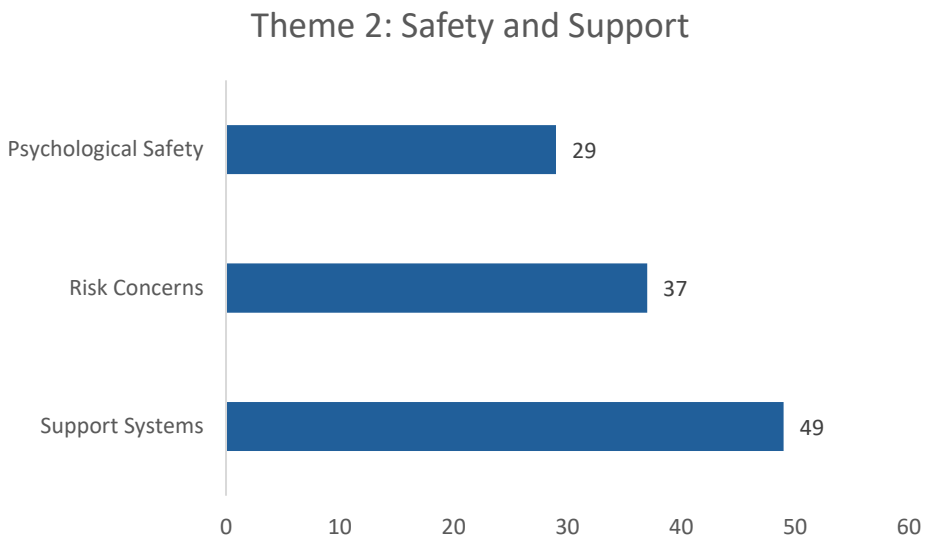

Figure 4.3 - Theme 2: Safety and Support, Category Frequency

The emphasis on safety concerns and the need for support structures connects objective 1, by reflecting stakeholders' readiness, with objective 2, by capturing views on feasibility.

4.2.3 Training and Education

Comprehensive training was universally recognised as essential to the success of a HHD programme. Closely linked to the safety and support theme, this theme focuses

on equipping patients and their caregivers with the necessary skills and knowledge for home dialysis.

Patients open to HHD often stated that they would only feel comfortable pursuing it if provided with extensive training**.** One patient who had experienced HHD abroad described how structured training and home visits gave them the confidence to manage their treatment independently. Healthcare professionals provided insight into existing training models. One specialist nurse explained that *"training for home haemodialysis is three weeks of theory and six weeks of practice"* (P2).

Focus groups with healthcare workers further revealed that general practitioners (GPs) and non-specialist nurses would also require education about HHD to provide better community-based support. One GP admitted, *"If HHD becomes common, we'd need to know how to guide patients and when to refer or intervene"* (P11). Policymakers echoed the need for structured training, suggesting the development of a standardised programme and certification for home dialysis patients. As summarised by a nurse, *"Patients need to be well-prepared and educated on what to expect. Information-giving and teaching are very important"* (P1). The overwhelming consensus was that education and training were the most effective ways to mitigate concerns about HHD implementation.

Table 4.4 presents the categories, codes, and quotes for Theme 3, Training and Education, outlining the personal attributes, training processes, and knowledge-building strategies that facilitate HHD implementation.

Table 4.4 - Theme 3 – Training and Education

Theme 3: Training and Education		
Category	**Code**	**Quote**
Candidate Suitability Personal attributes that make patients suitable for HHD	**Motivated to Self-Manage** Individuals keen on managing their own treatment	*"Younger patients tend to be more open to change"* (P3) *"Some patients are too comfortable with hospital care"* (P12)
	Adequate Cognitive Ability Capacity to understand and remember treatment procedures	*"Patients need to be physically and mentally stable"* (P3)
	Manual dexterity Physical ability to handle needles, equipment, and connections	*"Courage and dexterity [are] required for home haemodialysis"* (P16)
	Comfortable with Technology Confidence in operating dialysis machines	*"Some patients may be uncomfortable with medical equipment in their homes for cultural or personal reasons"* (P19)

Patient Training Education and practical preparation for HHD	**Structured Training** Formal programme, providing knowledge and skills, both to patients and staff	*"Training of home haemodialysis should include at least 3 weeks of theory and 6 weeks of practice"* (P1) *"Start with a small, well-selected cohort to refine the system"* (P11)
	Ongoing Assessment & Supervision Regular checks to maintain competence and safety	*"Staff need ongoing refresher courses to maintain competency and keep up with new technology"* (P3)
	Caregiver Training Instruction for partners or family members assisting with dialysis	*"Patients and caregivers need full technical training and also how to manage complications"* (P16)
Empowerment through Knowledge Building confidence through learning skills and peer support	**Education to Overcome Fear** Information and practice to reduce anxiety about HHD	*"Training should cover not just the machine, but water treatment systems and infection control"* (P18)
	Providing Information Access to clear and relevant guidance	*"Patients must be taught how to identify and respond to issues"* (P9)

	Peer Support Learning from the experiences of other HHD patients	*"Talking to someone who's been through it makes such a difference … they understand in a way no one else can"* (P5)

Figure 4.4 shows that *Empowerment through Knowledge* dominated discussions within Theme 3, exceeding the frequency of *Patient Training* and *Candidate Suitability*. It was the most commonly mentioned category across all five themes, underscoring the importance of education in building patient confidence for HHD. Participants perceived the provision of knowledge as the most critical enabler for treatment at home.

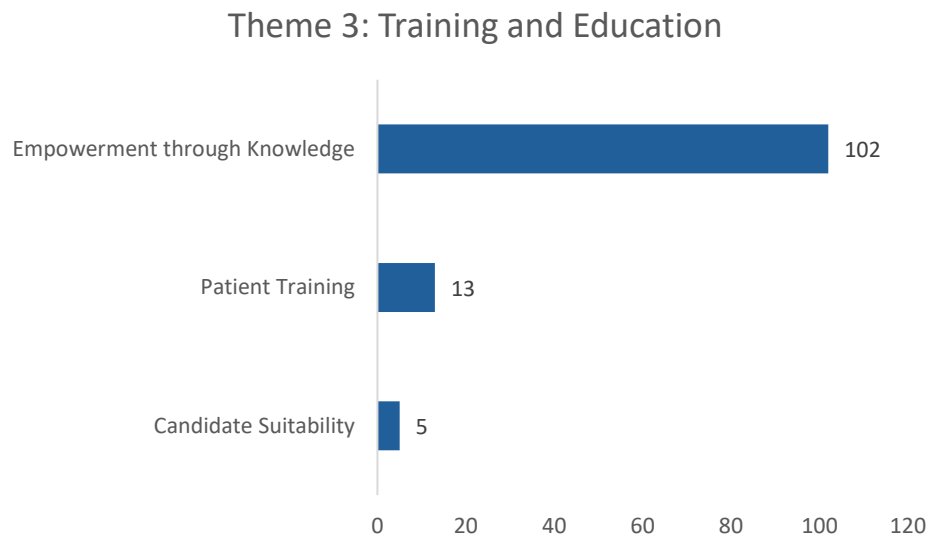

Figure 4.4 - Theme 3: Training and Education, Category Frequency

The findings on the training needs of stakeholders address objective 1 on readiness and expectations and objective 2 on perceived barriers to implementation, demonstrating that structured education is a requirement for feasibility.

4.2.4 Infrastructure and Logistics

Practical requirements such as storage space, plumbing, and equipment for HHD formed another important theme. The *“lack of space in Maltese homes"* was frequently mentioned as an issue, with one patient commenting they had *"no space to store the equipment”* (P7), reflecting concerns about finding room for dialysis machines and consumables.

Additional infrastructure needs included water supply modifications, electrical capacity upgrades, and infection control considerations. A healthcare professional noted, *“Upfront costs are quite high… plumbing, electricity, buying the necessary equipment”* (P6). Some administrators noted that not all homes would be suitable for HHD without modifications and that pre-assessments should be conducted to determine feasibility. Another logistical issue frequently raised was waste management**.** Dialysis generates clinical waste, including needles and dialyser cartridges, requiring proper disposal mechanisms. One participant stressed, *“Disposal of waste products, especially sharp objects such as needles”* (P3) must be planned for in advance.

Some interviewees commented that there was no need for HHD in Malta because travel distances to dialysis centres are not long. However, other participants saw the country's small geographic size as an advantage. One administrator noted, *"The short travel distance between patients' homes and the hospital is actually advantageous should home haemodialysis be introduced"* (P12) since patients can seek medical advice quickly should they need, demonstrating that while infrastructure concerns are significant, there are also benefits to the layout of the Maltese islands.

Table 4.5 summarises the categories, codes, and quotes relating to Theme 4, Infrastructure and Logistics, including the environmental, supply-related, and geographical considerations influencing the uptake of HHD.

Table 4.5 - Theme 4 – Infrastructure and Logistics

Theme 4: Infrastructure and Logistics		
Category	**Code**	**Quote**
Home Environment Suitability of the patient's living space for HHD setup	**Home Modifications** Changes to the home to accommodate HD equipment	*"Homes must be machine-ready, with water solutions and 24/7 support"* (P1)
	Lack of Space Insufficient room for storing machines and supplies	*"Lack of space in Maltese homes… no space to store the equipment"* (P17) *"Maltese homes are too small for equipment and waste storage"* (P25)
	Utilities Includes water and electricity expenses, subsidies and other related issues	*"Frequent power cuts could disrupt home dialysis sessions."* (P15)
Equipment and Supplies	**Bulky Supplies**	*"The amount of equipment can be a*

Management of HHD-related materials in the home	Large volumes of equipment and materials that require storage	*shock at first … it's not just the machine"* (P1)
	Waste Disposal Issues Challenges in discarding used materials	Referring to peritoneal dialysis disposables: *"It's surprising how much rubbish there is … I fill the wheelie bin on my own some weeks"* (P19)
	Delivery of Supplies Coordinating regular delivery of supplies	*"You've got to find somewhere to keep all the boxes. They deliver a month's worth at a time"* (P16)
Geographical Factors Location-based access influencing the practicality of HHD	**Hospital Proximity in a Small-sized Country** Geographic advantages and limitations affecting transportation and service provision	*"Patients chosen for home haemodialysis must have the required logistics to make use of the service"* (P13)
	Alternative Dialysis Units Smaller decentralised centres as alternatives	*"I'm only 3 minutes away from my satellite centre in the UK, which helps a lot, but in Malta, that kind of accessibility isn't always there"* (P18)

		"I'm not convinced that home haemodialysis is the best use of our resources in Malta. I think there might be better ways to improve dialysis services, like expanding renal unit or setting up satellite units" (P15)
	Emergency Accessibility Reliable means to reach hospital if urgent care is needed	*"Patients must be able to recognize warning signs and seek help promptly. Telemedicine could be a useful tool for providing remote support, but clear protocols are needed"* (P14)

Figure 4.5 shows that *Equipment and Supplies* was the most frequently mentioned category within Theme 4. Practical considerations such as storage space, delivery logistics, and waste disposal were major concerns for participants.

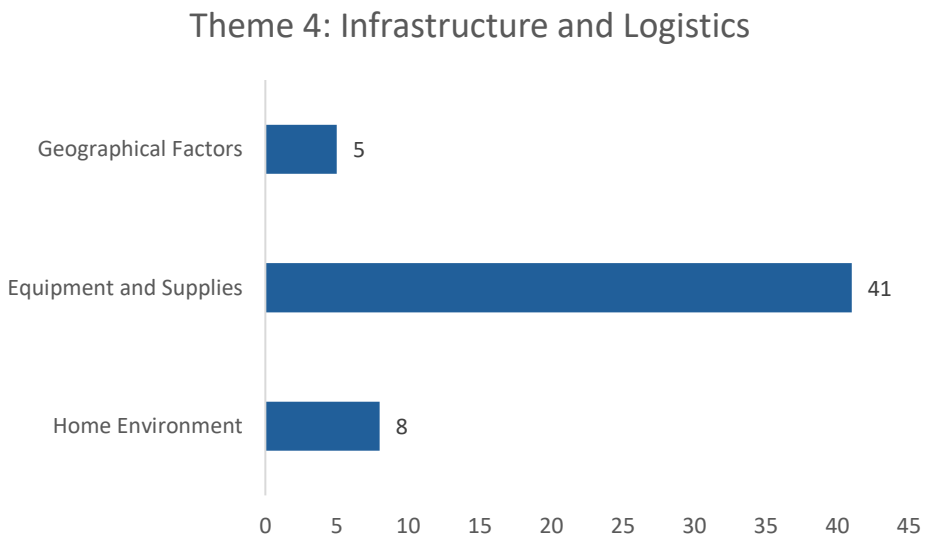

Figure 4.5 - Theme 4: Infrastructure and Logistics, Category Frequency

This theme addresses objective 2 by identifying logistical barriers and facilitators from the perspectives of healthcare workers and administrators, while also highlighting the systemic requirements necessary for HHD adoption in line with the aim of the study.

4.2.5 Sustainability, Strategy and Innovation

Participants believe that sustainability in HHD depends finances, policy and planning and the proper use of technology. Financial issues were discussed often, with concern over high start-up costs but also recognition of potential long-term savings. Policy discussions focused on national targets, clear guidelines, and incentives to increase uptake. Technology was valued for making treatment safer and more convenient through tools like remote monitoring and telemedicine.

Table 4.6 presents the categories, codes, and quotes for Theme 5, Sustainability, Strategy and Innovation, detailing the financial, policy, and technological factors that participants believe may influence the uptake of HHD.

Table 4.6 - Theme 5 – Sustainability, Strategy and Innovation

Theme 5: Sustainability, Strategy & Innovation		
Category	**Code**	**Quote**
Financial Considerations Economic factors affecting the adoption and sustainability of home dialysis	**Initial Costs** Set-up expense for equipment and installation	*"Upfront costs are quite high … plumbing, electricity, buying of the necessary equipment"* (P14) *"The machines and training will add financial pressure"* (P24)
	Long-term Savings Potential to reduce ongoing healthcare costs over time	*"The biggest benefit will be cost savings in the long run … we can reallocate those resources to other areas"* (P2) *"Long-term savings are possible, but only with a sustainable support system"* (P3)
Policy and Strategic Planning Organisational and government-level approaches to expanding home dialysis	**National Targets** Goals for increasing HHD participation	*"We're nowhere near the national target for home therapies"* (P14)

	Integration Coordinating HHD with national health strategies	*“Clear guidelines and strong protocols are needed, adapted from countries with HHD experience”* (P3) *“Decentralising dialysis could ease hospital strain but requires reliable logistics.”* (P14)
	Incentives Financial benefits to encourage home treatment	*"If there was some help with the extra costs, more people might consider it"* (P14) *There’s no financial incentive at the moment for patients to choose home dialysis"* (P5)
	Workforce Planning Ensuring enough trained staff available to support patients	*“Have a dedicated team, reliable supplier, and solid backup systems in place”* (P6)
Technology and Innovation New tools and methods to improve	**Choice of Machines** Portable, easier-to-transport dialysis devices	*"Not every machine works for every patient … having options would*

the safety and convenience of home dialysis		*make it easier to switch if there's a problem"* (P6)
	Remote Monitoring Technology enabling clinicians to track patients remotely	*"It's reassuring for patients to know someone is keeping an eye on them even though they're at home"* (P14)
	Telemedicine Virtual consultations and follow-ups to support patients at home	*"can do a video call instead of bringing them* (the patients) *in … it saves time and is less stressful for the patient"* (P1)

Figure 4.6 shows that *Financial Considerations* was the most frequently discussed category within Theme 5. Participants often compared the high initial costs of HHD against its potential for long-term savings. *Technology and Innovation* and *Policy and Strategic Planning* were discussed with similar frequency, reflecting the need for equipment and robust policy frameworks to ensure sustainable implementation. Financial concerns were prominent amongst stakeholders demonstrating that cost-related issues are perceived as an important factor affecting the implementation of HHD.

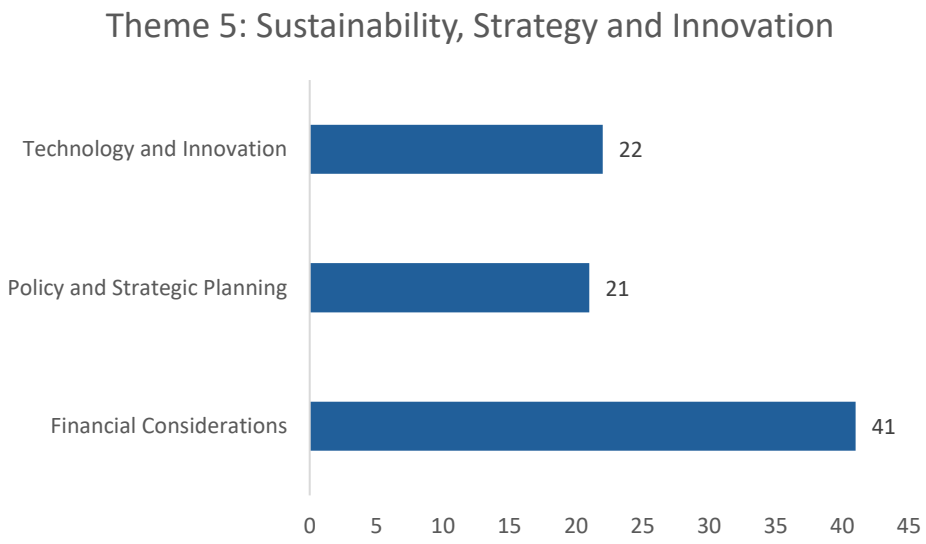

Figure 4.6 - Theme 5: Sustainability, Strategy and Innovation, Category Frequency

This theme addresses objective 2 by reflecting the stakeholders' perceptions of sustainability and innovation as key facilitators or barriers to introducing HHD in Malta's healthcare system.

4.3 Stakeholder Perspectives on Home Haemodialysis

While the thematic analysis provided a comprehensive overview of the key themes identified in this study, it is of value to explore these from the perspectives of different stakeholders to identify any trends and variations. Across the stakeholder groups, there were areas of agreement, such as the potential for improved patient autonomy and convenience, and differences in priorities and concerns. This section presents a breakdown of perspectives by stakeholder category, highlighting points of consensus and disagreement.

4.3.1 Patients and Caregivers

In both interviews and focus groups, many patients expressed hope that HHD would improve their quality of life by giving them more freedom and control. One long-term

dialysis patient noted that with HHD, *"I'll be able to fit it into my life instead of fitting my life around dialysis,"* describing the flexibility of dialysing on their own schedule as *"almost like living a normal life again"* (P19). Several patients agreed that *"the flexibility is a big plus"* and that more frequent home treatments could lead to *"fewer complications"* (P16).

At the same time, patients also expressed fears of potential challenges that they envisaged. Many raised concerns about the responsibility of self-care and lack of immediate help: *"There's a certain comfort in knowing that if something goes wrong* [in the dialysis unit]*, help is immediate"* (P17). Self-cannulation (inserting a needle into one's own fistula) emerged as a major psychological and technical barrier, with one interviewee admitting, *"Inserting a needle into my vein feels overwhelming. It's just not something I see myself doing"* (P20). Practical issues such as space constraints at home and the burden on family members were also highlighted. Some patients with previous exposure to home therapy were enthusiastic about the benefits associated with HHD:

> *There are so many benefits! For starters, it gives you flexibility. I won't have to go to the dialysis centre three times a week, stuck to someone else's schedule. It also offers better health outcomes, you know? More frequent dialysis, but for shorter periods. It's not as taxing on the body as the long in-centre sessions.* (P19)

Others, on the other hand, voiced reservations about it:

> *Dialysing at the Renal Unit has its advantages. You're in professional hands, and the machines are likely stronger and more efficient. For home haemodialysis, I see the administrative benefits… reducing the burden on renal units… but I don't see much personal benefit for me. Yes, the risk of complications is a big one. The added complexity of managing hygiene, supplies, and coordinating with family members is another concern. Overall, I*

> *don't think it's the right fit for me, but I can see it working for others under the right circumstances.* (P15)

Caregivers felt that home treatment could improve patients' health and mood while reducing the need for frequent hospital visits, provided that adequate support is in place (P23-25). However, some highlighted the need for comprehensive training to manage complex medical tasks and the emotional strain of monitoring treatment (P23-24). Many also expressed concerns about maintaining a healthy work-life balance, especially when juggling caregiving responsibilities with employment and other family duties (P25).

4.3.2 Healthcare Workers

Healthcare professionals recognised the clinical and lifestyle benefits that HHD could offer patients, yet they were also aware of the system-level requirements needed to make HHD safe and effective. All the nurses and doctors agreed that HHD can improve patients' well-being by *"allowing them to undergo treatment in the comfort of their own home"* (P4) and regain control of their time. They observed that home treatments, performed more frequently, could lead to faster recovery and less fluid intake and dietary restrictions. Healthcare workers balanced the costs with the potential advantages to be gained from HHD:

> *I think if it gets better patient outcomes, it's a benefit that it will reduce costs. In the beginning, you'll have the increased costs of setting up the service, but then in the long run, you will eventually get reduced costs, which means reduced admissions, reduced nursing requirements on the dialysis units. Each dialysis session would be cheaper.* (P10)

However, healthcare professionals also stressed the need for the appropriate selection of patients, with a senior doctor commenting that HHD *"isn't for someone*

living alone," and that patients must be *"carefully selected, considering their reliability, understanding, and social support"* (P7). Nurses emphasised the need for extensive training and support: patients (and their carers) would require thorough education, and staff would need to be on call 24/7 for emergencies. Additionally, dialysis staff noted that Maltese patients are accustomed to nurse-led care and that *"patients' mentality will need to shift"* towards more self-sufficiency (P6).

4.3.3 Policymakers and Administrators

Stakeholders in managerial or policy roles viewed HHD through the lens of feasibility and sustainability of the health system. Many agreed that HHD could be a *"win-win"* solution – improving patient quality of life while *"saving hospital space and slots"* (P13) by reducing in-centre dialysis demand. Administrators highlighted potential cost benefits, noting that other than reducing complications and hospital admissions, HHD could yield long-term savings:

> *For the healthcare system, it's about sustainability. Fewer patients in hospital means less strain on our resources. We'll also see fewer complications because patients will receive more frequent, better-quality dialysis at home.* (P13)

Policymakers were also pragmatic about short-term challenges, balancing the desirability of outcomes with practical viability. Initial investment costs were a common concern, though some argued that *"high upfront costs will eventually even out"* (P12) due to long-term savings. Others debated whether resources should be directed towards expanding satellite dialysis units instead. There was general agreement that successful implementation would require clear policies, operational guidelines, and stakeholder engagement to ensure a smooth transition.

4.3.4 Comparing Stakeholder Groups

Comparing perspectives across stakeholder groups (patients, caregivers, healthcare workers and policymakers) revealed both consensus and diversion. Table 4.7 compares the perceived benefits and key concerns regarding HHD across these groups.

Triangulating data across all stakeholder groups demonstrated an overlap in their acknowledgement that HHD could improve patient autonomy and convenience. However, contrasts in priorities were evident: patients focused on personal experiences (freedom vs. fear), healthcare workers on clinical safety and training, and administrators on system readiness and cost-effectiveness.

A key divergence was around the social aspect of dialysis. Some patients valued the camaraderie associated with in-centre dialysis, whereas professionals assumed patients would prefer the privacy of home. Another divide was in expectations of care duties. The shift in responsibility from healthcare workers to the patients and caregivers made the latter uneasy. While healthcare workers recognised this, they downplayed its significance, assuming education would help patients adjust.

Table 4.7 - Summary of Stakeholder Perspectives on HHD in Malta

Stakeholder Group	Perceived Benefits	Key Concerns
Patients	Greater freedom in scheduling and diet (less restrictive lifestyle) Dialysis in comfort of home, avoiding travel	Fear of self-needling and managing complications alone Loss of social support from in-centre sessions

	Potential for better well-being with more frequent dialysis	Burden on family members or desire not to “medicalise” home space
Caregivers	Patient could have improved health and mood at home More convenient than frequent hospital trips if well-supported	Need for training to perform complex medical tasks Stress and responsibility of monitoring loved one’s treatment Ensuring work-life balance while caregiving at home
Healthcare Workers	Improved patient outcomes (fewer complications, better fluid control) More patient empowerment and satisfaction Reduces strain on near capacity in-centre dialysis unit	Ensuring home environment meets technical requirements (space, water, power) High upfront costs for machines and home modifications Intensive training and ongoing support required for patients (and staff adaptation) Selecting suitable patients and not overburdening GPs/acute services (workforce strain)
Policymakers & Administrators	Long-term cost-effectiveness for healthcare system	Implementation logistics (procurement, policies, legal frameworks) Cultural resistance to change from institutional care

	System resilience: less pressure on central hospital dialysis unit Aligns with person-centred care trends and technology use (innovation)	Maintaining quality and safety standards in a decentralised model; ensuring equity and equal access, not just those with resources/support)

Overall, the interviews demonstrate a cautious optimism. There is a broad desire to improve dialysis patients' lives through home therapy where feasible, accompanied by an understanding of the challenges that must be overcome for HHD to be successfully introduced in the Maltese Islands.

4.4 Summary of Results

This chapter reported the findings from interviews and focus groups with patients, caregivers, healthcare professionals and administrators regarding HHD in Malta. Data presentation covered perceived benefits, challenges, differences, and similarities across stakeholder groups. The key themes were quality of life and independence, safety and support, training and education, infrastructure and logistical considerations, and sustainability, strategy and innovation. Variations in emphasis were observed between groups, with some areas of agreement and others of divergence.

Table 4.8 summarises the main benefits and concerns identified across the five themes and stakeholder groups. This provides a visual overview of the key outcomes before the discussion chapter.

Table 4.8 - Summary of Key Findings Across Themes and Stakeholder Groups

Theme	Patients	Caregivers	Healthcare Workers	Policymakers / Administrators
Quality of Life & Independence	Greater autonomy, flexibility; fear of self-needling	Improved mood; reduced travel burden	More empowerment, satisfaction	Supports person-centred care, efficiency
Safety & Support	Anxiety about emergencies	Stress of responsibility	Need for training/support systems	Concern for quality and equity of care
Training & Education	Need for hands-on guidance	Burden of learning tasks	Ongoing staff training requirements	Resource allocation challenges
Infrastructure & Logistics	Home space and equipment limitations	Balancing home/work life	Technical setup requirements	Policy, funding, procurement barriers
Sustainability & Innovation	Desire for improved long-term quality of life	Need for sustainable family support	Concerns over long-term costs and capacity	Alignment with innovation and health strategy

These themes collectively address the objectives of the study by exploring stakeholder needs and examining perceived benefits and barriers. They provide a comprehensive evidence base to evaluate the feasibility and desirability of HHD in

Malta, which aligns with the research question. The categories within each theme capture further aspects of stakeholder perceptions, demonstrating specific needs, readiness factors, and expectations (objective 1), as well as the perceived benefits, barriers, and facilitators to implementation (objective 2).

These results provide the basis for the next chapter, which will examine the findings in relation to existing literature, theoretical models, and implications for implementing HHD in Malta.

Chapter 5: Discussion

This chapter discusses the findings presented in Chapter 4 in relation to the research question: "To what extent is home haemodialysis (HHD) feasible and desirable in a small island state within the European Union?" The results are interpreted through the lens of the theoretical framework and existing literature to provide insight into both the feasibility and the desirability of HHD in Malta and elicit any facilitators and barriers that may determine service uptake.

5.1 Interpretation of Findings

Research indicates that HHD may achieve better clinical outcomes compared to in-centre dialysis, including improved blood pressure and fluid control (Shah et al., 2024; Kraus et al., 2007). HHD is also associated with fewer hospitalisations, partly due to the flexibility it affords patients in adapting treatment schedules and the self-care skills that support early management of complications (Tennankore et al., 2021; Desbiens et al., 2024b; Cornelis et al., 2014). Over the long term, frequent or intensive home dialysis has been linked with enhanced cardiovascular health, including regression of left ventricular hypertrophy and improved cardiac function (Girsberger et al., 2020). These advantages reflect the desirability of HHD from a clinical standpoint and align with the ‘outcome’ dimension of Donabedian’s model of quality. Systematic reviews suggest that outcomes and quality of life are comparable to in-centre dialysis but these findings are rated as low-certainty, and cost-effectiveness remains uncertain (Quinn & Lam, 2023; Cheetham et al., 2024).

Beyond clinical outcomes, HHD can enhance psychosocial wellbeing by improving autonomy and placing care within the patient's own environment (Bennett et al., 2015). However, the evidence base remains limited, with only a small number of randomised trials available, while non-randomised studies vary in quality and are prone to bias.

The findings of this study show that patients, caregivers, healthcare workers, and policymakers in Malta were cautiously optimistic about the potential introduction of HHD. As part of the needs analysis, stakeholders viewed HHD as an innovation with the capacity to improve clinical outcomes and patient autonomy, reflecting international evidence (Miller, 2010). Participants often highlighted improved flexibility and independence as desirable benefits, consistent with principles of person-centred care and enhanced quality of life (Tomaselli et al., 2020).

At the same time, participants recognised that feasibility did not equate to ease of implementation. Similar to international experiences where HHD uptake has been slow despite interest (Jayanti et al., 2014; Kendzia et al., 2022), Maltese stakeholders raised concerns around training requirements, home modifications, and patient safety. These concerns underscored the importance of phased planning, robust support systems, and gradual programme introduction for HHD to succeed in Malta (Power & Ashby, 2014).

Overall, the study revealed optimism, suggesting that with strategic investment and careful preparation, Malta can align with global trends and adopt HHD as a viable treatment option.

5.1.1 Theoretical Implications

The five themes elicited from this study and their respective categories align closely with the conceptual framework's three interrelated domains (Figure 2.5). Person-Centric Factors reflect patient readiness for HHD adoption and include independence and autonomy, social well-being (from the Quality of Life and Independence theme), psychological safety (Safety and Support theme), and candidate suitability (Training and Education theme). Interpreted through Maslow's Hierarchy of Needs, these findings highlight the importance of addressing safety and support before patients can benefit from the autonomy and flexibility HHD offers.

HHD changes the role of patients from passive recipients to active managers of their treatment. Patients report that they feel more independent when dialysing at home (Guerraoui et al., 2022). Rather than planning life around treatment, they integrate the treatment into their life (Antoun et al., 2023). Knowing that one can handle the dialysis machine and potential complications gives a sense of achievement and reduces the helplessness experienced in centre-based care (Hamidi et al., 2023), aligning with the highest tier of Maslow's Hierarchy of Needs (1943), self-actualisation.

Healthcare System Factors address feasibility and quality outcomes, corresponding to support systems (Safety and Support), patient training (Training and Education), home environment suitability, and the provision of equipment and supplies (Infrastructure and Logistics). In line with the Donabedian Model (1966), the results emphasise that robust structural resources and well-designed processes are essential for optimal outcomes. Policymaker and Stakeholder Engagement reflects systemic

support for HHD implementation, through financial considerations, policy and strategic planning, technology and innovation (Sustainability, Strategy and Innovation), and geographical factors (Infrastructure and Logistics).

As demonstrated by Christensen's Needs Analysis Framework (2018), meeting objective, subjective, and perceived needs at the policy level facilitates sustainable adoption. The integration of these factors determines the overall feasibility and desirability of HHD in Malta, as discussed in section 5.3.

5.1.2 Triangulation of Methodologies

Within the Person-Centric Factors domain, in focus group discussions, participants built on each other's perspectives and formed a strong consensus around the appeal of greater autonomy. This reinforced the perceived lifestyle benefits of HHD, aligning with the Quality of Life and Independence theme and reflecting higher-level needs in Maslow's Hierarchy, where autonomy and self-actualisation become achievable once safety and support are addressed. Individual interviews, on the other hand, revealed that patients unfamiliar with HHD often required prompting to identify potential benefits and challenges. This suggests that group settings can facilitate idea exchange and the understanding of possible impacts, stressing the role of social interaction and peer learning in shaping patient perceptions, further emphasising the importance of incorporating collaborative, peer-supported education into HHD preparation programmes.

5.1.3 Triangulation of Stakeholder Perspectives

In evaluating the diverse perspectives on HHD, it is important to recognise the similarities and differences between different stakeholder groups. The triangulation

of views presented below (Table 5.1) aligns with the thematic framework identified in this study (Figure 2.5), drawing upon insights from patients and caregivers, healthcare workers, and policymakers and mapping them against the five overarching themes and their categories. It captures the shared recognition of HHD's potential benefits and the nuanced concerns that shape its adoption and implementation.

In this context, it is also helpful to distinguish between felt needs (as articulated directly by patients and caregivers) and perceived needs (as identified by clinicians or policymakers), as well as between subjective needs (shaped by individual experiences) and objective needs (defined through clinical or policy criteria). These distinctions highlight how different groups frame priorities and challenges, underscoring the importance of integrating multiple perspectives in evaluating feasibility and desirability.

Table 5.1 - Stakeholder Perspectives on HHD: Thematic Triangulation

Theme & Category	Patients & Caregivers	Healthcare Workers	Policy & Administrators
Needs Category	***Felt Needs / Subjective Needs***	***Perceived Needs / Objective Needs***	***Perceived Needs / Objective Needs***
1. Quality of Life & Independence			
Independence & Autonomy	Value flexibility and control over treatment; fear of being forced into HHD	Support autonomy but stress safety and suitability	Focus on strategic benefits for system efficiency
	"I won't have to go to the dialysis centre three times a week, stuck to someone else's schedule" (P19)	*"Patients are keen on undergoing home haemodialysis as it gives them a certain amount of freedom" (P3)*	*"Allows patients to regain control of their time; spend more time with their families and even maintain employment" (P12)*

Social Well-being	Mixed: some value home privacy, others prefer social contact at unit	Recognise possible isolation, recommend support systems	Consider balancing patient choice with mental well-being needs
	"The environment at the Renal Unit is therapeutic in its own way" (P16)	*"Probably they might feel isolated or at risk if there is no one at their bedside all the time" (P20)*	*"Home dialysis is great for those who want the independence, but not everyone will cope well emotionally. It's about matching the right patient to the right setting" (P14)*
Travel & Appointments	Reduced travel a benefit; less relevant given short distances in Malta	Note reduced patient fatigue; small travel still a burden for frail and elderly	See reduced travel as facilitator for integrated support services
	"I had to stop working because the travel was just too much with the hospital transport schedule" (P5)	*"Even short travel is a burden for sick patients" (P1)*	*"Malta's size is an advantage for support … no patient is remote" (P12)*

Overall Health Outcomes	Expect improved well-being if HHD managed properly	Note better fluid and electrolyte control, fewer admissions due to more frequent dialysis	Value improved outcomes for cost-effectiveness and policy goals
	People on HHD *"feel generally healthier and more able to do daily activities" (P13)*	*"We've seen patients on home haemodialysis have better fluid control and fewer hospital admissions" (P1)*	*"The biggest benefit will be cost savings in the long run; we can reallocate those resources to other areas" (P13)*

2. Safety & Support			
Support Systems	Insist on 24/7 helpline, regular check-ins; fear of being alone	Advocate for on-call staff, buddy system, remote monitoring	Express need for proper frameworks, monitoring and support services
	"There's a fear of being alone" (P18)	*"A 24-hour on-call system for patient support is needed. Patients need to know that someone is available 24/7" (P1)*	*"Could use technology (telemedicine) to remotely monitor patients' parameters" (P13)*

Risk Concerns	Worry about self-care mistakes, complications, need caregiver present	Ensure that patients and their caregivers are fully trained to deal with issues	Ensure policies address safety standards
	“I need to know help is there if something goes wrong” (P18)	*“Patients and caregivers need full technical training and also how to manage complications” (P16)*	*“Address liability and safety in policy updates” (P12)*
Psychological Safety	Anxiety about new treatment, need gradual introduction	Recommend phased roll-out, confidence-building training	Support pilots to build evidence and acceptance
	“No matter how much training I get, I don’t see myself doing it” (P21)	*"Start with young motivated patients and build on that" (P2)*	*“Start with a small, well-selected cohort to refine the system” (P11)*

3. Training & Education			
Candidate Suitability	Some willing; others admit they would not be able to handle it	Stress screening for motivation, stability, skills	Set formal inclusion/exclusion criteria; participation voluntary
	"Courage and dexterity are required for home haemodialysis" (P16)	*"Some patients are too comfortable with hospital care" (P12); "Patients need to be physically and mentally stable" (P3)*	*"Set inclusion and exclusion criteria … avoid forcing it on unwilling patients" (P14)*
Patient Training	Want thorough hands-on practice before going solo	Require structured, supervised training programmes for patients & caregivers	Develop standardised protocols; may outsource to experienced providers
	"Need thorough hands-on practice before feeling confident" (P19)	*"Training should include at least 3 weeks of theory and 6 weeks of practice" (P1)*	*"Start with a small, well-selected cohort to refine the system" (P11)*

Ongoing Assessment	Want reassurance of continual supervision	Provide refresher training; assess competency regularly	Integrate competency checks into policy framework
	"I want reassurance that help is always available during learning" (P19)	*"Staff need ongoing refresher courses to maintain competency" (P3)*	*"Integrate training checks into regulations" (P12)*
Empowerment through Knowledge	Need information to overcome fear	Educate on technical and emergency aspects	Support educational resources and peer-support
	"Patients must be taught how to identify and respond to issues" (P9)	*"Training should cover not just the machine, but water treatment systems and infection control" (P18)*	*Support peer networks and comprehensive information packages (P13)*

4. Infrastructure & Logistics			
Home Environment	Concern over space for equipment; unsure about utilities	Require home suitability checks, hygiene/water/electric upgrades	Offer incentives, set evaluation criteria for home readiness
	"Finding space would be tough" (P15).	*"Need for site assessments and home modifications before start" (P6)*	*"Offer grants for necessary renovations" (P14)*
Equipment & Supplies	Worry about storage, waste disposal, deliveries	Plan reliable supply chain and waste management	Negotiate supplier contracts; integrate with existing logistics
	Comparing HHD to peritoneal dialysis: *"It's surprising how much rubbish there is. I fill the wheelie bin on my own some weeks" (P19)*	*"Ensure patients have consistent delivery of consumables" (P6)*	*"Integrate with existing PD supply chain" (P12)*

Geographical Factors	Split views: proximity to hospital reduces perceived need, but some value convenience	Can respond quickly due to short distances	Use small geography to integrate HHD into existing services
	"Home is never far from hospital in Malta" (P16)	*"Can reach patients quickly if needed" (P4)*	*"Malta's size will enable home-based care to be effectively integrated" (P12)*

5. Sustainability, Strategy & Innovation			
Financial Considerations	Concern about personal costs; expect system to cover utilities & modifications	Acknowledge high upfront but stress long-term savings	Explore funding models, stipends; justify capital investment with projected savings
	"Who pays for electricity, water, home adjustments?" (P23)	*"Initial costs are high but long-term savings likely" (P1)*	*"If there was some help with the extra costs, more people might consider it" (P14)*
Policy & Strategic Planning	No strong views on policy details	Need clear protocols, legal frameworks	Update regulations; plan pilot trials; integrate into national strategy

		"Need clear protocols … infection control, emergencies" (P8)	*"Plan a pilot to gather local evidence for policy refinement" (P14)*
Workforce Planning	Not directly discussed but note that nurses are busy	Concern over staff strain; suggest dedicated coordinator role	Address shortages via resource allocation, possible outsourcing
		"Have a dedicated team, reliable supplier, and solid backup systems" (P6)	*"Must allocate or hire staff for HHD programme" (P12)*
Technology & Innovation	Open to technology if it improves safety	Promote remote monitoring, telemedicine for follow-up	Invest in suitable tech; set standards for use in home care
	"I'd be happy to try the home machine if it's easy to use and I get proper training" (P8)	*"It's reassuring for patients to know someone is keeping an eye on them" (P14)*	*"Can do a video call instead of bringing them in … saves time and stress" (P1)*

Across stakeholders, there is substantial overlap on the benefits of the Quality of Life and Independence theme, especially in the Independence and Autonomy category and the Schedule Flexibility category, and on the importance of the Safety and Support theme, particularly the 24/7 Support Systems category and the Clear Emergency Protocols category. All groups value improved health outcomes when paired with robust training.

Divergence emerges in the Policy and Strategic Planning category, where policymakers emphasise national targets and cost-effectiveness, while patients focus more on personal choice and comfort. Within the Infrastructure and Logistics theme, healthcare workers often stress space and equipment storage concerns, which patients mention less. Additionally, in the Psychological Safety category, healthcare workers are more likely to flag fear of self-management, whereas some patients express confidence if training is adequate.

5.2 Feasibility & Desirability

As mentioned in Chapter 2, feasibility refers to the practical achievability of implementing a new service (Bowen et al., 2009) while desirability relates to the extent to which the service is valued by stakeholders (May et al., 2018). This section critically examines stakeholder perspectives on the feasibility and desirability of introducing HHD in Malta (Table 4.3), drawing on the five main themes identified in the analysis: Quality of Life & Independence; Safety & Support; Training & Education; Infrastructure & Logistics; and Sustainability, Strategy & Innovation.

5.2.1 Theme 1: Quality of Life and Independence

Feasibility: HHD has the potential to provide dialysis patients with improved autonomy. In order to achieve this, patients must be selected to ensure medical stability and motivation. Service uptake should be voluntary (Walker et al., 2015). Shifting from in-centre dialysis to home care may remove peer support, reducing engagement by those individuals who value this camaraderie. To mitigate this, alternative social supports may be offered (Walker et al., 2016). Dialysis treatment should be done regularly and as prescribed to ensure optimal health outcomes. Patients undergoing home therapy need to be monitored to ensure they adhere to their treatment (Jotterand Drepper, 2019; Yau, 2024).

Desirability: HHD may provide flexibility, comfort and a greater sense of control over one's life. Such advantages would be particularly valued by younger individuals, especially those who work, as they enable them to maintain productivity. While this independence is desirable for some, it is a source of anxiety for others, who worry about losing the social environment of in-centre dialysis (Jacquet & Trinh, 2019). This suggests that desirability is highest when autonomy is supported, while social contact is maintained through alternative means.

All stakeholders acknowledged that the improved autonomy and flexibility that HHD can provide are important facilitators. Patients, especially those with children or working, valued the possibility of dialysis in their own time, reducing the disruption of frequent hospital visits. This was corroborated by HCWs and administrators, who noted that patients who can maintain their employment are more likely to take up the service (Díaz-Buxó et al., 2015; Ni et al., 2022).

Decreased desirability is seen in the psychological barriers of HHD, particularly anxiety about self-care, were noted in this study as patients may have difficulty envisaging themselves managing treatment outside hospital. This is particularly evident among long-term in-centre patients who are used to the routine and professional supervision, and is consistent with prior evidence (Gupta & Zimmerman, 2021; Jayanti et al., 2014).

5.2.2 Theme 2: Safety and Support

Feasibility: Stakeholders viewed safety as essential. Elements such as a 24/7 helpline, on-call clinical staff, remote monitoring, and a system-wide integration with emergency services were identified as important needs. Without such measures, the perceived risks associated with HHD, such as self-cannulation or management of complications during haemodialysis, become a barrier (section 5.3) (Reddy et al., 2024). Ensuring readiness through gradual exposure and peer support was seen as a necessity.

Desirability: When service users feel confident that monitoring and assistance are available, the desirability of HHD increases considerably (Walker et al., 2016). This reassurance provided by systems in place compensates for the perceived risks, increasing the adoption of home treatment. On the other hand, a lack of safety systems is associated with a decrease in desirability as patients feel more vulnerable. Good safety planning is, therefore, both a feasibility enabler and a driver of desirability.

An important facilitator that would help in the implementation of HHD was the role of family caregivers and support networks. Patients and caregivers noted that having

assistance at home reduced anxiety, while administrators and HCWs highlighted that strong family involvement improves feasibility by ensuring consistent support during treatment. Peer mentoring from experienced home dialysis patients was also seen as a valuable way to build confidence. This reflects evidence that caregiver participation strengthens adherence and long-term retention in home dialysis programmes (Torres et al., 2021). In Malta, where family support is often strong, this factor was regarded by all groups as highly enabling.

Patients frequently mentioned that they were concerned about overburdening their caregivers, reflecting the findings by Torres et al. (2021), that caregiver strain discourages HHD uptake. Those lacking social support perceive HHD as unsafe (Virtanen et al., 2019), whereas the presence of caregivers has been shown to improve outcomes (Torres et al., 2021; Welch et al., 2014).

5.2.3 Theme 3: Training and Education

Feasibility: Stakeholders believe that a well-structured training programme combining theory and practice is important for safe implementation and, in line with Hawley et al. (2012), they perceive that candidate suitability must include motivation, cognitive capacity, manual dexterity, and technological confidence. They also advocate for pilot trials with small, well-selected cohorts to allow refinement before scaling up. Ongoing patient assessments and refresher courses for staff ensure sustained competence (Ulrich, 2022). Where caregivers are involved, their training in technical and emergency response is equally important.

Desirability: Confidence gained through training directly increases patient willingness to adopt HHD. Those who feel well-prepared view the home setting as empowering,

while those who feel underprepared may find it overwhelming (Wong et al., 2019). Stakeholders believe that rigorous training with regular assessments and visible ongoing support would reassure patients that they will not be left to cope alone. In this way, the same training that makes HHD safe to implement also makes it appealing to undertake.

Participants across groups stressed that well-designed training models are an important facilitator determining both feasibility and desirability. Patients reported that such support can help to reduce their fears of issues such as self-cannulation and equipment use. Studies support these observations. Paterson et al. (2021) linked training failure to patient loss, while Weinhandl and Collins (2018) showed telehealth support lowered attrition and improved training completion.

While supervision by experienced renal nurses would be valuable, this diversion of resources could further increase pressure on in-centre services. Inadequate training is a limiting factor in many settings (Kendzia et al., 2022), and while feasibility depends on human resources, desirability would be reduced if patients feel underprepared. Self-cannulation is a particularly challenging hurdle, reinforcing these concerns (Jayanti et al., 2014; Welch et al., 2014). Simplified techniques such as buttonhole cannulation, home assistance (Dhruve et al., 2019) and peer mentorship can mitigate these fears (Guerraoui et al., 2022).

5.2.4 Theme 4: Infrastructure and Logistics

Feasibility: To implement HHD, homes would need sufficient physical space to house the haemodialysis machine, store consumables, and appropriate hygiene conditions and waste disposal facilities (Harel et al., 2016). While stakeholders acknowledge

these, they are also aware that many Maltese homes, especially small apartments, do not have these amenities. Other barriers (Section 5.3) would include utility expenses and costs related to infrastructural modifications. These may be mitigated by subsidies (Manns et al., 2019) that would make them more affordable. Reliable supply of equipment and consumables is perceived to be another necessity. Malta's small geography allows for rapid emergency responses, potentially facilitating the service, but on the other hand, some stakeholders perceive the short travel distances and proximity of the in-centre unit to most households to make HHD unnecessary.

Desirability: HHD would appeal to patients who have a suitable home environment and dependable logistics. Regular deliveries (preferably weekly, rather than monthly, to avoid the need for large storage areas), proper waste disposal, and financial subsidies would facilitate uptake of the service. Should logistical issues not be addressed, however, implementing HHD would be impractical and undesirable.

HCWs noted that Malta's existing home dialysis service, i.e. peritoneal dialysis (PD), may be a potential facilitator for HHD. The PD model has already established pathways for home dialysis, supply delivery and emergency support. This may be adopted for HHD. Patients also perceived that building on this model would help reassure them that the service is reliable. Administrators agreed, noting that a home dialysis programme where patients can move from PD to HHD without needing in-centre dialysis could be set up. Using pathways already in place is an important enabler of feasibility, in line with the evidence found in literature that a strong PD service can pave the way for HHD implementation (Desbiens et al., 2024a).

Concerns about the home environment, such as the lack of storage space, higher utility expenses and proper waste disposal, were frequently mentioned by the patient and caregiver group, in line with what was reported in other studies (Ni et al., 2022; Pungchompoo et al., 2016). Other concerns were high upfront costs, regular maintenance, and the need for a regular supply of consumables, also noted in previous research (Power & Ashby, 2014; Scarpioni et al., 2021). Moreover, because travel distances are short in Malta, patients may feel less motivated than those in larger countries to move from in-centre dialysis to HHD, making the option less attractive.

5.2.5 Theme 5: Sustainability, Strategy and Innovation

Feasibility: The high upfront costs for procuring the equipment, organising training and making the necessary home adjustments may present a barrier to HHD implementation (Hager et al., 2019). Policymakers acknowledge this, but also hope to offset the initial costs with long-term savings from decreased transportation, reduction in hospital admissions and in-centre use. They advocate strict eligibility criteria, operation protocols, and legal frameworks in place. Administrators believe that, not only will the service be feasible, but it will also help reduce the strain on the hospital workforce, in particular, nursing staff and dialysis bed availability. Stakeholders believe that technology such as telemedicine, remote monitoring and smaller portable dialysis machines would enable the implementation of HHD.

Desirability: All stakeholder groups believe that HHD is more likely to be adopted if it is sustainable in the long term, both at the service provision and user levels. Financial incentives such as utility bill subsidies would make it more desirable for patients and

caregivers and would demonstrate a commitment from the health service provider, encouraging further uptake. For administrators, cost-effectiveness in the long term would make the programme more appealing.

At the macro-level (system and policy), policymakers noted that HHD could relieve pressure on Malta's overburdened dialysis service by shifting some stable patients into the community, creating capacity for acute cases and improving overall system efficiency. International studies confirm that HHD contributes to long-term cost-effectiveness and resilience in renal services (Guerraoui et al., 2022; Gorham et al., 2021).

At the meso-level (organisational level), HCWs and administrators recognised advances in telemedicine and remote monitoring as crucial facilitators. Integrating these technologies into service delivery ensures that patients can be safely monitored at home, making HHD more feasible by embedding safety into standard practice.

At the micro-level (individual level), patients and caregivers viewed remote monitoring as an important facilitator because it reduced anxiety about being alone during treatment and increased confidence in self-management. This reassurance enhances their perception of safety, reinforcing the desirability of HHD (Weinhandl & Collins, 2018; Rosner et al., 2017).

A cultural shift on every (macro, meso and micro) level is needed to move from in-centre treatment to community-based treatment; however, HCWs expressed limited familiarity with HHD, mirroring evidence from literature that resistance to change hinders adoption (Jayanti et al., 2014). Patient, caregiver and HCW buy-in is needed to ensure programme feasibility.

Figure 5.1 integrates desirability and feasibility perspectives to illustrate the key factors influencing HHD uptake, organised by the five main themes identified in the study. Quality of Life & Independence, Safety & Support, Training & Education, Infrastructure & Logistics, and Sustainability, Strategy & Innovation. Factors that increase uptake are positioned above the central axis, while those that reduce uptake appear below.

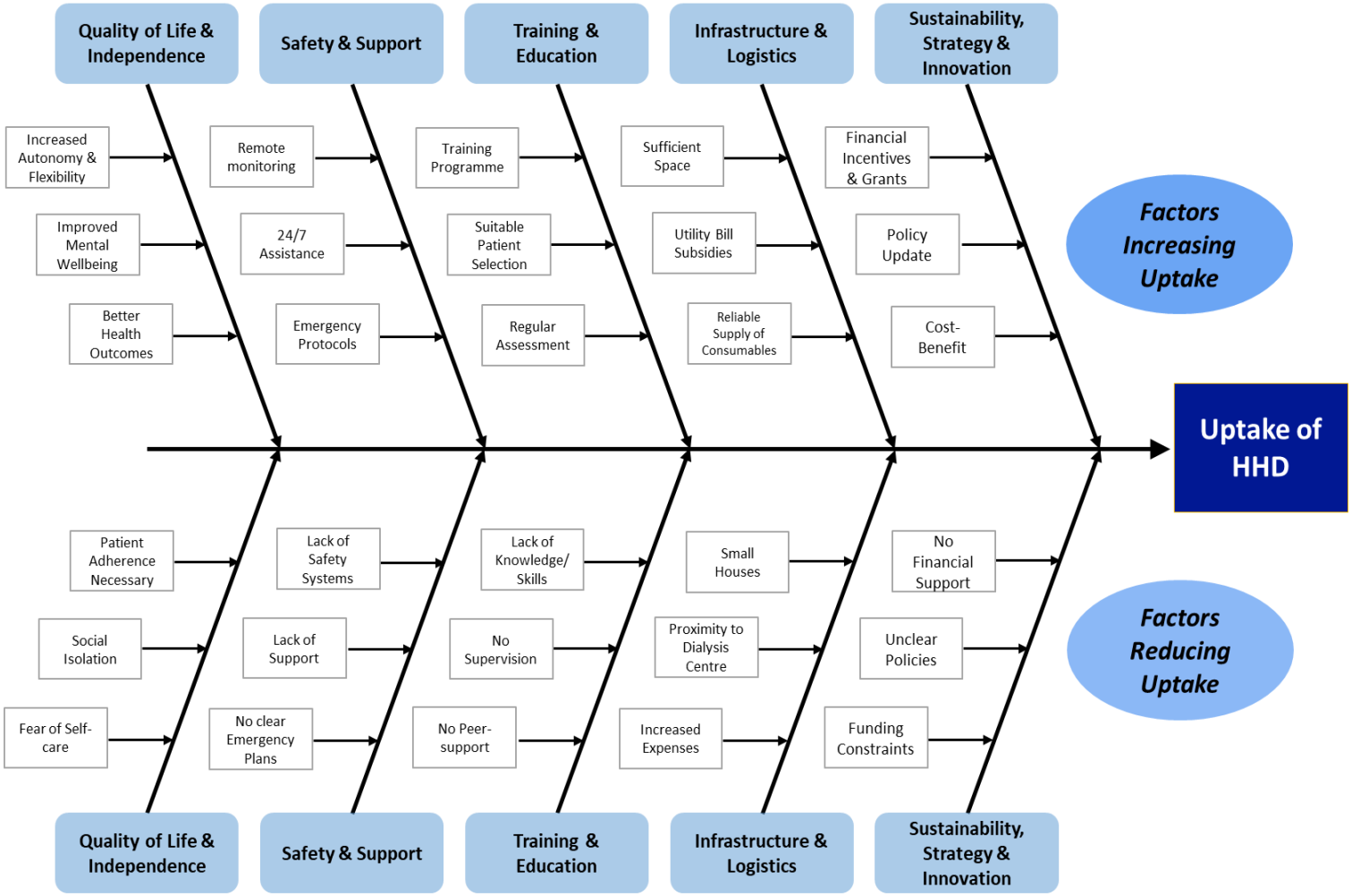

Figure 5.1 - Feasibility & Desirability Factors Influencing Uptake of HHD

Findings from Malta show that feasibility and desirability are interrelated. Across all five themes, support for HHD depended on meeting important viability needs such as strong safety systems, thorough training, suitable infrastructure, and sustainable planning. In effect, desirability was conditional. Patients value the autonomy and flexibility perceived with HHD, while Healthcare Workers (HCWs) value the associated health benefits. However, these advantages become less appealing if stakeholders feel there are safety risks, logistical problems or a lack of adequate resources.

The evidence on feasibility and desirability obtained from stakeholder perspectives addresses the research question, while the next section examines barriers and facilitators in line with objective 2.

5.3 Facilitators and Barriers

In the implementation of health system services, facilitators and barriers are important determinants that drive or hinder the uptake of the service. Facilitators (5.3.1) are enabling factors that encourage the adoption of new practices. In contrast, barriers (5.3.2) impede uptake and addressing both is essential for the effective introduction of a service (Earley et al., 2025).

Table 5.2 summarises the main facilitators and barriers to HHD implementation in Malta. Organised under themes, each factor is linked to feasibility and/or desirability. This framing provides a structured lens through which both opportunities and challenges can be examined in relation to stakeholder perceptions.

Table 5.2 - Themes Linking HHD Facilitators and Barriers to Feasibility and Desirability

Theme	Type	Factor	Determines
Quality of Life & Independence	Facilitator	Greater patient autonomy; flexible scheduling; ability to work or study; reduced travel burden; better health outcomes; reduced hospital admissions	Desirability
	Barrier	Anxiety about self-care; fear of isolation; preference for clinic routine	Desirability
Safety & Support	Facilitator	Telemedicine and remote monitoring; emergency support systems; caregiver involvement improves retention	Feasibility & Desirability
	Barrier	Fear of self-cannulation; risk of complications without immediate help; limited caregiver availability	Feasibility & Desirability
Training & Education	Facilitator	Adaptation of PD training model; structured peer mentoring; supervised practice opportunities; modular training programmes	Feasibility
	Barrier	Intensive staff training workload; patient/caregiver	Feasibility

		learning curve; risk of dropout during training	
Infrastructure & Logistics	Facilitator	Most homes adaptable with minor modifications; established PD supply chains; potential for centralised technical support	Feasibility
	Barrier	Limited home space; need for water/electricity modifications; higher utility costs; waste disposal concerns; supply chain reliability	Feasibility
Sustainability, Strategy & Innovation	Facilitator	Reduced strain on dialysis centre; improved service efficiency; potential long-term cost savings; alignment with person-centred care policies	Feasibility & Desirability
	Barrier	Workforce resistance to role change; limited HHD experience; competing resource priorities; cultural reliance on hospital-based care	Feasibility

The themes of training, infrastructure, and psychosocial support address objective 2 by identifying perceived benefits and barriers. Stakeholders recognised potential gains in quality of life and improved bed capacity, but also emphasised logistical and psychological barriers that must be overcome for successful adoption.

5.4 Management Implications

The themes identified by this study all have management implications affecting policy, workforce, and economy. Enhancing quality of life necessitates policies that promote person-centred models of care. Addressing safety requires investment in telemedicine and ensuring that rapid response systems are in place. The theme of training and education highlights the need for staff training and structured programmes for patients and caregivers. Infrastructure and resources carry economic implications to ensure appropriate staffing, carrying out necessary home modifications, and ensuring reliable supply chains. The findings of this study inform management strategies that balance policy direction, workforce readiness, and economic sustainability in implementing HHD.

5.4.1 Policy

The introduction of HHD in the Maltese Islands aligns with the priorities of both the *National Health Systems Strategy 2023–2030* and the *Health Workforce Strategy 2022–2030*. HHD facilitates a person-centred model of care (Tomaselli et al., 2020) by allowing patients to undergo treatment in their own homes, supporting the goal of providing *"the right care, in the right place, at the right time"* (Borg & Gatt, 2022), promoting patient autonomy, enhancing quality of life, and reducing reliance on overstretched hospital services, where dialysis units are operating at full capacity. HHD contributes to more efficient use of healthcare resources and strengthens continuity of care in the community. From a workforce standpoint, decentralising dialysis supports service innovation and improves staff resilience by relieving pressure on specialist personnel and enabling more strategic deployment of

resources. This approach supports the objective of empowering and sustaining Malta's health workforce while ensuring consistent, high-quality care (People Management Division, Ministry for Health, 2022), moving Maltese healthcare towards a more sustainable system that benefits both service users and professionals.

International evidence shows that HHD decreases hospital congestion. Increasing dialysis capacity without expanding hospital facilities would mitigate the initial expenses required to introduce HHD. The service would help alleviate the pressure on the in-centre dialysis unit, which frequently operates at full capacity, by shifting stable patients to community-based care and reserving hospital resources for complex cases (Ni et al., 2022). The COVID-19 pandemic demonstrated the importance of home therapy in health system resilience by reducing infection risks and maintaining treatment continuity during crises (Scarpioni et al., 2021).

To ensure equitable access to HHD Malta, clear regulatory frameworks defining patient eligibility, safety protocols and reimbursement provisions must be in place. Internationally, the absence of a clear policy has prevented the introduction of HHD, as seen in Poland, where implementation only progressed following supportive legislation and funding schemes (Kendzia et al., 2022). Malta can pre-empt such barriers by integrating HHD into national renal care plans and guaranteeing that home therapy patients face no financial or logistical disadvantages. As the service would likely be fully subsidised, health budgets must encompass equipment costs and ongoing support services such as training, home visits, and helplines. Early commitment to funding, infrastructure, and workforce development will ensure its success and alignment with national health priorities.

5.4.2 Human Resources

Implementing HHD requires workforce restructuring and staff upskilling. Initially, dialysis nurses and technicians must be trained as home therapy educators, which could temporarily strain resources as experienced staff balance unit-based dialysis with patient training and on-call support. Study participants emphasised that for the HHD programme to work, dedicated staff would need to oversee patient training, conduct regular home visits and provide 24/7 support. A structured training initiative, overseen by an appointed coordinator, is required, and may involve placements in HHD programmes abroad or expert-led workshops in Malta.

Over the long term, as HHD becomes routine, there could be efficiency gains for the workforce. For example, a dialysis nurse who previously cared for three in-centre patients per shift might remotely oversee double that number of HHD patients. While this model requires patients to be self-sufficient, it suggests that once the initial training is done, HHD can be more labour-efficient per treatment. Fewer in-centre patients could also reduce the need for some support services (for instance, patient transport), offsetting the new requirements for delivering supplies and maintaining machines at home. The role of nephrologists may shift by reducing routine reviews of stable in-centre patients with a greater focus on patient education and overseeing home dialysis patients at outpatient clinics and via telemedicine.

The economic and workforce implications of HHD require an initial resource investment, followed by potential cost savings and efficiency gains. Stakeholders recognised this, suggesting a pilot programme to assess feasibility without straining budgets, with successful outcomes strengthening the case for further investment.

5.4.3 Economic Implications

Stakeholders acknowledged the high upfront costs required for establishing an HHD but noted that long-term savings would eventually balance them out. Initial investments would include providing dialysis machines, installing water treatment systems and making modifications to accommodate the system in patients' homes. Training-related costs would also include setting up dedicated training programmes and allocating staff for home patient support roles. These findings align with international reports that HHD has higher initial expenses than in-centre dialysis (Power & Ashby, 2014; Kendzia et al., 2022). For a country with a predominantly state-funded healthcare system, budgeting for HHD start-up costs is required. Moreover, if only a few patients enrol in HHD at first, the cost per patient will be high until the program grows.

However, stakeholders also recognised that HHD could be financially advantageous in the long run. While hospital-based dialysis incurs ongoing costs for every session (staffing, use of consumables, facility overhead, patient transport), home dialysis has the potential to reduce the per-session cost burden on the hospital (Bamforth et al., 2021). Over time, as more patients train for HHD, the initial investments can be amortised (i.e. gradually spread out over time). Literature from health economics suggests that although HHD requires more upfront spending, it can become cost-effective as programmes mature and hospital utilisation decreases (Gorham et al., 2021).

HHD patients dialyse more frequently, resulting in fewer complications and hospitalisations (Kumar et al., 2007), reducing emergency visits and inpatient stay

costs. Study participants noted that keeping patients at home would significantly reduce the demand for in-centre slots. One administrator observed that a dialysis bed in the hospital is cumulatively occupied *"for years,"* whereas a machine at home is a one-time cost, underscoring the fact that investing in home machines could pay off over time. An Australian analysis found that providing dialysis closer to patients' homes achieved cost parity or savings by avoiding extensive travel and other indirect expenses (Gorham et al., 2021). Reducing the need for patient transport services, such as ambulance trips for thrice-weekly clinic dialysis, and enabling patients to miss fewer workdays through more flexible scheduling can generate broader economic benefits that may not be immediately visible on the hospital's balance sheet.

By triangulating patient, caregiver, professional, and administrative perspectives, the findings evaluate feasibility across multiple levels. At the micro level through individual readiness and experiences, at the meso level through organisational and professional practices, and at the macro level through policy and infrastructure requirements. They address objective 1 on stakeholder needs and expectations and objective 2 on perceived benefits and barriers, contributing to the research question on the feasibility and desirability of HHD in a small EU island state.

5.4.4 Sustainability and Social Responsibility Considerations

Beyond feasibility and desirability, it is important to reflect on how the introduction of HHD aligns with contemporary priorities in sustainability and social responsibility. Stakeholders in this study highlighted financial and logistical barriers, but also recognised that long-term adoption of home-based therapies may reduce strain on

hospital infrastructure, travel requirements, and resource consumption, thereby contributing to a more sustainable healthcare system (Connor et al., 2025).

From a social responsibility perspective, equitable access emerged as a central concern: evidence shows that disadvantaged groups, including racial and ethnic minorities, are less likely to access home dialysis modalities despite their potential benefits (Rizzolo et al., 2022). On a global scale, inequities in access to home dialysis remain pronounced, particularly in low- and middle-income countries, due to systemic and policy barriers (Htay et al., 2025).

Addressing these issues ensures that HHD is not merely regarded as a clinical innovation, but as part of a wider commitment to environmentally responsible, socially equitable, and patient-centred care that resonates with international healthcare sustainability agendas (Barraclough et al., 2010).

5.5 Strengths and Limitations

This study has both strengths and limitations, and acknowledging them is essential to ensure that the findings remain within scope while accurately addressing the research aim and central question.

5.5.1 Study Strengths

1. Alignment with Aim and Objectives: The qualitative case study design was well-suited to meet the aim of the study, and the inclusion of the various stakeholders allowed both objectives to be addressed: exploring needs and readiness (objective 1) while also investigating perceived benefits, barriers, and facilitators (objective 2).

2. Sampling Methods and Data Collection: Purposive and maximum variation sampling ensured representation across all stakeholder groups, while the use of both interviews and focus groups enabled the collection of rich data, capturing both individual perspectives and collective viewpoints.
3. Trustworthiness: Through methodological transparency, systematic thematic analysis, and triangulation, the study meets recognised criteria for qualitative trustworthiness, including credibility, dependability, confirmability, and transferability.
4. Triangulation Across Stakeholders: By drawing on patient, caregiver, HCW and administrative insights, feasibility was assessed at the micro level of individual readiness, the meso level of organisational practices, and the macro level of policy and infrastructure.
5. Use of Established Theoretical Frameworks: The analysis was anchored in Maslow's Hierarchy of Needs, Christensen's Needs Analysis Framework, and the Donabedian Model, providing a strong conceptual foundation and ensuring systematic linkage to feasibility and desirability.
6. Relevance: Researching HHD in Malta fills an important knowledge gap, examining feasibility and desirability in small EU island states and providing contextual relevance. These findings inform local decision-making while contributing insights that may be transferable to comparable healthcare systems.

5.5.2 Study Limitations

Although the study provides meaningful insights, it also has limitations, which must be acknowledged to frame the findings appropriately and prevent conclusions beyond the scope of the study.

1. Generalisability: This study is based on a case study of Malta, a small island nation with a distinct healthcare system. A qualitative approach allows for an in-depth exploration of the subject but limits its generalisability. The findings are influenced by Malta's specific context, including its geography, culture and infrastructure. Hence, the results may not be applicable to larger systems with decentralised care. Countries with multiple dialysis centres and regional variations may encounter different barriers to adopting HHD. The sample was sufficient for qualitative saturation but was limited to the stakeholder pool of the dialysis services in Malta. Thus, the results should be viewed as indicative of trends and perceptions, and caution is advised when applying these insights beyond comparable settings.
2. Cross-Sectional Design: This study uses a cross-sectional design to examine stakeholder perceptions of introducing an HHD programme in Malta, capturing views at a single point before implementing the novel service. While this approach helps assess perceived needs and readiness for HHD, since no patients were undergoing HHD during the study, it does not provide insights on outcomes over time. Participants' views are based on expectations rather than actual experiences. Conclusions about the feasibility and desirability of HHD, including

key factors like clinical effectiveness, cost-efficiency and quality of life, remain provisional and grounded in perceived readiness rather than empirical evidence.

3. Resource Constraints and Bias**:** This study was limited by time and resources, restricting its scope. Methods that could have enhanced the findings, such as large-scale surveys or observational visits abroad, were not feasible. The use of interviews and focus groups introduces potential biases, including response and social desirability bias; for example, patients may have expressed more favourable views towards HHD in the presence of a researcher, while staff may have minimised concerns. While confidentiality assurances and neutral questioning techniques were employed to reduce such biases, their influence cannot be entirely excluded. Essential operational factors, such as cost estimations, technical assessments of Maltese home infrastructure, and detailed workforce planning, were outside the study's scope and not incorporated into the feasibility analysis. These areas warrant further investigation to support comprehensive implementation planning.
4. Methodology: This study relies solely on qualitative methods, which may limit its ability to quantify certain aspects of feasibility (e.g., cost analysis and resource allocation).
5. Sample Size: The sample size of 25 participants may appear limited, particularly given the inclusion of diverse stakeholder groups. However, this is considered appropriate within the context of Malta's small population and centralised healthcare system serving just 253 haemodialysis patients.
6. Economic, Technological, and Policy Considerations: The study discusses financial, technological, and policy aspects but does not provide a detailed cost-benefit

analysis, a thorough examination of technological requirements (such as digital systems and data security), or concrete recommendations for addressing legal and administrative barriers. Further research is needed to integrate these areas to ensure sustainable implementation.

7. Dependence on Perceived Readiness: Stakeholder perceptions of readiness form the foundation of this analysis. However, without empirical outcome data or pilot programme evidence, conclusions remain provisional, shaped more by expectations than demonstrated practice.

While the study provides insights into the potential adoption of HHD in Malta, given the above-mentioned limitations, further research is needed to build on these results and address any remaining gaps, as discussed in Chapter 6.

Considering both the strengths and limitations of this study allows for a balanced interpretation of the findings, in line with the research aim and central question on the feasibility and desirability of HHD in Malta.

5.6 Synthesis of Findings

This discussion has demonstrated that the objectives of the study have been achieved. The needs, readiness, and expectations of stakeholders were explored, demonstrating an enthusiasm for HHD to improve quality of life and independence, alongside concerns relating to safety, the need for training, and the demands of infrastructure, policy and innovation to ensure sustainability. By triangulating the perspectives of patients, HCWs and policymakers, the study identified both facilitators and barriers to implementation, demonstrating that while HHD is desirable for many stakeholders, its feasibility relies on careful investment in

infrastructure and training, and supportive policy. The research question has therefore been addressed: HHD is both feasible and desirable in Malta, but only under conditions that respond directly to stakeholder concerns.

The next chapter will build on these findings by outlining the study's contributions and limitations, and by proposing recommendations for policy, practice, and future research to support the sustainable introduction of HHD in Malta and other small island states.

Chapter 6: Conclusions and Recommendations

6.1 Summary of Key Findings

In line with its aim, this study examined the feasibility and desirability of introducing home haemodialysis (HHD) in Malta, guided by its two objectives: to explore stakeholder needs and readiness, and to investigate perceived benefits and barriers.

The study assessed the feasibility and desirability of introducing HHD in Malta, examining the perspectives of key stakeholders (patients, their caregivers, healthcare professionals and administrators) who regard it as positive and innovative. They view HHD as a desirable modality and recognise its potential to improve clinical outcomes, patient autonomy, and quality of life. This aligns with the shift towards person-centred and community-based care. Patients view HHD as a means of integrating their treatment into their daily lives to regain a sense of normalcy. Healthcare professionals and policymakers agree that it enhances independence, increases dialysis slot availability, and reduces hospital service pressure. The findings are consistent with the literature, which indicates that HHD is associated with better results than in-centre dialysis (Wong et al., 2019), while noting that overall certainty remains low and robust randomised evidence remains limited (Cheetham et al., 2024).

The study identifies several key facilitators promoting the adoption of HHD in Malta. The country's small size and centralised health service allow for rapid support should the need arise. The established peritoneal dialysis (PD) programme demonstrates

that Malta is prepared for home dialysis and can serve as a model for developing the HHD service, mirroring international experiences where PD programmes lay the foundation for developing HHD services (Desbiens et al., 2024a). HHD aligns with national health policy objectives, where strategies prioritise community care, patient empowerment and sustainable use of resources (Borg & Gatt, 2022), as well as with international trends towards decentralising care.

Despite overall support for HHD, the study identified several barriers restraining stakeholder readiness and needs for its successful implementation. Participants noted that feasibility does not imply ease, reflecting international data where interest in HHD is usually higher than actual uptake due to practicality (Jayanti et al., 2014; Kendzia et al., 2022). Three main challenges were identified. Training and support needs for safe dialysis at home were frequently mentioned, with patients expressing anxiety about self-cannulation, handling of equipment and the lack of a nurse present. This was particularly evident amongst those used to in-centre care. Another concern was home environment suitability, with participants frequently mentioning space limitation, inadequate infrastructure and burdening family members as concerns. Systemic limitations were also noted, with healthcare professionals and administrators highlighting the need for more human resources to meet the additional demands of training and support. The need for funding and establishing policies for safe home dialysis was also raised. While desirable, the feasibility of implementing HHD in Malta will require careful planning, adequate resources and a good support framework.

This analysis indicates that HHD is feasible and desirable in Malta, under the right conditions. Stakeholders acknowledge the potential benefits of HHD but note that, for successful implementation, there is a need for investment in training, technology and infrastructure, patient support, and policy integration.

6.2 Recommendations

The following recommendations are derived from the five key themes identified in the study and are firmly grounded in the literature. Stakeholder perspectives provided insight into the facilitators that assist and barriers that must be overcome to implement HHD successfully in Malta, while international research offered comparative evidence. Together, these sources ensure that the recommendations are contextually relevant to the Maltese healthcare system, academically sound and address the needs of the patients, caregivers, healthcare workers and policymakers.

6.2.1 Phased Rollout via Pilot Programme

HHD would be introduced gradually through a pilot project involving 5-10 carefully selected patients. Ideal participants would be medically stable with good social support and prior experience with home dialysis. A 6-12-month trial period would allow close monitoring, identification of barriers and data collection on feasibility and outcomes. This approach would minimise risks and initial costs while building confidence through success. As Machowska et al. (2016) noted, pilot programmes can validate the model and encourage stakeholder support. Following the trial, a thorough examination would assess outcomes, patient experience and cost-benefit, and should the results be positive, the programme can be scaled up incrementally. A

stepwise rollout allows for iterative, evidence-based alterations to ensure long-term stakeholder engagement.

This recommendation is linked to both the safety and support and training and education themes. Stakeholders expressed that a gradual rollout would allow patients and staff to build confidence in a controlled environment, reflecting the need for safety reassurance and progressive education during implementation.

6.2.2 Workforce Development and Training

A successful HHD programme relies on having a dedicated team of skilled nurses and doctors trained in both the clinical and technical aspects of home dialysis and adult education. Training should cover emergency response, remote monitoring, and assessment of patients and their home environments.

Partnering with established HHD centres abroad would support this training. Short placements or workshops at leading European units would allow local staff to observe best practices first-hand. International experts could be brought to Malta to run locally tailored *'train-the-trainer'* sessions. A pilot mentorship programme for physicians by Abra et al., (2022) was well-received, indicating that peer support may improve prescription of home dialysis.

Once trained, the team should develop home-specific protocols and patient education materials. Adequate time and resources must be set aside to allow nurse educators and technicians to conduct patient and caregiver training and home visits. To avoid overburdening in-centre services, additional staff may be needed. Adjusting existing roles, such as cross-training peritoneal dialysis (PD) nurses and integrating PD and HHD into a unified home dialysis team would facilitate this process. Nephrologists

should stay updated through ongoing professional development in patient selection, monitoring, and home dialysis technologies.

The early phase of the programme will demand significant investment in training and team development to deliver safe and effective home dialysis in Malta; however, this would become cost-beneficial in time, especially with the implementation of efficient systems such as remote monitoring, where one healthcare worker can monitor multiple patients concurrently.

This corresponds to the training and education theme, which highlights the need for professional competence. Literature similarly stresses that healthcare workforce readiness is central to safe HHD adoption (Díaz-Buxó et al., 2015).

6.2.3 Patient Education

The study demonstrates the need for effective patient education, which is crucial for successfully adopting HHD. Informed patients are more likely to engage with home dialysis, so a structured, person-centred training programme should be offered (van Eck van der Sluijs et al., 2024). This should address technical aspects and patient concerns using diverse educational tools like online resources, videos, and booklets (Desbiens et al., 2024a).

HHD should be introduced early, ideally in the Low Clearance Clinic (LCC), where all treatment options are presented equally. Those choosing HHD would undergo phased training to develop technical skills in machine use, infection control, self-needling, and handling emergencies (Raphael et al., 2015). Starting in a supervised, simulated environment and gradually transitioning responsibility to the patient can also ease the transition by offering support and reducing isolation.

This recommendation aligns with the themes of quality of life and independence, as well as training and education. Patient and caregivers consistently emphasised the need for structured training to gain confidence, and the literature reinforces that education is the key to self-management and autonomy (McIsaac et al., 2022).

6.2.4 Infrastructure and Logistics

The study highlights the need for planning infrastructure, technology, and support systems to ensure the successful implementation of HHD. A dedicated team should conduct pre-dialysis home assessments to evaluate suitability and recommend necessary modifications, including installation of water filtration systems (e.g. reverse osmosis), appropriate outlets, and creating a clean space for dialysis. All essential equipment and modifications should be subsidised by the health system.

Essential needs identified by the study include technical support for equipment setup and maintenance, and having a reliable supply of consumables. Clear contingency plans for equipment failure must be in place. Telemedicine would also play an important role, enabling connected, supervised home care, with remote monitoring devices transmitting real-time data for timely intervention. Participants frequently mentioned having a 24/7 support line as another important need to provide patient safety and reassurance. This approach was found to result in lower dropout rates and better outcomes (Weinhandl & Collins, 2018). Regular follow-up by the dialysis team, through daily calls and weekly home visits, supports patients, increases adherence and addresses concerns. This *"virtual ward"* model has proven effective during the HHD transition (Raphael et al., 2015). Good infrastructure and strong support systems will improve uptake and adherence to the new service.

This recommendation links directly to the theme of infrastructure and logistics, where stakeholders identified barriers such as equipment, water supply, and space, mirroring the literature in emphasising that logistical readiness is essential to programme success (François et al., 2015).

6.2.5 Policy and Funding

Clear policy frameworks and sustainable funding are further needs for introducing HHD in Malta. HHD frameworks must be aligned with the national health policy, including eligibility criteria, training protocols and safety standards, and making any legislative reforms necessary to address equipment licensing, waste disposal and professional liability (Kendzia et al., 2022). Utility costs associated with the service should be refunded to prevent penalising patients for opting for home-based therapy (Kendzia et al., 2022). To optimise resource use and reduce costs, the HHD programme could be integrated with the existing peritoneal dialysis (PD) programme under a unified home dialysis framework, ensuring all suitable patients are offered a home-based option before initiating in-centre haemodialysis. Awareness is another need identified in the study. Public education can enhance the acceptance of HHD. Engagement with community and hospital doctors is necessary to promote referrals and increase confidence in the modality.

This recommendation relates to the sustainability, strategy and innovation theme, where participants emphasised the need for long-term planning. Literature confirms that reimbursement and strategic policy are decisive in enabling HHD adoption (Pérez-Alba et al., 2020).

The above recommendations offer evidence-based guidance informed by stakeholder input, addressing key needs and overcoming identified barriers, with the potential to improve patient outcomes, reduce pressure on hospital services, and establish home dialysis as a standard component of care in Malta.

6.3 Theoretical and Practical Contributions of the Study

6.3.1 Contribution to Knowledge

Prior to this study, there was a significant gap in the literature regarding the adoption of HHD in small health systems like Malta. Much of the existing research on HHD originates from larger countries with different healthcare structures, and few studies have focused on how a centralised, resource-limited system might approach home dialysis.

This dissertation addresses a previously underexplored setting by investigating the feasibility and desirability of HHD in Malta. It offers comprehensive analyses of stakeholder perspectives on HHD in a small island EU member state, listing the unique challenges and facilitators present in such a context. By considering geographical and cultural elements as well as the impact of having a single tertiary hospital for all specialised care, the study provides insights that further extend the understanding of HHD implementation globally.

Beyond its immediate context, this study contributes to knowledge through a needs-driven approach that includes multiple stakeholders. In contrast to prior research that often focuses on clinical outcomes or a single stakeholder group, typically patients, this study triangulated perspectives from patients, healthcare workers and administrators offering a holistic understanding of the feasibility and desirability of

HHD, exposing both points of consensus and divergence. For example, patients' aspirations for flexibility were contrasted with providers' concerns regarding safety and resources, providing a more comprehensive understanding of HHD implementation. Using Christensen's (2018) framework to group needs into objective, subjective, felt, and perceived categories offers a new way to understand dialysis services.

6.3.2 Contribution to Theory

This dissertation contributes to theory by combining three established frameworks (Maslow's Hierarchy of Needs, Christensen's Needs Analysis model and the Donabedian Model) into the unique context of Malta, a small island state in the European Union, extending their applicability to health systems with limited resources. By demonstrating how concepts of independence, safety, system quality, and person-centred care can be operationalised through HHD, the study adds to the theoretical understanding of healthcare feasibility and desirability.

Theoretical integration is relatively uncommon in previous studies, which prioritise clinical outcomes. In this research, theoretical concepts were utilised to inform study design and result interpretation, connecting conceptual models to practical application and integrating two major theoretical frameworks to enhance its analyses. Maslow's Hierarchy of Needs (1943) provided further insight into the psychological factors influencing patient engagement with home-based care, including safety, self-esteem and self-actualisation. Donabedian's (1966) Structure-Process-Outcome Model helped to determine the structural and procedural elements that will result in the desired quality outcomes of HHD.

6.3.3 Contribution to Practice

This study contributes to practice by identifying context-specific insights to guide the introduction of HHD in Malta based on identified stakeholder needs. The study outlines facilitators, barriers, and stakeholder readiness and provides policymakers, administrators, and healthcare workers with evidence-based recommendations to design, implement, and manage effective, person-centred dialysis services.

The findings can inform other small jurisdictions or developing health systems that are considering a shift towards home-based renal therapies. The knowledge generated by this study adds a nuanced understanding to the literature on HHD. It shows that strategies need to be modified for the setting to ensure the successful adoption of innovative therapies, such as HHD, in smaller systems.

6.4 International Insights

Despite its clinical advantages, HHD remains underutilised globally, with only 1–2% of dialysis patients in Europe and 12–14% in the United States receiving home-based therapies, predominantly peritoneal dialysis (Vanholder et al., 2017). In Australia and New Zealand, early investment in patient education and supportive policies led to HHD rates of up to 30%, demonstrating that uptake can improve with systemic support (Power & Ashby, 2014). Malta currently offers no HHD, but international examples, including Poland's recent efforts to establish HHD through legal reform and infrastructure development, show that jurisdictions can successfully implement programmes with proper policy commitment (Kendzia et al., 2022).

The adoption of HHD is influenced more by supportive policies, cultural attitudes, and strong system infrastructure than by a country’s size or wealth (Al Sahlawi et al.,

2022). Successful HHD programmes worldwide have often developed in places that focused on thorough training, continual patient support, and appropriate financial backing, making it possible to introduce the service even where resources were limited (Kneipp et al., 2004). For Malta, international experience suggests that a sustainable HHD service will require a phased approach, starting with pilot programmes, as seen in New Zealand, coupled with investment in patient education across the care pathway (Machowska et al., 2016) and clear funding mechanisms, as implemented in Canada and Australia (Marshall et al., 2015).

6.5 Further Research

Building on the findings and acknowledging the limitations of this study, several avenues for future research are proposed to enhance understanding and inform ongoing efforts to implement HHD in Malta and comparable settings:

1. Longitudinal Studies: Should HHD be introduced in Malta, both quantitative and qualitative longitudinal research will be essential to evaluate its overall impact, including clinical outcomes (such as hospitalisation rates and complications), patient and staff experiences (including quality of life and satisfaction), and cost-benefit compared to in-centre dialysis. A pilot study would provide early insights, while long-term research would demonstrate changes in stakeholder perspectives as they gain experience.
2. Comparative Studies: Comparative studies can further strengthen the evidence for HHD in Malta. These may include cross-national comparisons, examining how similar countries, in particular small island states, have implemented HHD and identifying any strategies that might be used locally. Quantitative analyses using

patient records and surveys would help validate HHD's advantages in the Maltese context and identify patient subgroups most likely to benefit from the service, informing selection criteria and policy decisions.

3. Socio-Cultural Influences: Given Malta's unique social and cultural context, further research should explore how socio-cultural elements influence the feasibility and desirability of HHD. Research may include examining perceptions towards caregiving and treatment at home and trust in healthcare providers. Barriers such as stigma or misconceptions would be examined. Anthropological and sociological methods, including community surveys and targeted in-depth interviews, would aid in uncovering beliefs and needs not identified in the initial analysis.
4. Mixed Methods Approach: Combining qualitative insights with quantitative data could offer a more comprehensive understanding and support better evaluation of outcomes, patient uptake, and the overall cost-effectiveness.
5. Action Research: Further research should include studies to evaluate interventions addressing barriers identified in this research. Support programmes could be tested for their impact on patient confidence and HHD uptake. Comparative trials of training methods (e.g., simulation-based versus bedside teaching) could assess the effects on patient competency and preparedness. Piloting the use of telemedicine and real-time monitoring may reveal benefits in clinical outcomes. Evidence gained from such studies will inform best practices for training, supporting and retaining HHD patients.
6. Policy and Economic Analyses: Health policy and economic evaluation are pivotal for guiding decision-making on HHD implementation. A cost-benefit analysis

comparing home dialysis with in-centre dialysis, considering expenses such as equipment costs, training and home support against outcomes like quality-adjusted life years and hospitalisations, would provide an evidence-based rationale for scaling up or down the service. Policy research would explore how HHD is integrated into the national health system, examining decision-making processes, stakeholder involvement and policy impact on the choice of dialysis modality.

7. Sample Size: Future research should consider the recruitment of a larger sample across other small states. This would allow for comparative insights and more comprehensive data on the feasibility and desirability of HHD in similar settings.

Future research should build on the study's findings. Monitoring patient outcomes, comparing modalities and evaluating interventions will further supplement the evidence base for HHD. This research may help the Maltese healthcare system in moving from planning to piloting and implementing home-based haemodialysis treatment. On an international level, it can help inform strategies for adopting HHD and support improved patient care in treating end-stage kidney disease.

6.6 Conclusion

This chapter has brought together the findings from the data analysis, identifying the key barriers and facilitators to implementing HHD in Malta. In addressing the central research question, the study has met its objectives by evaluating feasibility and desirability through the perspectives of patients, caregivers, healthcare professionals, and policymakers. It contributes to knowledge by framing these perspectives within established theoretical frameworks and, in doing so, extending understanding of how

new healthcare services can be adapted within the context of small island health systems.

The introduction of HHD in Malta would mark the beginning of a process that must be evidence-driven and responsive to the needs of all stakeholders. This dissertation affirms that with careful preparation, investment and stakeholder collaboration, HHD can develop from a theoretical possibility to a practical reality, offering a more person-centred and forward-looking model of renal care.

References

Abela, L., Pace, A., & Buttigieg, S. C. (2019). What affects length of hospital stay? A case study from Malta. *Journal of Health Organization and Management*, *33*(6), 714–736. https://doi.org/10.1108/JHOM-10-2018-0280

Abra, G., Poyan Mehr, A., Chan, C. T., & Schiller, B. (2022). The implementation of a virtual home dialysis mentoring program for nephrologists. *Kidney360*, *3*(4), 734–736. https://doi.org/10.34067/KID.0000202022

Al Sahlawi, M. A., & Dahlan, R. A. (2022). Nephrologists' perspectives of the potential utilization of home hemodialysis in Saudi Arabia. *Saudi Journal of Kidney Diseases and Transplantation*, *33*(6), 730–737. https://doi.org/10.4103/1319-2442.390252

Antoun, J., Brown, D. J., Jones, D. J. W., Clarkson, B. G., Shepherd, A. I., Sangala, N. C., Lewis, R. J., McNarry, M. A., Mackintosh, K. A., Mason, L., Corbett, J., & Saynor, Z. L. (2023). Exploring patients' experiences of the impact of dialysis therapies on quality of life and wellbeing. *Journal of Renal Care*, *49*(1), 15–23. https://doi.org/10.1111/jorc.12416

Baldacchino, I., Debattista, S., Debattista, D., Balzan, G., Abdilla, S., Baldacchino, L., Borg, G., Buttigieg, S., Calleja Stafrace, N., Cutajar, C., Galea, M., Sciberras, W., Xerri, T., Camilleri, L., & Farrugia, E. (2019). *National analyses on survival in Maltese adult patients on renal replacement therapy started during 2009–2012*. https://www.um.edu.mt/library/oar/handle/123456789/55745

Bamforth, R. J., Beaudry, A., Ferguson, T. W., Rigatto, C., Tangri, N., Bohm, C., & Komenda, P. (2021). Costs of assisted home dialysis: A single-payer

Canadian model from Manitoba. *Kidney Medicine*, *3*(6), 942-950.e1. https://doi.org/10.1016/j.xkme.2021.04.019

Barraclough, K. A., Agar, J. W. M., & Walker, R. (2010). Sustainability in dialysis: Reuse and recycling of resources. *American Journal of Kidney Diseases,* 56(4), 779–786. https://doi.org/10.1053/j.ajkd.2010.06.010

Beby, A. T., Cornelis, T., Zinck, R., & Liu, F. X. (2016). Cost-effectiveness of high dose hemodialysis in comparison to conventional in-center hemodialysis in the Netherlands. *Advances in Therapy, 33*(11), 2032–2048. https://doi.org/10.1007/s12325-016-0408-4

Bello, A. K., Okpechi, I. G., Osman, M. A., Cho, Y., Htay, H., Jha, V., Wainstein, M., & Johnson, D. W. (2022). Epidemiology of haemodialysis outcomes. *Nature Reviews Nephrology*, *18*(6), 378–395. https://doi.org/10.1038/s41581-022-00542-7

Bennett, P. N., Schatell, D., & Shah, K. D. (2015). Psychosocial aspects in home hemodialysis: A review. *Hemodialysis International*, *19*(S1). https://doi.org/10.1111/hdi.12258

Berger, P. L., & Luckmann, T. (2011). *The social construction of reality: A treatise in the sociology of knowledge*. Open Road Media Integrated Media.

Berwick, R. (1989). Needs assessment in language programming: From theory to practice. In R. K. Johnson (Ed.), *The Second Language Curriculum* (pp. 48–62). Cambridge University Press. https://doi.org/10.1017/CBO9781139524520.006

Bieber, S. D., & Young, B. A. (2021). Home hemodialysis: Core curriculum 2021. *American Journal of Kidney Diseases*, *78*(6), 876–885. https://doi.org/10.1053/j.ajkd.2021.01.025

Borg, A., & Gatt, A. (2022, December 14). *A national health systems strategy for Malta 2023–2030: Investing successfully for a healthy future*. Ministry for Health.

Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., Bakken, S., Kaplan, C. P., Squiers, L., Fabrizio, C., & Fernandez, M. (2009). How we design feasibility studies. *American Journal of Preventive Medicine*, *36*(5), 452–457. https://doi.org/10.1016/j.amepre.2009.02.002

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Brindley, G. (1989). The role of needs analysis in adult ESL programme design. In R. K. Johnson (Ed.), *The Second Language Curriculum* (1st ed., pp. 63–78). Cambridge University Press. https://doi.org/10.1017/CBO9781139524520.007

Bryman, A. (2015). *Social research methods.* (5th ed.). OUP Oxford.

Buttigieg, S. C., Abela, L., & Pace, A. (2018). Variables affecting hospital length of stay: A scoping review. *Journal of Health Organization and Management*, *32*(3), 463–493. https://doi.org/10.1108/JHOM-10-2017-0275

Buttigieg, S., Dey, P. K., & Gauci, D. (2016). Business process management in health care: Current challenges and future prospects. *Innovation and Entrepreneurship in Health*, 1. https://doi.org/10.2147/IEH.S68183

Calleja, C. (2019, September 21). *Stark reality of kidney disease in Malta*. Times of Malta. https://timesofmalta.com/article/stark-reality-of-kidney-disease-in-malta.736133

Carter, N., Bryant-Lukosius, D., DiCenso, A., Blythe, J., & Neville, A. J. (2014). The use of triangulation in qualitative research. *Oncology Nursing Forum*, *41*(5), 545–547. https://doi.org/10.1188/14.ONF.545-547

Chan, C. T., Li, G. H., Valaperti, A., & Liu, P. (2015). Intensive hemodialysis preserved cardiac injury. *ASAIO Journal*, *61*(5), 613–619. https://doi.org/10.1097/MAT.0000000000000255

Cheetham, M. S., Ethier, I., Krishnasamy, R., Cho, Y., Palmer, S. C., Johnson, D. W., Craig, J. C., Stroumza, P., Frantzen, L., Hegbrant, J., & Strippoli, G. F. (2024). Home versus in-centre haemodialysis for people with kidney failure. Cochrane Database of Systematic Reviews, 2024(5). https://doi.org/10.1002/14651858.CD009535.pub3

Cherukuri, S., Bajo, M., Colussi, G., Corciulo, R., Fessi, H., Ficheux, M., Slon, M., Weinhandl, E., & Borman, N. (2018). Home hemodialysis treatment and outcomes: Retrospective analysis of the Knowledge to Improve Home Dialysis Network in Europe (Kihdney) cohort. *BMC Nephrology*, *19*(1), 262. https://doi.org/10.1186/s12882-018-1059-2

Christensen, B. D. (2018). From needs assessment to needs analysis. *Performance Improvement*, *57*(7), 36–44. https://doi.org/10.1002/pfi.21785

Connor, A., Broadbent, A., Greaves, C., & McCulloch, A. (2025). Environmental impact of haemodialysis: Opportunities for sustainable practice. *Clinical Kidney Journal,* 18(2), 264–272. https://doi.org/10.1093/ckj/sfae407

Cornelis, T., Tennankore, K. K., Goffin, E., Rauta, V., Honkanen, E., Őzyilmaz, A., Thanaraj, V., Jayanti, A., Mitra, S., Van Der Sande, F. M., Kooman, J. P., & Chan, C. T. (2014). An international feasibility study of home haemodialysis

in older patients. *Nephrology Dialysis Transplantation*, *29*(12), 2327–2333. https://doi.org/10.1093/ndt/gfu260

Coyne, I. T. (1997). Sampling in qualitative research. Purposeful and theoretical sampling; merging or clear boundaries? *Journal of Advanced Nursing*, *26*(3), 623–630. https://doi.org/10.1046/j.1365-2648.1997.t01-25-00999.x

Creswell, J. W., & Creswell, J. D. (2023). *Research design: Qualitative, quantitative, and mixed methods approaches* (Sixth edition). SAGE.

Crowe, S., Cresswell, K., Robertson, A., Huby, G., Avery, A., & Sheikh, A. (2011). The case study approach. *BMC Medical Research Methodology*, *11*(1), 100. https://doi.org/10.1186/1471-2288-11-100

Daliri, S., Bekker, C. L., Buurman, B. M., Scholte Op Reimer, W. J. M., Van Den Bemt, B. J. F., & Karapinar – Çarkit, F. (2019). Barriers and facilitators with medication use during the transition from hospital to home: A qualitative study among patients. *BMC Health Services Research*, *19*(1), 204. https://doi.org/10.1186/s12913-019-4028-y

Denzin, N. K. (2001). *Interpretive interactionism* (2nd ed). Sage Publications.

Denzin, N. K., & Lincoln, Y. S. (Eds.). (2018). *The SAGE handbook of qualitative research* (Fifth edition). SAGE.

Desbiens, L.-C., Bargman, J. M., Chan, C. T., & Nadeau-Fredette, A.-C. (2024a). Integrated home dialysis model: Facilitating home-to-home transition. *Clinical Kidney Journal*, *17*(Supplement_1), i21–i33. https://doi.org/10.1093/ckj/sfae079

Desbiens, L.-C., Tennankore, K. K., Goupil, R., Perl, J., Trinh, E., Chan, C. T., & Nadeau-Fredette, A.-C. (2024b). Outcomes of integrated home dialysis care:

Results from the Canadian organ replacement register. *American Journal of Kidney Diseases*, *83*(1), 47-57.e1. https://doi.org/10.1053/j.ajkd.2023.05.011

Díaz-Buxó, J. A., Zeller-Knuth, C. E., Rambaran, K. A., & Himmele, R. (2015). Home hemodialysis dose: Balancing patient needs and preferences. *Blood Purification*, *39*(1–3), 45–49. https://doi.org/10.1159/000368944

DiCicco-Bloom, B., & Crabtree, B. F. (2006). The qualitative research interview. *Medical Education*, *40*(4), 314–321. https://doi.org/10.1111/j.1365-2929.2006.02418.x

Donabedian, A. (1966). Evaluating the quality of medical care. *The Milbank Memorial Fund Quarterly*, *44*(3), 166. https://doi.org/10.2307/3348969

Dhruve, M., Faratro, R., D'Gama, C., Fung, S., Arustei, D., Wong, E., & Chan, C. T. (2019). The use of nurse-administered vascular access audit in home hemodialysis patients: A quality initiative. *Hemodialysis International, 23*(2), 133–138. https://doi.org/10.1111/hdi.12708

Dubin, R., & Rubinsky, A. (2019). A digital modality decision program for patients with advanced chronic kidney disease. *JMIR Formative Research*, *3*(1), e12528. https://doi.org/10.2196/12528

Earley, Á., Lydon, S., Walker, R. C., Gannon, L., Reddan, D., Durack, L., & O'Connor, P. (2025). A systematic review of the qualitative research on barriers and facilitators to home hemodialysis. *Hemodialysis International*, hdi.13266. https://doi.org/10.1111/hdi.13266

Eilers, D. (2018). Person-centered approach to deciding on long-term dialysis. *Clinical Journal of the American Society of Nephrology*, *13*(8), 1133–1134. https://doi.org/10.2215/CJN.07300618

Etikan, I. (2016). Comparison of convenience sampling and purposive sampling. *American Journal of Theoretical and Applied Statistics*, *5*(1), 1. https://doi.org/10.11648/j.ajtas.20160501.11

European Data Protection Supervisor. (2021, December 21). *Pseudonymous data: Processing personal data while mitigating risks.* https://www.edps.europa.eu/press-publications/press-news/blog/pseudonymous-data-processing-personal-data-while-mitigating

European Parliament & Council of the European Union. (2021). *Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ("EU4Health Programme") for the period 2021–2027, and repealing Regulation (EU) No 282/2014*. Publications Office of the European Union; Official Journal of the European Union, L 107, 1–29. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R0522

European Renal Association (Director). (2023, February). *Home haemodialysis: How to build a program that works?* [Video recording]. EuDial (European Dialysis Working Group). https://www.era-online.org/video-pages/home-haemodialysis-how-to-build-a-program-that-works/

Farnsworth, J., & Boon, B. (2010). Analysing group dynamics within the focus group. *Qualitative Research*, *10*(5), 605–624. https://doi.org/10.1177/1468794110375223

Farzi, S., Farzi, S., Moladoost, A., Ehsani, M., Shahriari, M., & Moinei, M. (2019). Caring burden and quality of life of family caregivers in patients undergoing hemodialysis: A descriptive-analytic study. *International Journal of*

Community Based Nursing & Midwifery, 7(2). https://doi.org/10.30476/ijcbnm.2019.44888

François, K., Ghazan-Shah, S., & Chan, C. T. (2015). Modalities and prescribing strategies in intensive home hemodialysis: A narrative review. *Minerva Urol Nefrol*, *67*(1), 75–84.

Friesen, T., Jassal, D. S., Zhu, M., Eng, F., Rigatto, C., Tangri, N., Sood, M. M., Karlstedt, E., Premecz, S., & Komenda, P. (2015). Cardiovascular remodeling during long-term nocturnal home hemodialysis. *Clinical and Experimental Nephrology, 19*(3), 514–520. https://doi.org/10.1007/s10157-014-0992-z

Gedney, N., & Kalantar-Zadeh, K. (2018). Dialysis patient-centeredness and precision medicine: Focus on incremental home hemodialysis and preserving residual kidney function. *Seminars in Nephrology*, *38*(4), 426–432. https://doi.org/10.1016/j.semnephrol.2018.05.012

Girsberger, M., Trinh, E., & Chan, C. T. (2020). Ventricular ejection fraction over time in patients on intensive home hemodialysis: A retrospective cohort study. *Hemodialysis International*, *24*(3), 290–298. https://doi.org/10.1111/hdi.12838

Gorham, G., Howard, K., Cunningham, J., Barzi, F., Lawton, P., & Cass, A. (2021). Do remote dialysis services really cost more? An economic analysis of hospital and dialysis modality costs associated with dialysis services in urban, rural and remote settings. *BMC Health Services Research*, *21*(1), 582. https://doi.org/10.1186/s12913-021-06612-z

Grant, Y. L. (1994). *Needs assessment in program planning*. College quarterly - articles. https://collegequarterly.ca/1994-vol02-num02-winter/young.html

Guba, E. G., & Lincoln, Y. S. (1994). Competing paradigms in qualitative research. In *Handbook of qualitative research* (1st Edition, pp. 105–117). Sage Publications, Inc.

Guerraoui, A., Galland, R., Belkahla-Delabruyere, F., Didier, O., Berger, V., Sauvajon, P., Serve, C., Zuriaga, J. C., Riquier, F., & Caillette-Beaudoin, A. (2022). Design of therapeutic education workshops for home haemodialysis in a patient-centered chronic kidney diseases research: A qualitative study. *BMC Nephrology*, *23*(1), 53. https://doi.org/10.1186/s12882-022-02683-0

Gupta, A., & Zimmerman, D. (2021). Complications and challenges of home hemodialysis: A historical review. *Seminars in Dialysis*, *34*(4), 269–274. https://doi.org/10.1111/sdi.12960

Hager, D., Ferguson, T. W., & Komenda, P. (2019). Cost controversies of a "home dialysis first" policy. *Canadian Journal of Kidney Health and Disease*, *6*, 2054358119871541. https://doi.org/10.1177/2054358119871541

Hanson, C. S., Chapman, J. R., Craig, J. C., Harris, D. C., Kairaitis, L. K., Nicdao, M., Mikaheal, M., & Tong, A. (2017). Patient experiences of training and transition to home haemodialysis: A mixed-methods study. *Nephrology, 22*(8), 631–641. https://doi.org/10.1111/nep.12827

Hamidi, S., Zarnke, S., Turcotte, K., & Silver, S. A. (2023). The feasibility of a transitional care unit for patients newly started on in-center hemodialysis: A research letter. *Canadian Journal of Kidney Health and Disease*, *10*, 20543581231162235. https://doi.org/10.1177/20543581231162235

Harel, Z., Silver, S. A., McQuillan, R. F., Weizman, A. V., Thomas, A., Chertow, G. M., Nesrallah, G., Chan, C. T., & Bell, C. M. (2016). How to diagnose solutions to a quality of care problem. *Clinical Journal of the American*

Society of Nephrology, *11*(5), 901–907. https://doi.org/10.2215/CJN.11481015

Hejazi, S. S., Hosseini, M., Ebadi, A., & Alavi Majd, H. (2021). Components of quality of life in hemodialysis patients from family caregivers' perspective: A qualitative study. *BMC Nephrology*, *22*(1), 379. https://doi.org/10.1186/s12882-021-02584-8

Htay, H., Cho, Y., Teitelbaum, I., & Johnson, D. W. (2025). International equity in access to home dialysis. *Current Opinion in Nephrology and Hypertension,* 34(1), 78–85. https://doi.org/10.1097/MNH.0000000000000932

Huang, S.-H. S., MacRae, J., Ross, D., Imtiaz, R., Hollingsworth, B., Nesrallah, G. E., Copland, M. A., McFarlane, P. A., Chan, C. T., & Zimmerman, D. (2019). Buttonhole versus stepladder cannulation for home hemodialysis: A multicenter, randomized, pilot trial. *Clinical Journal of the American Society of Nephrology*, *14*(3), 403–410. https://doi.org/10.2215/CJN.08310718

Ibraheem, A. S., Nwosu, C. B., Omowumi, R. K., & Ayodapo, A. O. (2025). Managing population health through prevention and early detection of cancer and other non-communicable diseases: A call for action. *Discover Public Health*, *22*(1), 143. https://doi.org/10.1186/s12982-025-00529-2

Jacquet, S., & Trinh, E. (2019). The potential burden of home dialysis on patients and caregivers: A narrative review. *Canadian Journal of Kidney Health and Disease*, *6*, 2054358119893335. https://doi.org/10.1177/2054358119893335

Jamshed, S. (2014). Qualitative research method-interviewing and observation. *Journal of Basic and Clinical Pharmacy*, *5*(4), 87. https://doi.org/10.4103/0976-0105.141942

Jayanti, A., Morris, J., Stenvinkel, P., & Mitra, S. (2014). Home hemodialysis: Beliefs, attitudes, and practice patterns. *Hemodialysis International*, *18*(4), 767–776. https://doi.org/10.1111/hdi.12176

Jayanti, A., Wearden, A. J., Morris, J., Brenchley, P., Abma, I., Bayer, S., Barlow, J., & Mitra, S. (2013). Barriers to successful implementation of care in home haemodialysis (Basic-hhd):1. Study design, methods and rationale. *BMC Nephrology*, *14*(1), 197. https://doi.org/10.1186/1471-2369-14-197

Jotterand Drepper, V. (2019). Practical aspects on use of sharesource in remote patient management. In C. Ronco, C. Crepaldi, & M. H. Rosner (Eds.), *Contributions to Nephrology* (Vol. 197, pp. 28–34). S. Karger AG. https://doi.org/10.1159/000496315

Juan, L. I. (2014). Literature review of the classifications of 'needs' in needs analysis theory. *International Journal of Education and Literacy Studies*, *2*(3), 12–16. https://journals.aiac.org.au/index.php/IJELS/article/view/535

Kallio, H., Pietilä, A., Johnson, M., & Kangasniemi, M. (2016). Systematic methodological review: Developing a framework for a qualitative semi-structured interview guide. *Journal of Advanced Nursing*, *72*(12), 2954–2965. https://doi.org/10.1111/jan.13031

Karkar, A., Hegbrant, J., & Strippoli, G. F. M. (2015). Benefits and implementation of home hemodialysis: A narrative review. *Saudi Journal of Kidney Diseases and Transplantation*, *26*(6), 1095. https://doi.org/10.4103/1319-2442.168556

Kendzia, D., Lima, F., Zawierucha, J., Busink, E., Apel, C., Malyszko, J. S., Zebrowski, P., & Malyszko, J. (2022). Main barriers to the introduction of a home haemodialysis programme in Poland: A review of the challenges for

implementation and criteria for a successful programme. *Journal of Clinical Medicine*, *11*(14), 4166. https://doi.org/10.3390/jcm11144166

Khan, I., Pintelon, L., Martin, H., & Khan, R. A. (2022). Exploring stakeholders and their requirements in the process of home hemodialysis: A literature review. *Seminars in Dialysis*, *35*(1), 15–24. https://doi.org/10.1111/sdi.13019

Kneipp, E., Murray, R., Warr, K., Fitzclarence, C., Wearne, M., & Maguire, G. (2004). Bring me home: Renal dialysis in the Kimberley. *Nephrology*, *9*(s4). https://doi.org/10.1111/j.1440-1797.2004.00346.x

Kraus, M., Burkart, J., Hegeman, R., Solomon, R., Coplon, N., & Moran, J. (2007). A comparison of center-based vs. Home-based daily hemodialysis for patients with end-stage renal disease. *Hemodialysis International*, *11*(4), 468–477. https://doi.org/10.1111/j.1542-4758.2007.00229.x

Krueger, R. A., & Casey, M. A. (2015). *Focus groups: A practical guide for applied research* (5th edition). SAGE.

Kumar, V. A., Ledezma, M. L., & Rasgon, S. A. (2007). Daily home hemodialysis at a health maintenance organization: Three-year experience. *Hemodialysis International*, *11*(2), 225–230. https://doi.org/10.1111/j.1542-4758.2007.00173.x

Lavoie-Cardinal, M., & Nadeau-Fredette, A.-C. (2021). Physical infrastructure and integrated governance structure for home hemodialysis. *Advances in Chronic Kidney Disease*, *28*(2), 149–156. https://doi.org/10.1053/j.ackd.2021.02.008

Levey, A. S., & Coresh, J. (2012). Chronic kidney disease. *The Lancet*, *379*(9811), 165–180.

Machowska, A., Alscher, M. D., Reddy Vanga, S., Koch, M., Aarup, M., Qureshi, A. R., Lindholm, B., & Rutherford, P. A. (2016). Factors influencing access to

education, decision making, and receipt of preferred dialysis modality in unplanned dialysis start patients. *Patient Preference and Adherence*, *10*, 2229–2237. https://doi.org/10.2147/PPA.S119243

Manns, B., Agar, J. W. M., Biyani, M., Blake, P. G., Cass, A., Culleton, B., Kleophas, W., Komenda, P., Lobbedez, T., MacRae, J., Marshall, M. R., Scott-Douglas, N., Srivastava, V., & Magner, P. (2019). Can economic incentives increase the use of home dialysis? *Nephrology Dialysis Transplantation*, *34*(5), 731–741. https://doi.org/10.1093/ndt/gfy223

Marshall, M. R., Polkinghorne, K. R., Boudville, N., & McDonald, S. P. (2021). Home versus facility dialysis and mortality in Australia and New Zealand. *American Journal of Kidney Diseases*, *78*(6), 826-836.e1. https://doi.org/10.1053/j.ajkd.2021.03.018

Marshall, M. R., Polkinghorne, K. R., Kerr, P. G., Agar, J. W. M., Hawley, C. M., & McDonald, S. P. (2015a). Temporal changes in mortality risk by dialysis modality in the Australian and New Zealand dialysis population. *American Journal of Kidney Diseases*, *66*(3), 489–498. https://doi.org/10.1053/j.ajkd.2015.03.014

Marshall, M. R., Young, B. A., Fox, S. J., Cleland, C. J., Walker, R. J., Masakane, I., & Herold, A. M. (2015b). The home hemodialysis hub: Physical infrastructure and integrated governance structure. *Hemodialysis International*, *19*(S1). https://doi.org/10.1111/hdi.12273

Maslow, A. H. (1943). A theory of human motivation. *Psychological Review*, *50*(4), 370–396. https://doi.org/10.1037/h0054346

May, C. R., Cummings, A., Girling, M., Bracher, M., Mair, F. S., May, C. M., Murray, E., Myall, M., Rapley, T., & Finch, T. (2018). Using Normalization

Process Theory in feasibility studies and process evaluations of complex healthcare interventions: A systematic review. *Implementation Science*, *13*(1), 80. https://doi.org/10.1186/s13012-018-0758-1

McIsaac, M., Chan, C. T., & Auguste, B. L. (2022). The need for individualizing teaching and assurance of knowledge transmission to patients training for home dialysis. *Nephrology*, *27*(9), 733–738. https://doi.org/10.1111/nep.14040

McLeod, S. (2024, December 17). *Reflexivity in qualitative research*. https://www.simplypsychology.org/reflexivity-in-qualitative-research.html

Miller, J. (2010). Does home haemodialysis produce better outcomes for patients? *British Journal of Nursing*, *19*(20), 1275–1280. https://doi.org/10.12968/bjon.2010.19.20.79679

Morita, P. P., Huynh, K., Zakir, A., Cafazzo, J. A., McQuillan, R. F., Bargman, J. M., & Chan, C. T. M. (2019). Supporting the establishment of new home dialysis programs through the explore home dialysis program. *Kidney International Reports*, *4*(2), 293–300. https://doi.org/10.1016/j.ekir.2018.10.019

Ni, Z., Zhou, Y., Lu, R., Shen, J., Gu, L., Mou, S., Zhao, L., Zhang, H., Zhang, B., Fang, Y., Fang, W., Wang, Q., Zhang, W., Zhang, J., & Li, W. (2022). The initial attempt at home hemodialysis in mainland China. *BMC Nephrology*, *23*(1), 389. https://doi.org/10.1186/s12882-022-03018-9

Nonkes, L. J. P., Gelder, M. K. van, Kemperman, H., Abrahams, A. C., Boereboom, F. T. J., Berg, M. J. ten, & Gerritsen, K. G. F. (2019). Improving home haemodialysis: Stability evaluation of routine clinical chemistry analytes in blood samples of haemodialysis patients. *Biochemia Medica*, *29*(1), 0–0. https://doi.org/10.11613/BM.2019.010709

Noy, C. (2008). Sampling knowledge: The hermeneutics of snowball sampling in qualitative research. *International Journal of Social Research Methodology*, *11*(4), 327–344. https://doi.org/10.1080/13645570701401305

Olmos-Vega, F. M., Stalmeijer, R. E., Varpio, L., & Kahlke, R. (2023). A practical guide to reflexivity in qualitative research: AMEE Guide No. 149. *Medical Teacher*, *45*(3), 241–251. https://doi.org/10.1080/0142159X.2022.2057287

Orb, A., Eisenhauer, L., & Wynaden, D. (2001). Ethics in qualitative research. *Journal of Nursing Scholarship*, *33*(1), 93–96. https://doi.org/10.1111/j.1547-5069.2001.00093.x

Palmer, S. C., Palmer, A. R., Craig, J. C., Johnson, D. W., Stroumza, P., Frantzen, L., Leal, M., Hoischen, S., Hegbrant, J., & Strippoli, G. F. (2014). Home versus in-centre haemodialysis for end-stage kidney disease. Cochrane Database of Systematic Reviews, 2014(12). https://doi.org/10.1002/14651858.CD009535.pub2

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Moher, D. (2021). The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *BMJ, 372*, n71. https://doi.org/10.1136/bmj.n71

Palinkas, L. A., Horwitz, S. M., Green, C. A., Wisdom, J. P., Duan, N., & Hoagwood, K. (2015). Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Administration and Policy in Mental Health and Mental Health Services Research*, *42*(5), 533–544. https://doi.org/10.1007/s10488-013-0528-y

Patton, M. Q. (1999). Enhancing the quality and credibility of qualitative analysis. *Health Services Research*, *34*(5 Pt 2), 1189–1208. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1089059/

People Management Division, Ministry for Health. (2022). *Health workforce strategy 2022–2030: Supporting and empowering the healthcare workforce*. Government of Malta.

Pérez-Alba, A., Reque-Santiváñez, J., Vázquez-Gómez, M., & Pons-Prades, R. (2020). Expanded home hemodialysis: Case reports. *International Urology and Nephrology*, *52*(5), 977–980. https://doi.org/10.1007/s11255-020-02455-5

Perl, J., Brown, E. A., Chan, C. T., Couchoud, C., Davies, S. J., Kazancioğlu, R., Klarenbach, S., Liew, A., Weiner, D. E., Cheung, M., Jadoul, M., Winkelmayer, W. C., Wilkie, M. E., Abrahams, A. C., Anumudu, S. J., Bargman, J. M., Moore, G. B., Blake, P. G., Borman, N., … Williams, J. (2023). Home dialysis: Conclusions from a kidney disease: improving global outcomes (Kdigo) controversies conference. *Kidney International*, *103*(5), 842–858. https://doi.org/10.1016/j.kint.2023.01.006

Pirhonen, L., Gyllensten, H., Fors, A., & Bolin, K. (2020). Modelling the cost-effectiveness of person-centred care for patients with acute coronary syndrome. *The European Journal of Health Economics*, *21*(9), 1317–1327. https://doi.org/10.1007/s10198-020-01230-8

Poon, C. K. Y., Tang, H., Wong, J. H. S., Law, W., Lam, C., Yim, K., Cheuk, A., Lee, W., Chau, K., Tong, M. K. L., & Fung, S. K. S. (2015). Effect of alternate night nocturnal home hemodialysis on anemia control in patients with end-stage renal disease. *Hemodialysis International, 19*(2), 235–241. https://doi.org/10.1111/hdi.12227

Power, A., & Ashby, D. (2014). Haemodialysis: Hospital or home? *Postgraduate Medical Journal*, *90*(1060), 92–97. https://doi.org/10.1136/postgradmedj-2012-131405

Pungchompoo, W., Richardson, A., & Brindle, L. A. (2016). Experiences and needs of older people with end stage renal disease: Bereaved carers perspective. *International Journal of Palliative Nursing*, *22*(10), 490–499. https://doi.org/10.12968/ijpn.2016.22.10.490

Quinn, R. R., & Lam, N. N. (2023). Home dialysis in North America: The current state. Clinical Journal of the American Society of Nephrology, 18(10), 1351–1358. https://doi.org/10.2215/CJN.0000000000000273

Raphael, M. J., Nadeau-Fredette, A.-C., Tennankore, K. K., & Chan, C. T. (2015). A virtual ward for home hemodialysis patients – a pilot trial. *Canadian Journal of Kidney Health and Disease*, *2*, 72. https://doi.org/10.1186/s40697-015-0072-7

Reddy, Y. N. V., Kearney, M. D., Ward, M., Burke, R. E., O'Hare, A. M., Reese, P. P., Lane-Fall, M. B., Jones, J., Liu, F., Martin, A., McGraw, A., Neumann, J., Pettis, A., & Salenger, P. (2024). Identifying major barriers to home dialysis (The im-home study): Findings from a national survey of patients, care partners, and providers. *American Journal of Kidney Diseases*, *84*(5), 567-581.e1. https://doi.org/10.1053/j.ajkd.2024.04.007

Rivard, L., & Lehoux, P. (2020). When desirability and feasibility go hand in hand: Innovators' perspectives on what is and is not responsible innovation in health. *Journal of Responsible Innovation*, *7*(1), 76–95. https://doi.org/10.1080/23299460.2019.1622952

Rizzolo, K., Hsu, J. Y., Mehrotra, R., Navaneethan, S. D., & Obi, Y. (2022). Racial and ethnic disparities in utilization of home dialysis in the United States. *Kidney360,* 3(8), 1374–1382. https://doi.org/10.34067/KID.0001652022

Robinson, O. C. (2014). Sampling in interview-based qualitative research: A theoretical and practical guide. *Qualitative Research in Psychology*, *11*(1), 25–41. https://doi.org/10.1080/14780887.2013.801543

Rocco, M. V., Daugirdas, J. T., Greene, T., Lockridge, R. S., Chan, C., Pierratos, A., Lindsay, R., Larive, B., Chertow, G. M., Beck, G. J., Eggers, P. W., & Kliger, A. S. (2015). Long-term effects of frequent nocturnal hemodialysis on mortality: The frequent hemodialysis network (Fhn) nocturnal trial. *American Journal of Kidney Diseases*, *66*(3), 459–468. https://doi.org/10.1053/j.ajkd.2015.02.331

Rosengren, K., Buttigieg, S. C., Badanta, B., & Carlstrom, E. (2023). Diffusion of person-centred care within 27 European countries – interviews with managers, officials, and researchers at the micro, meso, and macro levels. *Journal of Health Organization and Management*, *37*(1), 17–34. https://doi.org/10.1108/JHOM-02-2022-0036

Saber, A. (2024). *The role of positionality in enhancing trustworthiness: A methodological framework for qualitative researchers*. https://doi.org/10.20944/preprints202411.2017.v1

Saunders, M. N. K., Lewis, P., & Thornhill, A. (2023). *Research methods for business students* (Ninth edition). Pearson.

Scarpioni, R., Ricardi, M., Manini, A., Chiappini, P., Ballocchi, L., Albertazzi, V., DeAmicis, S., Melfa, L., Rocca, C., Valsania, T., Blanco, V., & Fenocchio, C. (2021). What can a home hemodialysis program offer to patients in a nursing

home setting? A case series and feasibility analysis. *Hemodialysis International*, *25*(2), 147–153. https://doi.org/10.1111/hdi.12904

Schreiber, M. J., Chatoth, D. K., & Salenger, P. (2021). Challenges and opportunities in expanding home hemodialysis for 2025. *Advances in Chronic Kidney Disease*, *28*(2), 129–135. https://doi.org/10.1053/j.ackd.2021.06.009

Sever, M. Ş., Jager, K. J., Vanholder, R., Stengel, B., Harambat, J., Finne, P., Tesař, V., Barbullushi, M., Bumblytė, I. A., Zakharova, E., Spasovski, G., Resic, H., Wiecek, A., Blankestijn, P. J., Bruchfeld, A., Cozzolino, M., Goumenos, D., Soler, M. J., Rychlík, I., … Massy, Z. A. (2021). A roadmap for optimizing chronic kidney disease patient care and patient-oriented research in the Eastern European nephrology community. *Clinical Kidney Journal*, *14*(1), 23–35. https://doi.org/10.1093/ckj/sfaa218

Shah, S., Weinhandl, E., Gupta, N., Leonard, A. C., Christianson, A. L., & Thakar, C. V. (2024). Cardiovascular outcomes in patients on home hemodialysis and peritoneal dialysis. Kidney360, 5(2), 205–215. https://doi.org/10.34067/KID.0000000000000360

Sidani, S., Epstein, D. R., Bootzin, R. R., Moritz, P., & Miranda, J. (2009). Assessment of preferences for treatment: Validation of a measure. *Research in Nursing & Health*, *32*(4), 419–431. https://doi.org/10.1002/nur.20329

Smith, J. A. (2024). *Qualitative psychology: A practical guide to research methods* (Fourth). Sage.

Stern, L. D., & Waikar, S. (2020). Time to expand access and utilization of home dialysis: Lessons from the covid-19 pandemic. *Mayo Clinic Proceedings*, *95*(7), 1323–1324. https://doi.org/10.1016/j.mayocp.2020.04.038

Stewart, F., Kistler, K., Du, Y., Singh, R. R., Dean, B. B., & Kong, S. X. (2024). Exploring kidney dialysis costs in the United States: A scoping review. *Journal of Medical Economics*, *27*(1), 618–625. https://doi.org/10.1080/13696998.2024.2342210

Susantitaphong, P., Koulouridis, I., Balk, E. M., Madias, N. E., & Jaber, B. L. (2012). Effect of frequent or extended hemodialysis on cardiovascular parameters: A meta-analysis. *American Journal of Kidney Diseases*, *59*(5), 689–699. https://doi.org/10.1053/j.ajkd.2011.12.020

Tennankore, K. K., Chan, C. T., & Curran, S. P. (2012). Intensive home haemodialysis: Benefits and barriers. *Nature Reviews Nephrology*, *8*(9), 515–522. https://doi.org/10.1038/nrneph.2012.145

Tennankore, K. K., Nadeau-Fredette, A.-C., Matheson, K., Chan, C. T., Trinh, E., & Perl, J. (2021). Home versus in-center dialysis and day of the week hospitalization: A cohort study. *Kidney360*, 3(1), 103–112. https://doi.org/10.34067/KID.0003552021

The Global Burden of Disease Collaboration. (2020). Global, regional, and national burden of chronic kidney disease, 1990–2017: A systematic analysis for the Global Burden of Disease Study 2017. *The Lancet*, *395*(10225), 709–733. https://doi.org/10.1016/

Thomas-Hawkins, C., Payne, G. M., & Bednarski, D. (2022). The growing demand for home dialysis therapies: Challenges and potential solutions. *Nephrology Nursing Journal*, *49*(2), 109. https://doi.org/10.37526/1526-744X.2022.49.2.109

Tomaselli, G., Buttigieg, S. C., Rosano, A., Cassar, M., & Grima, G. (2020). Person-centered care from a relational ethics perspective for the delivery of high

quality and safe healthcare: A scoping review. *Frontiers in Public Health*, *8*, 44. https://doi.org/10.3389/fpubh.2020.00044

Tomori, K., Inoue, T., Sugiyama, M., Ohashi, N., Murasugi, H., Ohama, K., Amano, H., Watanabe, Y., & Okada, H. (2024). Long-term survival of patients receiving home hemodialysis with self-punctured arteriovenous access. *PLOS ONE*, *19*(5), e0303055. https://doi.org/10.1371/journal.pone.0303055

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (Coreq): A 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*, *19*(6), 349–357. https://doi.org/10.1093/intqhc/mzm042

Torres, G. C. S., Sumile, E. F. R., Rebueno, Ma. C. D. R., Parial, L. L. B., Malong-Consolacion, C. P., Estrada, M. G., Macindo, J. R. B., & Hendrix, C. C. (2021). Exploring the challenges and needs of home caregivers of hemodialysis patients in the Philippines: A mixed methods study. *Nursing Forum*, *56*(4), 823–833. https://doi.org/10.1111/nuf.12618

Turner, D. (2014). Qualitative interview design: A practical guide for novice investigators. *The Qualitative Report*. https://doi.org/10.46743/2160-3715/2010.1178

Turner, L., & Jenkins, R. (2023). *Navigating bias in qualitative research: Identifying and mitigating its impact—Qrca*. https://www.qrca.org/blogpost/1488356/506750/Navigating-Bias-in-Qualitative-Research-Identifying-and-Mitigating-Its-Impact

Ulrich, B. (2022). From the editor-in-chief—Expansion of home dialysis therapies will require additional knowledge and competence. *Nephrology Nursing Journal*, *49*(6), 477. https://doi.org/10.37526/1526-744X.2022.49.6.477

Usvyat, L., Dalrymple, L. S., & Maddux, F. W. (2018). Using technology to inform and deliver precise personalized care to patients with end-stage kidney disease. *Seminars in Nephrology*, *38*(4), 418–425. https://doi.org/10.1016/j.semnephrol.2018.05.011

Van Eck Van Der Sluijs, A., Vonk, S., Bonenkamp, A. A., Prantl, K., Riemann, A. T., Van Jaarsveld, B. C., Abrahams, A. C., & DOMESTICO study group. (2024). Value of patient decision aids for shared decision-making in kidney failure. *Journal of Renal Care*, *50*(1), 15–23. https://doi.org/10.1111/jorc.12468

Vanholder, R., Annemans, L., Brown, E., Gansevoort, R., Gout-Zwart, J. J., Lameire, N., Morton, R. L., Oberbauer, R., Postma, M. J., Tonelli, M., Biesen, W. V., & Zoccali, C. (2017). Reducing the costs of chronic kidney disease while delivering quality health care: A call to action. *Nature Reviews Nephrology*, *13*(7), 393–409. https://doi.org/10.1038/nrneph.2017.63

Virtanen, H., Tuominen, R., Kiukainen, S., Koskinen, J., Koskenniemi, J., Laulaja, J., Numanovic, V., & Leino-Kilpi, H. (2019). Experiences of safety among patients receiving home dialysis therapies. *Journal of Renal Care*, *45*(4), 223–231. https://doi.org/10.1111/jorc.12298

Walker, R. C., Hanson, C. S., Palmer, S. C., Howard, K., Morton, R. L., Marshall, M. R., & Tong, A. (2015). Patient and caregiver perspectives on home hemodialysis: A systematic review. *American Journal of Kidney Diseases*, *65*(3), 451–463. https://doi.org/10.1053/j.ajkd.2014.10.020

Walker, R. C., Howard, K., Morton, R. L., Palmer, S. C., Marshall, M. R., & Tong, A. (2016). Patient and caregiver values, beliefs and experiences when considering home dialysis as a treatment option: A semi-structured interview

study. *Nephrology Dialysis Transplantation*, *31*(1), 133–141. https://doi.org/10.1093/ndt/gfv330

Walker, R. C., Marshall, R., Howard, K., Morton, R. L., & Marshall, M. R. (2017). "Who matters most?": Clinician perspectives of influence and recommendation on home dialysis uptake. Nephrology, 22(12), 977–984. https://doi.org/10.1111/nep.12920

Weinhandl, E. D. (2021). Economic impact of home hemodialysis. *Advances in Chronic Kidney Disease*, *28*(2), 136–142. https://doi.org/10.1053/j.ackd.2021.06.010

Weinhandl, E. D., & Collins, A. J. (2018). Relative risk of home hemodialysis attrition in patients using a telehealth platform. *Hemodialysis International*, *22*(3), 318–327. https://doi.org/10.1111/hdi.12621

Welch, J. L., Thomas-Hawkins, C., Bakas, T., McLennon, S. M., Byers, D. M., Monetti, C. J., & Decker, B. S. (2014). Needs, concerns, strategies, and advice of daily home hemodialysis caregivers. *Clinical Nursing Research*, *23*(6), 644–663. https://doi.org/10.1177/1054773813495407

Wild, R. (1983). Decision-making in operations management. *Management Decision*, *21*(1), 9–21. https://doi.org/10.1108/eb001307

Wiles, R., Crow, G., Heath, S., & Charles, V. (2008). The management of confidentiality and anonymity in social research. *International Journal of Social Research Methodology*, *11*(5), 417–428. https://doi.org/10.1080/13645570701622231

Wong, C. K. H., Chen, J. Y., Fung, S. K. S., Lo, W. K., Lui, S. L., Chan, T. M., Cheng, Y. L., Kong, I., Wan, E. Y. F., & Lam, C. L. K. (2019). Health-related quality of life and health utility of Chinese patients undergoing nocturnal

home haemodialysis in comparison with other modes of dialysis. *Nephrology*, *24*(6), 630–637. https://doi.org/10.1111/nep.13429

Wong, L. (2008). Data analysis in qualitative research: A brief guide to using nvivo. *Malaysian Family Physician : The Official Journal of the Academy of Family Physicians of Malaysia*, *3*(1), 14–20. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4267019/

Woolf, N. H., & Silver, C. (2017). *Qualitative analysis using NVivo: The five-level qda® method* (1st ed.). Routledge. https://doi.org/10.4324/9781315181660

Wright, S. & Leicester General Hospital NHS Trust. (1994). Psychological needs assessment in renal failure. *Clinical Psychology Forum*, *1*(71), 14–16. https://doi.org/10.53841/bpscpf.1994.1.71.14

Yau, T. (2024). *Barriers to home dialysis: An interview*. AJKD Blog. https://ajkdblog.org/2024/11/06/barriers-to-home-dialysis-an-interview/

Yin, R. K. (2018). *Case study research and applications: Design and methods* (Sixth edition). SAGE.

Further Reading

Agar, J. W. M., Schatell, D., & Walker, R. (2015). Home hemodialysis needs you! *Hemodialysis International*, *19*(S1). https://doi.org/10.1111/hdi.12283

Agraharkar, M., Barclay, C., & Agraharkar, A. (2002). Staff-assisted home hemodialysis in debilitated or terminally ill patients. *International Urology and Nephrology*, *33*(1), 139–144. https://doi.org/10.1023/A:1014417002040

Alsaqqa, H. (2020). Toward organizational evidence-based management in healthcare organizations. *International Journal of Health Services Research and Policy*, *5*(2), 162–177. https://doi.org/10.33457/ijhsrp.688181

Ankawi, G., Tangirala, N., Jesudason, S., & Hladunewich, M. A. (2025). Pregnancy in patients receiving home dialysis. *Clinical Journal of the American Society of Nephrology*, *20*(2), 292–300. https://doi.org/10.2215/CJN.0000000000000437

Archana, S., Karmacharya, B. M., Rashmi, M., Abhinav, V., Meghnath, D., Natalia, O., Rajeev, S., Prajjwal, P., Annette, F., David, C., Swornim, B., Roman, X. D., Donna, S., & Rajendra, K. (2019). Stakeholder engagement in planning the design of a national needs assessment for cardiovascular disease prevention and management in Nepal. *Global Heart*, *14*(2), 181. https://doi.org/10.1016/j.gheart.2019.05.002

Asadi-Lari, M., Packham, C., & Gray, D. (2005). Psychometric properties of a new health needs analysis tool designed for cardiac patients. *Public Health*, *119*(7), 590–598. https://doi.org/10.1016/j.puhe.2004.09.005

Aspelund, A., Valkonen, P., Virtanen, J., & Rauta, V. (2024). Designing for improved patient experiences in home dialysis: Usability and user experience findings

from user-based evaluation study with patients with chronic conditions. *JMIR Human Factors*, *11*, e53691. https://doi.org/10.2196/53691

Attalla, M., Friedman, Z., McKeown, S., Harel, Z., Hingwala, J., Molnar, A. O., Norman, P., & Silver, S. A. (2020). Characteristics and effectiveness of dedicated care programs for patients starting dialysis: A systematic review. *Kidney360*, *1*(11), 1244–1253. https://doi.org/10.34067/KID.0004052020

Barends, E., & Rousseau, D. M. (2018). *Evidence-based management: How to use evidence to make better organizational decisions*. Kogan Page Ltd.

Barua, M., Hladunewich, M., Keunen, J., Pierratos, A., McFarlane, P., Sood, M., & Chan, C. T. (2008). Successful pregnancies on nocturnal home hemodialysis. *Clinical Journal of the American Society of Nephrology*, *3*(2), 392–396. https://doi.org/10.2215/CJN.04110907

Batt, J., Linton, K., & Bennett, P. N. (2012). Home hemodialysis: A successful option for obese and bariatric people with end-stage kidney disease. *Hemodialysis International*, *16*(S1). https://doi.org/10.1111/j.1542-4758.2012.00747.x

Blankenship, D. M., Usvyat, L., Kraus, M. A., Chatoth, D. K., Lasky, R., Turk, J. E., & Maddux, F. W. (2023). Assessing the impact of transitional care units on dialysis patient outcomes: A multicenter, propensity score-matched analysis. *Hemodialysis International*, *27*(2), 165–173. https://doi.org/10.1111/hdi.13068

Bowen, B. (2021). The matrix of needs: Reframing Maslow's hierarchy. *Health*, *13*(05), 538–563. https://doi.org/10.4236/health.2021.135041

Bowling, A. (2014). *Research methods in health: Investigating health and health services* (Fourth edition). Open University Press.

Brown, J. D. (1995). *The elements of language curriculum: A systematic approach to program development*. Heinle & Heinle.

Brown, J. D. (2001). *Using surveys in language programs*. Cambridge University Press.

Buttigieg, S. C., Abela, L., & Pace, A. (2018). Variables affecting hospital length of stay: A scoping review. *Journal of Health Organization and Management*, *32*(3), 463–493. https://doi.org/10.1108/JHOM-10-2017-0275

Buttigieg, S., Dey, P. K., & Gauci, D. (2016). Business process management in health care: Current challenges and future prospects. *Innovation and Entrepreneurship in Health*, 1. https://doi.org/10.2147/IEH.S68183

Cafazzo, J. A., Leonard, K., Easty, A. C., Rossos, P. G., & Chan, C. T. (2009). Patient-perceived barriers to the adoption of nocturnal home hemodialysis. *Clinical Journal of the American Society of Nephrology*, *4*(4), 784–789. https://doi.org/10.2215/CJN.05501008

Chow, J. (2005). A pre-training assessment tool for home dialysis(Jpat). *EDTNA-ERCA Journal*, *31*(1), 19–23. https://doi.org/10.1111/j.1755-6686.2005.tb00384.x

Community health assessment and group evaluation (Change) action guide: Building a foundation of knowledge to prioritize community needs. (n.d.). Retrieved 18 August 2025, from https://www.communitycommons.org/entities/4226783c-f5e8-4d3c-b20b-4c71d91c92f0

Community health assessment toolkit | achi. (n.d.). Retrieved 18 August 2025, from https://www.healthycommunities.org/resources/community-health-assessment-toolkit

Cornelis, T., Tennankore, K. K., Goffin, E., Rauta, V., Honkanen, E., Őzyilmaz, A., Thanaraj, V., Jayanti, A., Mitra, S., Van Der Sande, F. M., Kooman, J. P., & Chan, C. T. (2014). An international feasibility study of home haemodialysis in older patients. *Nephrology Dialysis Transplantation*, *29*(12), 2327–2333. https://doi.org/10.1093/ndt/gfu260

Daliri, S., Bekker, C. L., Buurman, B. M., Scholte Op Reimer, W. J. M., Van Den Bemt, B. J. F., & Karapinar – Çarkit, F. (2019). Barriers and facilitators with medication use during the transition from hospital to home: A qualitative study among patients. *BMC Health Services Research*, *19*(1), 204. https://doi.org/10.1186/s12913-019-4028-y

Denzin, N. K. (2001). *Interpretive interactionism* (2nd ed). Sage Publications.

DePasquale, N., Cabacungan, A., Ephraim, P. L., Lewis-Boyér, L., Powe, N. R., & Boulware, L. E. (2019). Family members' experiences with dialysis and kidney transplantation. *Kidney Medicine*, *1*(4), 171–179. https://doi.org/10.1016/j.xkme.2019.06.001

Donabedian, A. (2005). Evaluating the quality of medical care. *The Milbank Quarterly*, *83*(4), 691–729. https://doi.org/10.1111/j.1468-0009.2005.00397.x

Dubin, R., & Rubinsky, A. (2019). A digital modality decision program for patients with advanced chronic kidney disease. *JMIR Formative Research*, *3*(1), e12528. https://doi.org/10.2196/12528

Duteau, J. (2013). Improving the uptake of independent dialysis using the humanbecoming theoretical approach. *Seminars in Dialysis*, *26*(2), 180–183. https://doi.org/10.1111/sdi.12079

El Nahas, A. M., & Bello, A. K. (2005). Chronic kidney disease: The global challenge. *The Lancet*, *365*(9456), 331–340. https://doi.org/10.1016/S0140-6736(05)17789-7

Gatti, E., & Ronco, C. (2011). Seeking an optimal renal replacement therapy for the chronic kidney disease epidemic: The case for on-line hemodiafiltration. In G. Krick & C. Ronco (Eds.), *Contributions to Nephrology* (Vol. 175, pp. 170–185). S. Karger AG. https://doi.org/10.1159/000333636

Geary, D. F., Piva, E., Gajaria, M., Tyrrel, J., Picone, G., & Harvey, E. (2004). Daily hemodialysis—selected topics: Development of a nocturnal home hemodialysis (Nhhd) program for children. *Seminars in Dialysis*, *17*(2), 115–117. https://doi.org/10.1111/j.0894-0959.2004.17207.x

Geary, D. F., Piva, E., Tyrrell, J., Gajaria, M. J., Picone, G., Keating, L. E., & Harvey, E. A. (2005). Home nocturnal hemodialysis in children. *The Journal of Pediatrics*, *147*(3), 383–387. https://doi.org/10.1016/j.jpeds.2005.04.034

George, C. R. P. (1983). Feasibility of universal home haemodialysis with simplified techniques. *The Lancet*, *322*(8355), 895–897. https://doi.org/10.1016/S0140-6736(83)90881-4

Girsberger, M., Trinh, E., & Chan, C. T. (2020). Ventricular ejection fraction over time in patients on intensive home hemodialysis: A retrospective cohort study. *Hemodialysis International*, *24*(3), 290–298. https://doi.org/10.1111/hdi.12838

Glidewell, L., Boocock, S., Pine, K., Campbell, R., Hackett, J., Gill, S., & Wilkie, M. (2013). Using behavioural theories to optimise shared haemodialysis care: A qualitative intervention development study of patient and professional

experience. *Implementation Science*, *8*(1), 118. https://doi.org/10.1186/1748-5908-8-118

Golden, S. H., Hager, D., Gould, L. J., Mathioudakis, N., & Pronovost, P. J. (2017). A gap analysis needs assessment tool to drive a care delivery and research agenda for integration of care and sharing of best practices across a health system. *The Joint Commission Journal on Quality and Patient Safety*, *43*(1), 18–28. https://doi.org/10.1016/j.jcjq.2016.10.004

Graham-Brown, M. P. M., Churchward, D. R., Smith, A. C., Baines, R. J., & Burton, J. O. (2015). A 4-month programme of in-centre nocturnal haemodialysis was associated with improvements in patient outcomes. *Clinical Kidney Journal*, *8*(6), 789–795. https://doi.org/10.1093/ckj/sfv096

Graves, K. (Ed.). (2009). *Teachers as course developers* (Nachdr.). Cambridge University Press.

Groome, P. A., Hutchinson, T. A., & Tousignant, P. (1994). Content of a decision analysis for treatment choice in end-stage renal disease: Who should be consulted? *Medical Decision Making*, *14*(1), 91–97. https://doi.org/10.1177/0272989X9401400111

Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? : An experiment with data saturation and variability. *Field Methods*, *18*(1), 59–82. https://doi.org/10.1177/1525822X05279903

Guraya, S. S., Harkin, D. W., Yusoff, M. S. B., & Guraya, S. Y. (2023). Paradigms unfolded – developing, validating, and evaluating the Medical Education e-Professionalism framework from a philosophical perspective. *Frontiers in Medicine*, *10*, 1230620. https://doi.org/10.3389/fmed.2023.1230620

Hamer, R., Hameed, A., Damery, S., Jenkins, K., Dasgupta, I., & Baharani, J. (2023). Do we practice what we preach? Dialysis modality choice among healthcare workers in the United Kingdom. *Seminars in Dialysis*, *36*(5), 407–413. https://doi.org/10.1111/sdi.13160

Harwood, L., & Clark, A. M. (2013). Understanding pre-dialysis modality decision-making: A meta-synthesis of qualitative studies. *International Journal of Nursing Studies*, *50*(1), 109–120. https://doi.org/10.1016/j.ijnurstu.2012.04.003

Hodge, M. H. (2008). Longer and better lives for patients … and their centers: A strategy for building a home hemodialysis program. *Hemodialysis International*, *12*(1), 1–5. https://doi.org/10.1111/j.1542-4758.2008.00232.x

Hodge, M. H. (2010). The path to a paradigm shift in hemodialysis. *Hemodialysis International*, *14*(1), 5–10. https://doi.org/10.1111/j.1542-4758.2009.00425.x

Horl, W. H. (1999). Healthcare systems and end-stage renal disease (Esrd) therapies--an international review: Access to ESRD treatments. *Nephrology Dialysis Transplantation*, *14*(suppl_6), 10–15. https://doi.org/10.1093/ndt/14.suppl_6.10

Hu, H.-W., Liu, C.-H., Du, Y.-C., Chen, K.-Y., Lin, H.-M., & Lin, C.-C. (2022). Real-time internet of medical things system for detecting blood leakage during hemodialysis using a novel multiple concentric ring sensor. *Sensors*, *22*(5), 1988. https://doi.org/10.3390/s22051988

Huber, J., Nepal, S., Bauer, D., Wessels, I., Fischer, M. R., & Kiessling, C. (2015). Tools and instruments for needs assessment, monitoring and evaluation of health research capacity development activities at the individual and

organizational level: A systematic review. *Health Research Policy and Systems*, *13*(1), 80. https://doi.org/10.1186/s12961-015-0070-3

Jhaveri, D., Larkins, S., & Sabesan, S. (2015). Telestroke, tele-oncology and teledialysis: A systematic review to analyse the outcomes of active therapies delivered with telemedicine support. *Journal of Telemedicine and Telecare*, *21*(4), 181–188. https://doi.org/10.1177/1357633X15569959

Jones, L. A., Gordon, E. J., Hogan, T. P., Fiandaca, C. A., Smith, B. M., Stroupe, K. T., & Fischer, M. J. (2021). Challenges, facilitators, and recommendations for implementation of home dialysis in the veterans health administration: Patient, caregiver, and clinician perceptions. *Kidney360*, *2*(12), 1928–1944. https://doi.org/10.34067/KID.0000642021

Juan, L. I. (2014). Literature review of the classifications of 'needs' in needs analysis theory. *International Journal of Education and Literacy Studies*, *2*(3), 12–16. https://journals.aiac.org.au/index.php/IJELS/article/view/535

Just, P. M., De Charro, F. Th., Tschosik, E. A., Noe, L. L., Bhattacharyya, S. K., & Riella, M. C. (2008). Reimbursement and economic factors influencing dialysis modality choice around the world. *Nephrology Dialysis Transplantation*, *23*(7), 2365–2373. https://doi.org/10.1093/ndt/gfm939

Kaushik, V., & Walsh, C. A. (2019). Pragmatism as a research paradigm and its implications for social work research. *Social Sciences*, *8*(9), 255. https://doi.org/10.3390/socsci8090255

Kennedy, C., McGrath-Chong, M., Arustei, D., d'Gama, C., Faratro, R., Fung, S., Magtoto, E., Wong, E., & Chan, C. T. (2019). A prototype line clamp for venous access bleeding in hemodialysis: A prospective cohort study.

Hemodialysis International, *23*(2), 151–157. https://doi.org/10.1111/hdi.12737

Kerr, P. G., Agar, J. W. M., & Hawley, C. M. (2011). Alternate night nocturnal hemodialysis: The australian experience. *Seminars in Dialysis*, *24*(6), 664–667. https://doi.org/10.1111/j.1525-139X.2011.00997.x

Kutner, N. G., Zhang, R., Barnhart, H., & Collins, A. J. (2005). Health status and quality of life reported by incident patients after 1 year on haemodialysis or peritoneal dialysis. *Nephrology Dialysis Transplantation*, *20*(10), 2159–2167. https://doi.org/10.1093/ndt/gfh973

Lacson, E., Wang, W., DeVries, C., Leste, K., Hakim, R. M., Lazarus, M., & Pulliam, J. (2011). Effects of a nationwide predialysis educational program on modality choice, vascular access, and patient outcomes. *American Journal of Kidney Diseases*, *58*(2), 235–242. https://doi.org/10.1053/j.ajkd.2011.04.015

Lee, H., Manns, B., Taub, K., Ghali, W. A., Dean, S., Johnson, D., & Donaldson, C. (2002). Cost analysis of ongoing care of patients with end-stage renal disease: The impact of dialysis modality and dialysis access. *American Journal of Kidney Diseases*, *40*(3), 611–622. https://doi.org/10.1053/ajkd.2002.34924

Ludlow, M. J., Lauder, L. A., Mathew, T. H., Hawley, C. M., & Fortnum, D. (2012). Australian consumer perspectives on dialysis: First national census. *Nephrology*, *17*(8), 703–709. https://doi.org/10.1111/j.1440-1797.2012.01651.x

Mahadevan, K., Pellicano, R., Reid, A., Kerr, P., Polkinghorne, K., & Agar, J. (2006). Comparison of biochemical, haematological and volume parameters

in two treatment schedules of nocturnal home haemodialysis. *Nephrology*, *11*(5), 413–418. https://doi.org/10.1111/j.1440-1797.2006.00670.x

Manns, B. J., Garg, A. X., Sood, M. M., Ferguson, T., Kim, S. J., Naimark, D., Nesrallah, G. E., Soroka, S. D., Beaulieu, M., Dixon, S. N., Alam, A., Allu, S., & Tangri, N. (2022). Multifaceted intervention to increase the use of home dialysis: A cluster randomized controlled trial. *Clinical Journal of the American Society of Nephrology*, *17*(4), 535–545. https://doi.org/10.2215/CJN.13191021

Marron, B., Craver, L., Remon, C., Prieto, M., Gutierrez, J. M., & Ortiz, A. (2010). 'Reality and desire' in the care of advanced chronic kidney disease. *Clinical Kidney Journal*, *3*(5), 431–435. https://doi.org/10.1093/ndtplus/sfq116

Marshall, M. R., Hawley, C. M., Kerr, P. G., Polkinghorne, K. R., Marshall, R. J., Agar, J. W. M., & McDonald, S. P. (2011). Home hemodialysis and mortality risk in Australian and New Zealand populations. *American Journal of Kidney Diseases*, *58*(5), 782–793. https://doi.org/10.1053/j.ajkd.2011.04.027

Marshall, M. R., Young, B. A., Fox, S. J., Cleland, C. J., Walker, R. J., Masakane, I., & Herold, A. M. (2015). The home hemodialysis hub: Physical infrastructure and integrated governance structure. *Hemodialysis International*, *19*(S1). https://doi.org/10.1111/hdi.12273

Maslow, A. H. (1943). A theory of human motivation. *Psychological Review*, *50*(4), 370–396. https://doi.org/10.1037/h0054346

Maslow, A. H. (2019). *Theory of human motivation*. GENERAL PRESS.

McKillip, J. (1987). *Need analysis*. SAGE Publications, Inc. https://doi.org/10.4135/9781412985260

McPhatter, L., & Lockridge, R. S. J. (2004). Daily dialysis: Nutritional implications and advantages for a state-of-the-art treatment option. *Nephrology Nursing Journal: Journal of the American Nephrology Nurses' Association*, *31*(2), 223–224.

Mehrabian, S., Morgan, D., Schlaeper, C., Kortas, C., & Lindsay, R. M. (2003). Equipment and water treatment considerations for the provision of quotidian home hemodialysis. *American Journal of Kidney Diseases*, *42*, 66–70. https://doi.org/10.1016/S0272-6386(03)00541-9

Mitra, S., Cress, C., & Goovaerts, T. (2015). Workforce development and models of care in home hemodialysis. *Hemodialysis International*, *19*(S1). https://doi.org/10.1111/hdi.12291

Moran, J., & Kraus, M. (2007). Starting a home hemodialysis program. *Seminars in Dialysis*, *20*(1), 35–39. https://doi.org/10.1111/j.1525-139X.2007.00239.x

Paterson, B., Fox, D. E., Lee, C. H., Riehl-Tonn, V., Qirzaji, E., Quinn, R., Ward, D., & MacRae, J. M. (2021). Understanding home hemodialysis patient attrition: A cohort study. Canadian Journal of Kidney Health and Disease, 8, 20543581211022195. https://doi.org/10.1177/20543581211022195

Patton, M. Q. (1999). Enhancing the quality and credibility of qualitative analysis. *Health Services Research*, *34*(5 Pt 2), 1189–1208. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1089059/

Pérez Fontán, M., Rodríguez-Carmona, A., López-Muñiz, A., & García-Falcón, T. (2012). Getting the right patient on the right renal replacement therapy. In C. Ronco, M. H. Rosner, & C. Crepaldi (Eds.), *Contributions to Nephrology* (Vol. 178, pp. 40–46). S. Karger AG. https://doi.org/10.1159/000337806

Piccoli, G. B., Calderini, M., Bechis, F., Iadarola, A. M., Iacuzzo, C., Mezza, E., Vischi, M., Trione, L., Poltronieri, E., Gai, M., Anania, P., Pacitti, A., Jeantet, A., & Segoloni, G. P. (2001). Modelling the 'ideal' self care—Limited care dialysis center. *Journal of Nephrology*, *14*(3), 162–168.

Piccoli, G. B., Ferraresi, M., Consiglio, V., Scognamiglio, S., Deagostini, M. C., Randone, O., Vigotti, F. N., & Calderale, P. M. (2012). Why home hemodialysis? A systematic "marketing" analysis. *Journal of Nephrology*, *25*(2), 159–169. https://doi.org/10.5301/jn.5000088

Pierratos, A. (2008). Daily nocturnal hemodialysis—A paradigm shift worthy of disrupting current dialysis practice. *Nature Clinical Practice Nephrology*, *4*(11), 602–603. https://doi.org/10.1038/ncpneph0938

Public health | fact sheets on the European union | European Parliament. (2025, March 31). https://www.europarl.europa.eu/factsheets/en/sheet/49/public-health

Rao, M., Muirhead, N., Klarenbach, S., Moist, L., & Lindsay, R. M. (2003). Management of anemia with quotidian hemodialysis. *American Journal of Kidney Diseases*, *42*, 18–23. https://doi.org/10.1016/S0272-6386(03)00533-X

Robinson, O. C. (2014). Sampling in interview-based qualitative research: A theoretical and practical guide. *Qualitative Research in Psychology*, *11*(1), 25–41. https://doi.org/10.1080/14780887.2013.801543

Rocco, M. V., Lockridge, R. S., Beck, G. J., Eggers, P. W., Gassman, J. J., Greene, T., Larive, B., Chan, C. T., Chertow, G. M., Copland, M., Hoy, C. D., Lindsay, R. M., Levin, N. W., Ornt, D. B., Pierratos, A., Pipkin, M. F., Rajagopalan, S., Stokes, J. B., Unruh, M. L., … Kliger, A. S. (2011). The

effects of frequent nocturnal home hemodialysis: The Frequent Hemodialysis Network Nocturnal Trial. *Kidney International*, *80*(10), 1080–1091. https://doi.org/10.1038/ki.2011.213

Rosner, M. H., Lew, S. Q., Conway, P., Ehrlich, J., Jarrin, R., Patel, U. D., Rheuban, K., Robey, R. B., Sikka, N., Wallace, E., Brophy, P., & Sloand, J. (2017). Perspectives from the kidney health initiative on advancing technologies to facilitate remote monitoring of patient self-care in rrt. *Clinical Journal of the American Society of Nephrology*, *12*(11), 1900–1909. https://doi.org/10.2215/CJN.12781216

Schachter, M. E., Bargman, J. M., Copland, M., Hladunewich, M., Tennankore, K. K., Levin, A., Oliver, M., Pauly, R. P., Perl, J., Zimmerman, D., & Chan, C. T. (2014). Rationale for a home dialysis virtual ward: Design and implementation. *BMC Nephrology*, *15*(1), 33. https://doi.org/10.1186/1471-2369-15-33

Schwartz, C. E., Merriman, M. P., Reed, G., & Byock, I. (2005). Evaluation of the missoula-vitas quality of life index—revised: Research tool or clinical tool? *Journal of Palliative Medicine*, *8*(1), 121–135. https://doi.org/10.1089/jpm.2005.8.121

Shim, E.-J., Lee, kyung-S., Park, J.-H., & Park, J.-H. (2011). Comprehensive needs assessment tool in cancer (Cnat): The development and validation. *Supportive Care in Cancer*, *19*(12), 1957–1968. https://doi.org/10.1007/s00520-010-1037-0

Smith, M. D., Robson, A. M., Woodward, R. S., Michelman, J. E., Valerius, T. J., & Hong, B. A. (1985). Geographic access to health care services: The case of

maintenance hemodialysis. *American Journal of Kidney Diseases*, *5*(1), 19–26. https://doi.org/10.1016/S0272-6386(85)80130-X

Taylor, K. S., Novick, T. K., Santos, S. R., Chen, Y., Smith, O. W., Perrin, N. A., & Crews, D. C. (2023). Material need insecurities among people on hemodialysis: Burden, sociodemographic risk factors, and associations with substance use. *Kidney360*, *4*(11), 1590–1597. https://doi.org/10.34067/KID.0000000000000279

Technical aspects of home hemodialysis. (2009). *Saudi Journal of Kidney Diseases and Transplantation*, *20*(2), 185–191. https://doi.org/PMID 19237801

Tejada-Tayabas, L. M., Partida-Ponce, K. L., & Hernández-Ibarra, L. E. (2015). Coordinated hospital-home care for kidney patients on hemodialysis from the perspective of nursing personnel. *Revista Latino-Americana de Enfermagem*, *23*(2), 225–233. https://doi.org/10.1590/0104-1169.0058.2546

Tennankore, K. K., Kim, S. J., & Chan, C. T. (2013). The feasibility of caregiver-assisted home nocturnal hemodialysis. *Nephron Clinical Practice*, *122*(1–2), 17–23. https://doi.org/10.1159/000348419

Thompson, S., Marnoch, C. A., Habib, S., Robinson, H., & Pauly, R. P. (2011). A successful term pregnancy using in-center intensive quotidian hemodialysis. *Hemodialysis International*, *15*(S1). https://doi.org/10.1111/j.1542-4758.2011.00603.x

Tomori, K., & Okada, H. (2018). Home hemodialysis: Benefits, risks, and barriers. In H. Nakamoto, K. Nitta, K. Tsuchiya, H. Okada, & H. Hasegawa (Eds.), *Contributions to Nephrology* (Vol. 196, pp. 178–183). S. Karger AG. https://doi.org/10.1159/000485719

Walker, R. C., Walker, C., Reynolds, A., Haselden, R., Hay, S., & Palmer, S. C. (2024). Consumer values, perspectives and experiences of psychological health when living with dialysis at home: An in-depth interview study. *Peritoneal Dialysis International: Journal of the International Society for Peritoneal Dialysis*, *44*(3), 185–193. https://doi.org/10.1177/08968608231202899

Weinhandl, E. D., & Collins, A. J. (2018). Relative risk of home hemodialysis attrition in patients using a telehealth platform. Hemodialysis International, 22(3), 318–327. https://doi.org/10.1111/hdi.12621

Weinhandl, E. D., Gilbertson, D. T., & Collins, A. J. (2016). Mortality, hospitalization, and technique failure in daily home hemodialysis and matched peritoneal dialysis patients: A matched cohort study. *American Journal of Kidney Diseases*, *67*(1), 98–110. https://doi.org/10.1053/j.ajkd.2015.07.014

Weinhandl, E. D., Nieman, K. M., Gilbertson, D. T., & Collins, A. J. (2015). Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. *American Journal of Kidney Diseases*, *65*(1), 98–108. https://doi.org/10.1053/j.ajkd.2014.06.015

Welch, J. L., Thomas-Hawkins, C., Bakas, T., McLennon, S. M., Byers, D. M., Monetti, C. J., & Decker, B. S. (2014). Needs, concerns, strategies, and advice of daily home hemodialysis caregivers. *Clinical Nursing Research*, *23*(6), 644–663. https://doi.org/10.1177/1054773813495407

Winterbottom, A. E., Gavaruzzi, T., Mooney, A., Wilkie, M., Davies, S. J., Crane, D., Tupling, K., Baxter, P. D., Meads, D. M., Mathers, N., & Bekker, H. L. (2016). Patient acceptability of the Yorkshire dialysis decision aid (Yodda)

booklet: A prospective non-randomized comparison study across 6 predialysis services. *Peritoneal Dialysis International: Journal of the International Society for Peritoneal Dialysis*, *36*(4), 374–381. https://doi.org/10.3747/pdi.2014.00274

Wong, C. K. H., Chen, J., Fung, S. K. S., Mok, M. M. Y., Cheng, Y. L., Kong, I., Lo, W. K., Lui, S. L., Chan, T. M., & Lam, C. L. K. (2019). Direct and indirect costs of end-stage renal disease patients in the first and second years after initiation of nocturnal home haemodialysis, hospital haemodialysis and peritoneal dialysis. *Nephrology Dialysis Transplantation*, *34*(9), 1565–1576. https://doi.org/10.1093/ndt/gfy395

Woods, J. D., Port, F. K., Stannard, D., Blagg, C. R., & Held, P. J. (1996). Comparison of mortality with home hemodialysis and center hemodialysis: A national study. *Kidney International*, *49*(5), 1464–1470. https://doi.org/10.1038/ki.1996.206

Wright, S. & Leicester General Hospital NHS Trust. (1994). Psychological needs assessment in renal failure. *Clinical Psychology Forum*, *1*(71), 14–16. https://doi.org/10.53841/bpscpf.1994.1.71.14

Yang, W.-L., Zhang, F., He, L., Zhang, A.-H., Wang, T., Suzie, B., Yang, L.-J., & Lai, C. (2013). Experiences with establishing the first self-care hemodialysis program in a hospital in mainland China. *Renal Failure*, *35*(2), 257–261. https://doi.org/10.3109/0886022X.2012.747141

Zhang, Y., & Baharani, J. (2023). Dialysis education and options for late presenters—An ongoing dilemma. *Hemodialysis International*, *27*(3), 224–230. https://doi.org/10.1111/hdi.13082

Zimmerman, D. L., Swedko, P. J., Posen, G. A., & Burns, K. D. (2003). Daily hemofiltration with a simplified method of delivery. *ASAIO Journal (American Society for Artificial Internal Organs: 1992)*, *49*(4), 426–429.

Word Count

Chapter 1: 1931 words

Chapter 2: 4027 words

Chapter 3: 4482 words

Chapter 4: 2961 words

Chapter 5: 5621 words

Chapter 6: 3055 words

Total: 22,101 words

Appendices

A Comprehensive List of the Articles Identified Through the Literature Search

Participation Consent Form – Patients and Caregivers (English)

Participation Consent Form – Patients and Caregivers (Maltese)

Participation Consent Form – Healthcare Workers and Administrators (English)

Participation Consent Form – Healthcare Workers and Administrators (Maltese)

Information Letter – Patients and Caregivers (English)

Information Letter – Patients and Caregivers (Maltese)

Information Letter – Healthcare Workers and Administrators (English)

Information Letter – Healthcare Workers and Administrators (Maltese)

Interview Guide – Patients

Interview Guide – Healthcare Workers

Interview Guide – Administrators and Policymakers

Caregiver Questionnaire (Qualitative Survey) (English)

Caregiver Questionnaire (Qualitative Survey) (Maltese)

FREC Approval

UREC Approval

DPO Approval

Mater Dei Hospital CEO Approval

Table 1 (Appendices) - A Comprehensive List of the Articles Identified Through the Literature Search

	Authors	Year	Journal	Title
1	Pérez-Alba et al. (2020)	2020	International urology and nephrology	Expanded home hemodialysis: case reports.
2	Power et al. (2014)	2014	Postgraduate medical journal	Haemodialysis: hospital or home?
3	Diaz-Buxo et al. (2015)	2015	Blood purification	Home hemodialysis dose: balancing patient needs and preferences.
4	Yang et al. (2013)	2013	Renal failure	Experiences with establishing the first self-care hemodialysis program in a hospital in mainland China.
5	Desbiens et al. (2024)	2024	American journal of kidney diseases (AJKD)	Outcomes of Integrated Home Dialysis Care: Results from the Canadian Organ Replacement Register.
6	Tennankore et al. (2012)	2012	Nature reviews. Nephrology	Intensive home haemodialysis: benefits and barriers.

7	François et al. (2015)	2015	Minerva urologica e nefrologica, The Italian journal of urology and nephrology	Modalities and prescribing strategies in intensive home hemodialysis: a narrative review.
8	Usvyat et al. (2018)	2018	Seminars in nephrology	Using Technology to Inform and Deliver Precise Personalized Care to Patients With End-Stage Kidney Disease.
9	Ankawi et al. (2024)	2024	Clinical journal of the American Society of Nephrology (CJASN)	Pregnancy in Patients Receiving Home Dialysis.
10	Virtanen et al. (2019)	2019	Journal of renal care	Experiences of safety among patients receiving home dialysis therapies.
11	Cornelis et al. (2014)	2014	Nephrology, dialysis, transplantation: official publication of the European	An international feasibility study of home haemodialysis in older patients.

			Dialysis and Transplant Association - European Renal Association	
12	Ni et al. (2022)	2022	BMC nephrology	The initial attempt at home hemodialysis in mainland China.
13	Rosner et al. (2017)	2017	Clinical journal of the American Society of Nephrology (CJASN)	Perspectives from the Kidney Health Initiative on Advancing Technologies to Facilitate Remote Monitoring of Patient Self-Care in RRT.
14	Blankenship et al. (2023)	2023	Hemodialysis international. International Symposium on Home Hemodialysis	Assessing the impact of transitional care units on dialysis patient outcomes: A multicenter, propensity score-matched analysis.
15	Torres et al. (2021)	2021	Nursing forum	Exploring the challenges and needs of home caregivers of hemodialysis patients in the Philippines: A mixed methods study.

16	Jayanti et al. (2013)	2013	BMC nephrology	Barriers to successful implementation of care in home haemodialysis (BASIC-HHD):1. Study design, methods and rationale.
17	Guerraoui et al. (2022)	2022	BMC nephrology	Design of therapeutic education workshops for home haemodialysis in a patient-centered chronic kidney diseases research: a qualitative study.
18	Miller (2010)	2010	British journal of nursing (Mark Allen Publishing)	Does home haemodialysis produce better outcomes for patients?
19	Huang et al. (2019)	2019	Clinical journal of the American Society of Nephrology (CJASN)	Buttonhole versus Stepladder Cannulation for Home Hemodialysis: A Multicenter, Randomized, Pilot Trial.
20	Marrón et al. (2010)	2010	NDT plus	'Reality and desire' in the care of advanced chronic kidney disease.

21	Gorham et al. (2021)	2021	BMC health services research	Do remote dialysis services really cost more? An economic analysis of hospital and dialysis modality costs associated with dialysis services in urban, rural and remote settings.
22	Aspelund et al. (2024)	2024	JMIR human factors	Designing for Improved Patient Experiences in Home Dialysis: Usability and User Experience Findings from User-Based Evaluation Study with Patients with Chronic Conditions.
23	Raphael et al. (2015)	2015	Canadian journal of kidney health and disease	A virtual ward for home hemodialysis patients - a pilot trial.
24	Machowska et al. (2016)	2016	Patient preference and adherence	Factors influencing access to education, decision making, and receipt of preferred dialysis modality in unplanned dialysis start patients.

25	Hamidi et al. (2023)	2023	Canadian journal of kidney health and disease	The Feasibility of a Transitional Care Unit for Patients Newly Started on In-Center Hemodialysis: A Research Letter.
26	Scarpioni et al. (2021)	2021	Hemodialysis international. International Symposium on Home Hemodialysis	What can a home hemodialysis program offer to patients in a nursing home setting? A case series and feasibility analysis.
27	Cornelis et al. (2012)	2012	Seminars in dialysis	Intensive hemodialysis in the (nursing) home: the bright side of geriatric ESRD care?
28	Pérez Fontán et al. (2012)	2012	Contributions to nephrology	Getting the right patient on the right renal replacement therapy.
29	Batt et al. (2012)	2012	Hemodialysis international. International Symposium on Home Hemodialysis	Home hemodialysis: a successful option for obese and bariatric people with end-stage kidney disease.

30		2016	Nephrology news & issues	CQI proiect Every other day nocturnal HHD - An alternative approach to reduce burden.
31	Noyes et al. (2021)	2021	BMJ Open	Understanding the low take-up of home-based dialysis through a shared decision-making lens: a qualitative study
32	Desbiens et al. (2024)	2024	Clinical kidney journal	Integrated home dialysis model: facilitating home-to-home transition.
33	Al Sahlawi et al. (2022)	2022	Saudi journal of kidney diseases and transplantation	Nephrologists' Perspectives of the Potential Utilization of Home Hemodialysis in Saudi Arabia.
34	Welch et al. (2014)	2014	Clinical nursing research	Needs, concerns, strategies, and advice of daily home hemodialysis caregivers.
35	DePasquale et al. (2019)	2019	Kidney medicine	Family Members' Experiences with Dialysis and Kidney Transplantation.

36	Tennankore et al. (2012)	2012	Nephron. Clinical practice	The feasibility of caregiver-assisted home nocturnal hemodialysis.
37	Dubin et al. (2019)	2019	JMIR formative research	A Digital Modality Decision Program for Patients with Advanced Chronic Kidney Disease.
38	Jayanti et al. (2014)	2014	Hemodialysis international. International Symposium on Home Hemodialysis	Home hemodialysis: beliefs, attitudes, and practice patterns.
39	Marshall et al. (2015)	2015	American journal of kidney diseases (AJKD)	Temporal Changes in Mortality Risk by Dialysis Modality in the Australian and New Zealand Dialysis Population.
40	Ludlow et al. (2012)	2012	Nephrology (Carlton, Vic.)	Australian consumer perspectives on dialysis: first national census.

41	Lacson et al. (2011)	2011	American journal of kidney diseases (AJKD)	Effects of a nationwide predialysis educational program on modality choice, vascular access, and patient outcomes.
42	Glidewell et al. (2013)	2013	Implementation science (IS)	Using behavioural theories to optimise shared haemodialysis care: a qualitative intervention development study of patient and professional experience.
43	Piccoli et al. (2012)	2012	Journal of nephrology	Why home hemodialysis? A systematic "marketing" analysis.
44	Girsberger et al. (2020)	2020	Hemodialysis international. International Symposium on Home Hemodialysis	Ventricular ejection fraction over time in patients on intensive home hemodialysis: A retrospective cohort study.
45	Hodge (2010)	2010	Hemodialysis international. International Symposium on Home Hemodialysis	The path to a paradigm shift in hemodialysis.

46	Thompson et al. (2011)	2011	Hemodialysis international. International Symposium on Home Hemodialysis	A successful term pregnancy using in-center intensive quotidian hemodialysis.
47	Elbokl et al. (2022)	2022	Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis	Home-to-home dialysis transition: A 24-year single-centre experience.
48	Abra et al. (2022)	2022	Kidney360	The Implementation of a Virtual Home Dialysis Mentoring Program for Nephrologists.
49	Khan et al. (2022)	2022	Seminars in dialysis	Exploring stakeholders and their requirements in the process of home hemodialysis: A literature review.
50	Taha et al. (2022)	2022	Kidney medicine	Patient Navigators for CKD and Kidney Failure: A Systematic Review.

51	Pungchompoo et al. (2024)	2024	BMC geriatrics	The feasibility of integrating a home telehealth model for older persons living with hemodialysis.
52	Devoe et al. (2016)	2016	American journal of kidney diseases (AJKD)	Patient Education and Peritoneal Dialysis Modality Selection: A Systematic Review and Meta-analysis.
53	Rousseau-Gagnon et al. (2016)	2016	Hemodialysis international. International Symposium on Home Hemodialysis	The use of vascular access audit and infections in home hemodialysis.
54	Finamore et al. (2021)	2021	Aging clinical and experimental research	Clustering of patients with end-stage chronic diseases by symptoms: a new approach to identify health needs.
55	Gage et al. (2020)	2020	The journal of vascular access	An immediate access dialysis graft designed to prevent needle-related complications: Results from the initial pre-clinical studies.

56	Dhruve et al. (2019)	2019	Hemodialysis international. International Symposium on Home Hemodialysis	The use of nurse-administered vascular access audit in home hemodialysis patients: A quality initiative.
57	Sledge et al. (2023)	2023	Kidney medicine	Kidney Failure Patients' Perceptions and Definitions of Health: A Qualitative Study.
58	Tong et al. (2012)	2012	BMJ open	Clinician beliefs and attitudes about home haemodialysis: a multinational interview study.
59	Cartwright et al. (2021)	2021	Peritoneal dialysis international: journal of the International Society for Peritoneal Dialysis	eHealth interventions to support patients in delivering and managing peritoneal dialysis at home: A systematic review.
60	Finderup et al. (2018)	2018	Journal of renal care	Developing and pilot testing a shared decision-making intervention for dialysis choice.

61	Tong et al. (2013)	2013	BMJ open	The beliefs and expectations of patients and caregivers about home haemodialysis: an interview study.
62	Vestman et al. (2014)	2014	Nursing research and practice	Freedom and confinement: patients' experiences of life with home haemodialysis.
63	Cheng et al. (2024)	2024	Clinical journal of the American Society of Nephrology (CJASN)	The Feasibility of Implementing Patient-Centered Objective Structured Clinical Examination during Home Hemodialysis Training.
64	Kaiser et al. (2020)	2020	Journal of medical Internet research	A Virtual Multidisciplinary Care Program for Management of Advanced Chronic Kidney Disease: Matched Cohort Study.
65	Chan et al. (2023)	2023	Kidney medicine	Home Dialysis Curriculum Implementation for Health Care Workers Using Project ECHO Principles: A Feasibility Report From NKF-KDOQI.

66	Hemmelgarn et al. (2018)	2018	Canadian journal of kidney health and disease	Implementation and Evaluation of a Risk-Based Approach to Guide Chronic Kidney Disease Care: Protocol for a Multiphase Mixed-Methods Study.
67	Cornelis et al. (2010)	2010	Nephrology, dialysis, transplantation: official publication of the European Dialysis and Transplant Association - European Renal Association	Home dialysis is a successful strategy in nonrenal solid organ transplant recipients with end-stage renal disease.
68	Weaver et al. (2012)	2012	Professional case management	An analysis of a case manager-driven emergent dialysis program.
69	Gilbertson et al. (2019)	2019	American journal of kidney diseases (AJKD)	Burden of Care and Quality of Life Among Caregivers for Adults Receiving Maintenance Dialysis: A Systematic Review.

70	Rioux et al. (2011)	2011	Clinical journal of the American Society of Nephrology (CJASN)	Effect of an in-hospital chronic kidney disease education program among patients with unplanned urgent-start dialysis.
71	Wallace et al. (2020)	2020	Kidney360	ESKD Treatment Choices Model: Responsible Home Dialysis Growth Requires Systems Changes.
72	Antoun et al. (2023)	2023	Journal of renal care	Exploring patients' experiences of the impact of dialysis therapies on quality of life and wellbeing.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Consent Form for Participation in Research Interviews

Project Code: FHS-2024-00090

Researcher: Matthias Azzopardi

Institution: University of Malta, Faculty of Health Sciences

You are invited to participate in a research study aimed at evaluating the feasibility and desirability of introducing home haemodialysis in the Maltese Islands. This study is part of a Master's thesis project under the supervision of Prof S. Buttigieg. The following consent form outlines the purpose of the study, the nature of your participation, and the management of the information you provide.

This study seeks to understand the perspectives, readiness, and concerns of various stakeholders, including healthcare workers and administrative staff, regarding the potential introduction of home haemodialysis in Malta.

If you agree to participate, you will be asked to participate in one or more interviews. Each interview will last approximately 30 minutes and will be conducted at a time and location (or virtually) convenient to you.

Your participation in this study is confidential. Your identity will not be disclosed in any report or publication resulting from this study. All data will be pseudonymised and used solely for this research purpose, and only aggregated findings will be presented. Audio recordings from interviews will be transcribed, and the original recordings will be securely deleted after transcription.

The Supervisor of the research project (Prof. S. Buttigieg [sandra.buttigieg@um.edu.mt]) and the members of the Examination Board may have access to the personal data collected for the purpose of evaluating the project and its findings. In case any participant wishes to know which examiner accessed their personal data, they may obtain this information by calling the provided contact number: +356 2340 1120.

Participating in this study poses minimal risks, including potential psychological distress from sensitive topics. To mitigate these risks, a safe, confidential environment will be ensured, regular check-ins will be conducted to monitor emotional well-being during interviews, and contact details of any necessary support services will be provided.

Your participation is entirely voluntary. You may choose not to participate or withdraw from the study at any time. You may decline to answer any questions that make you uncomfortable. Should you choose to withdraw from this study, any data collected from your interview will be erased as long as this is technically possible (for

Please retain a copy of this consent form for your records.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

example, before it is anonymised or published), unless erasure of data would render impossible or seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.

While there will be no direct benefit to you from participating, your responses will help contribute to a better understanding of the needs and challenges related to the introduction of home haemodialysis in Malta, which could lead to improved patient care and system eficiency.

To indicate your willingness to participate, please return the signed consent form to the researcher. By signing this form, you are indicating that you have understood the above information, the purpose of this study, and agree to participate voluntarily.

Participant Name: _____

Signature: _____

Date: _____

Researcher's Signature: _____ Supervisor's Signature: _____

Date: _____ Date: _____

Please retain a copy of this consent form for your records.

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Formola ta' Kunsens għall-Parteċipazzjoni f'Intervisti ta' Riċerka

Kodiċi tal-Proġett: FHS-2024-00090

Riċerkatur: Matthias Azzopardi

Istituzzjoni: Università ta' Malta, Fakultà tax-Xjenzi tas-Saħħa

Inti mistieden tipparteċipa f'studju ta' riċerka li għandu l-għan li jevalwa l-fatibilità u d-dežiderabbiltà tal-introduzzjoni tad-dijalisi fid-dar fil-Gżejjer Maltin. Dan l-istudju huwa parti minn proġett ta' teżi tal-Masters taħt is-superviżjoni tal-Prof S. Buttigieg. Il-formola ta' kunsens li ġejja tispjega l-għan tal-istudju, in-natura tal-parteċipazzjoni tiegħek, u l-immaniġġjar tal-informazzjoni li tipprovdi.

Dan l-istudju jfittex li jifhem il-perspetivi, il-preparazzjoni, u t-tħassib ta' diversi partijiet interessati, inklużi l-ħaddiema tas-saħħa u l-istaff amministrativ, rigward il-potenzjal għall-introduzzjoni tad-dijalisi fid-dar f'Malta.

Jekk taqbel li tipparteċipa, tintalab tipparteċipa f'intervista jew aktar. Kull intervista ddum madwar 30 minuta u ssir f'ħin u post (jew virtwalment) konvenjenti għalik.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija kunfidenzjali. L-identità tiegħek ma tiġix żvelata f'xi rapport jew pubblikazzjoni li tirriżulta minn dan l-istudju. Id-dejta kollha ser tiġi psewdonimizzata u użata biss għal skopijiet ta' din ir-riċerka, u jingħataw biss ir-riżultati aggregati. Ir-reġistrazzjonijiet awdjo mill-intervisti jiġu traskriti, u r-reġistrazzjonijiet oriġinali jiġu mħassra b'mod sigur wara t-traskrizzjoni.

Is-Superviżura tal-proġett tar-riċerka (Prof. S. Buttigieg [sandra.Buttigieg@um.edu.mt]) u l-membri tal-Bord tal-Eżami jistgħu jkollhom aċċess għad-data personali miġbura għall-għan ta' evalwazzjoni tal-proġett u s-sejbiet tiegħu. F'każ li xi parteċipant jixtieq ikun jaf liema eżaminatur aċċessa d-data personali tiegħu, jista' jikseb din l-informazzjoni billi jċempel in-numru ta' kuntatt provdut: +356 2340 1120.

Il-parteċipazzjoni f'dan l-istudju għandha riskji minimi, li jistgħu jinkludu tensjoni psikoloġika minħabba suġġeti sensitivi. Biex jiġu mtafija dawn ir-riskji, se tiġi żgurata ambjent sikur u kunfidenzjali, se jsiru verifiki regolari biex tiġi mmonitorjata l-benessri emozzjonali waqt l-intervisti, u se jingħataw id-dettalji ta' kuntatt tas-servizzi ta' appoġġ meħtieġa.

Il-parteċipazzjoni tiegħek hija kompletament volontarja. Tista' tagħżel li ma tipparteċipax jew li tirtira mill-istudju f'kull ħin. Tista' tirrifjuta li twieġeb xi mistoqsijiet li jagħmluk skomdu. Jekk tagħżel li tirtira minn dan l-istudju, id-dejta kollha miġbura mill-intervista tiegħek se titħassar sakemm dan ikun possibbli teknoloġikament (pereżempju, qabel ma tiġi anonimizzata jew ippubblikata), sakemm it-tħassir tad-dejta ma jagħmilx impossibbli jew ma jimpedix serjament il-kisba tal-objetivi tar-riċerka, f'liema każ id-dejta se tinżamm f'forma anonimizzata.

Jekk jogħġbok iżomm kopja ta' din il-formola ta' kunsens għar-rekords tiegħek.

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Filwaqt li ma jkunx hemm benefiċċju dirett għalik milli tipparteċipa, ir-risposti tiegħek jgħinu jikkontribwixxu għal fehim aħjar tal-ħtiġijiet u l-isfidi relatati mal-introduzzjoni tad-dijalisi fid-dar f'Malta, li jista' jwassal għal titjib fil-kura tal-pazjent u l-efiċjenza tas-sistema

Biex tindika l-volontà tiegħek li tipparteċipa, jekk jogħġbok rritorna l-formola tal-kunsens ifirmata lir-riċerkatur. Billi tifirma din il-formola, qed tindika li fhimt l-informazzjoni t'hawn fuq, l-iskop ta' dan l-istudju, u taqbel li tipparteċipa volontarjament.

Isem tal-Parteċipant: _____

Firma: _____

Data: _____

Firma tar-Riċerkatur: _____

Data: _____

Firma tas-Superviżur: _____

Date: _____

Jekk jogħġbok iżomm kopja ta' din il-formola ta' kunsens għar-rekords tiegħek.

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Consent Form for Participation in Research Interviews

Project Code: FHS-2024-00090

Researcher: Matthias Azzopardi

Institution: University of Malta, Faculty of Health Sciences

You are invited to participate in a research study aimed at evaluating the feasibility and desirability of introducing home haemodialysis in the Maltese Islands. This study is part of a Master's thesis project under the supervision of Prof S. Buttigieg. The following consent form outlines the purpose of the study, the nature of your participation, and the management of the information you provide.

This study seeks to understand the perspectives, readiness, and concerns of various stakeholders, including healthcare workers and administrative staff, regarding the potential introduction of home haemodialysis in Malta.

If you agree to participate, you will be asked to participate in one or more interviews. Each interview will last approximately 30 minutes and will be conducted at a time and location (or virtually) convenient to you.

Your participation in this study is confidential. Your identity will not be disclosed in any report or publication resulting from this study. All data will be pseudonymised and used solely for this research purpose, and only aggregated findings will be presented. Audio recordings from interviews will be transcribed, and the original recordings will be securely deleted after transcription.

The Supervisor of the research project (Prof. S. Buttigieg [sandra.Buttigieg@um.edu.mt]) and the members of the Examination Board may have access to the personal data collected for the purpose of evaluating the project and its findings. In case any participant wishes to know which examiner accessed their personal data, they may obtain this information by calling the provided contact number: +356 2340 1120.

Participating in this study poses minimal risks, including potential psychological distress from sensitive topics. To mitigate these risks, a safe, confidential environment will be ensured, regular check-ins will be conducted to monitor emotional well-being during interviews, and contact details of any necessary support services will be provided.

Your participation is entirely voluntary. You may choose not to participate or withdraw from the study at any time. You may decline to answer any questions that make you uncomfortable. Should you choose to withdraw from this study, any data collected from your interview will be erased as long as this is technically possible (for

Please retain a copy of this consent form for your records.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

example, before it is anonymised or published), unless erasure of data would render impossible or seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.

While there will be no direct benefit to you from participating, your responses will help contribute to a better understanding of the needs and challenges related to the introduction of home haemodialysis in Malta, which could lead to improved patient care and system eficiency.

To indicate your willingness to participate, please return the signed consent form to the researcher. By signing this form, you are indicating that you have understood the above information, the purpose of this study, and agree to participate voluntarily.

Participant Name: _____

Signature: _____

Date: _____

Researcher's Signature: _____ Supervisor's Signature: _____

Date: _____ Date: _____

Please retain a copy of this consent form for your records.

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Formola ta' Kunsens għall-Parteċipazzjoni f'Intervisti ta' Riċerka

Kodiċi tal-Proġett: FHS-2024-00090

Riċerkatur: Matthias Azzopardi

Istituzzjoni: Università ta' Malta, Fakultà tax-Xjenzi tas-Saħħa

Inti mistieden tipparteċipa f'studju ta' riċerka li għandu l-għan li jevalwa l-fatibilità u d-dežiderabbiltà tal-introduzzjoni tad-dijalisi fid-dar fil-Gżejjer Maltin. Dan l-istudju huwa parti minn proġett ta' teżi tal-Masters taħt is-superviżjoni tal-Prof S. Buttigieg. Il-formola ta' kunsens li ġejja tispjega l-għan tal-istudju, in-natura tal-parteċipazzjoni tiegħek, u l-immaniġġjar tal-informazzjoni li tipprovdi.

Dan l-istudju jfittex li jifhem il-perspetivi, il-preparazzjoni, u t-tħassib ta' diversi partijiet interessati, inklużi l-ħaddiema tas-saħħa u l-istaff amministrativ, rigward il-potenzjal għall-introduzzjoni tad-dijalisi fid-dar f'Malta.

Jekk taqbel li tipparteċipa, tintalab tipparteċipa f'intervista jew aktar. Kull intervista ddum madwar 30 minuta u ssir f'ħin u post (jew virtwalment) konvenjenti għalik.

Il-parteċipazzjoni tiegħek f'dan l-istudju hija kunfidenzjali. L-identità tiegħek ma tiġix żvelata f'xi rapport jew pubblikazzjoni li tirriżulta minn dan l-istudju. Id-dejta kollha ser tiġi psewdonimizzata u użata biss għal skopijiet ta' din ir-riċerka, u jingħataw biss ir-riżultati aggregati. Ir-reġistrazzjonijiet awdjo mill-intervisti jiġu traskriti, u r-reġistrazzjonijiet oriġinali jiġu mħassra b'mod sigur wara t-traskrizzjoni.

Is-Superviżura tal-proġett tar-riċerka (Prof. S. Buttigieg [sandra.Buttigieg@um.edu.mt]) u l-membri tal-Bord tal-Eżami jistgħu jkollhom aċċess għad-data personali miġbura għall-għan ta' evalwazzjoni tal-proġett u s-sejbiet tiegħu. F'każ li xi parteċipant jixtieq ikun jaf liema eżaminatur aċċessa d-data personali tiegħu, jista' jikseb din l-informazzjoni billi jċempel in-numru ta' kuntatt provdut: +356 2340 1120.

Il-parteċipazzjoni f'dan l-istudju għandha riskji minimi, li jistgħu jinkludu tensjoni psikoloġika minħabba suġġeti sensitivi. Biex jiġu mtafija dawn ir-riskji, se tiġi żgurata ambjent sikur u kunfidenzjali, se jsiru verifiki regolari biex tiġi mmonitorjata l-benessri emozzjonali waqt l-intervisti, u se jingħataw id-dettalji ta' kuntatt tas-servizzi ta' appoġġ meħtieġa.

Il-parteċipazzjoni tiegħek hija kompletament volontarja. Tista' tagħżel li ma tipparteċipax jew li tirtira mill-istudju f'kull ħin. Tista' tirrifjuta li twieġeb xi mistoqsijiet li jagħmluk skomdu. Jekk tagħżel li tirtira minn dan l-istudju, id-dejta kollha miġbura mill-intervista tiegħek se titħassar sakemm dan ikun possibbli teknoloġikament (pereżempju, qabel ma tiġi anonimizzata jew ippubblikata), sakemm it-tħassir tad-dejta ma jagħmilx impossibbli jew ma jimpedix serjament il-kisba tal-objetivi tar-riċerka, f'liema każ id-dejta se tinżamm f'forma anonimizzata.

Jekk jogħġbok iżomm kopja ta' din il-formola ta' kunsens għar-rekords tiegħek.

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Filwaqt li ma jkunx hemm benefiċċju dirett għalik milli tipparteċipa, ir-risposti tiegħek jgħinu jikkontribwixxu għal fehim aħjar tal-ħtiġijiet u l-isfidi relatati mal-introduzzjoni tad-dijalisi fid-dar f'Malta, li jista' jwassal għal titjib fil-kura tal-pazjent u l-effiċjenza tas-sistema

Biex tindika l-volontà tiegħek li tipparteċipa, jekk jogħġbok rritorna l-formola tal-kunsens ifirmata lir-riċerkatur. Billi tifirma din il-formola, qed tindika li fhimt l-informazzjoni t'hawn fuq, l-iskop ta' dan l-istudju, u taqbel li tipparteċipa volontarjament.

Isem tal-Parteċipant: _____

Firma: _____

Data: _____

Firma tar-Riċerkatur: _____ Firma tas-Superviżur: _____

Data: _____ Date: _____

Jekk jogħġbok iżomm kopja ta' din il-formola ta' kunsens għar-rekords tiegħek.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Information on Participation in Home Haemodialysis Research Project

Dear Participant,

As my research project for the Master of Science in Health Systems Management & Leadership at the University of Malta, I will be conducting a detailed study titled "Introduction of Home Haemodialysis in the Maltese Islands: A Needs Analysis." [Code: FHS-2024-00090]. This project aims to explore the feasibility and desirability of implementing home haemodialysis in Malta, considering the perspectives of various stakeholders within our healthcare system.

Purpose of the Study:

This research aims to explore the feasibility and desirability of introducing home haemodialysis in the Maltese Islands. It seeks to gather insights from various stakeholders—including patients, caregivers, healthcare professionals, and policymakers—to assess the potential advantages and challenges of implementing home haemodialysis as an alternative to the current renal replacement therapies available in Malta.

What to Expect:

As a participant, you will be invited to partake in in-depth interviews and discussions that will help us understand your expectations, readiness, and concerns regarding home haemodialysis.

Confidentiality and Pseudonymity:

Please be assured that all information shared during the interviews will be kept confidential. Data will be pseudonymised and used solely for this research purpose. Strict ethical guidelines with be adhered to in order to protect your privacy and the integrity of the research. The Supervisor of the research project (Prof. S. Buttigieg [sandra.Buttigieg@um.edu.mt]) and the members of the Examination Board will have access to the coded data collected for the purpose of evaluating the project and its findings.

In exceptional circumstances, the supervisor and examiners may have access to personal data too, for verification purposes. In case any participant wishes to know which examiner accessed their personal data, they may obtain this information by calling the provided contact number: +356 2340 1120.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Your confidentiality and pseudonymity will be assured through the use of codes. This means that instead of using your real name, we will assign a code to your responses to ensure your identity is protected.

Data Storage and Security

Your personal data will be stored ofline in an encrypted version on an external hard disk to ensure its security. This data will be accessible only to the research team.

As a participant, you have the right under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation to access, rectify, and where applicable ask for the data concerning you to be erased (or retained in anonymised form).

Data Necessity and Usage

You will only be asked to share data that is necessary for the research. Personally identifiable data will be deleted when it is no longer necessary, which will be September 2025. Anonymised data will be retained for an indefinite period.

Should you choose to withdraw, any data collected from your interview will be erased as long as this is technically possible (for example, before it is anonymised or published), unless erasure of data would render impossible or seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.

Voluntary Participation and Withdrawal

Please be assured that refusing to participate or withdrawing from the study at any time will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation is entirely voluntary.

Benefits and Risks of Participating:

Your participation is crucial in helping identify key factors that can make home haemodialysis a viable and beneficial option for patients with end-stage kidney disease in Malta. By sharing your experiences and opinions, you will be contributing to a broader understanding of the needs and preferences that influence healthcare services.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Participating in this study poses minimal risks, which may include potential psychological distress from sensitive topics. To mitigate these risks, a safe, confidential environment will be ensured, regular check-ins will be conducted to monitor emotional well-being during interviews, and contact details of any necessary support services will be provided.

Next Steps:

Availability to participate should be indicated by returning the signed Consent Form to the researcher. Once the form is received, an interview invitation will be provided.

Questions or Concerns:

Should you have any questions or require further information about the research or your participation, please do not hesitate to contact me or my supervisor.

Thank you for your interest in participating in this important study. I look forward to your valuable input and hope that together, we can enhance the quality of renal care in Malta.

Kind regards

_____

Matthias Azzopardi

M. Sc. Health Systems Management & Leadership Student

Faculty of Health Sciences,

University of Malta

_____

Prof Sandra C Buttigieg
M.D.(Melit.),M.Sc.(Pub.Hlth.),M.B.A.(Exec.)(Melit.),Ph.D.(Aston),F.F.P.H.(UK),M.M.C.F.D.

Research Supervisor

Faculty of Health Sciences, University of Malta

(T: +356 2340 1906)

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Informazzjoni dwar il-Parteċipazzjoni fil-Proġett tar-Riċerka tad-Dijalisi tad-Dar

Għażiż Parteċipant,

Bħala parti mir-riċerka għall-*Masters* se nkun qed inwettaq studju dettaljat bl-isem ta' "Introduzzjoni tad-Dijalisi tad-Dar fil-Gżejjer Maltin: Analiżi tan-Necessitajiet." [Kodiċi: FHS-2024-00090]. Dan il-proġett għandu l-għan li jesplora l-fatibbiltà u d-dežiderabbiltà tal-implimentazzjoni tad-dijalisi tad-dar f'Malta, billi jqis il-perspetivi ta' diversi stakeholders fis-sistema tas-saħħa tagħna.

Skop tal-Istudju:

Din ir-riċerka għandha l-għan li tesplora l-fatibilità u d-dežirabbiltà li jintroduċi d-dijalisi tad-dar fil-Gżejjer Maltin. Tixtieq tiġbor għarfien minn diversi partijiet interessati—inklużi pazjenti, dawk li jieħdu ħsiebhom, professjonisti fis-settur tas-saħħa, u policymakers—biex tevalwa l-vantaġġi u l-isfidi potenzjali tal-implimentazzjoni tad-dijalisi tad-dar bħala alternativa għat-terapiji attwali ta' sostituzzjoni renali disponibbli f'Malta.

Bħala parteċipant, inti ser tiġi mistieden tipparteċipa f'intervisti fondi u diskussjonijiet li jgħinuna nifhmu l-aspettativi, il-preparazzjoni, u t-tħassib tiegħek rigward id-dijalisi tad-dar.

Kunfidenzjalità u Psewdonimita'

Jekk jogħġbok kun assigurat li kull informazzjoni maqsuma matul l-intervisti ser tinżamm kunfidenzjali. Id-data ser tiġi psewdonimizzatau użata biss għal skopijiet din ir-riċerka. Linji gwida eticiċi streti ser jiġu segwiti biex jipproteġu l-privatezza tiegħek u l-integrità tar-riċerka. Is-Superviżura tal-proġett tar-riċerka (Prof. S. Buttigieg [sandra.Buttigieg@um.edu.mt]) u l-membri tal-Bord tal-Eżami ser ikollhom aċċess għad-data kodifikata miġbura għall-għan ta' evalwazzjoni tal-proġett u s-sejbiet tiegħu.

F'ċirkostanzi eċċezzjonali, is-superviżur u l-eżaminaturi jista' jkollhom aċċess għad-dejta personali wkoll, għal skopijiet ta' verifika. F'każ li xi parteċipant jixtieq ikun jaf liema eżaminatur aċċessa d-data personali tiegħu, jista' jikseb din l-informazzjoni billi jċempel in-numru ta' kuntatt provdut: +356 2340 1120.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Il-kunfidenzjalità u l-psewdonimita' tiegħek se jkunu assigurati permezz tal-użu ta' kodiċijiet. Dan ifisser li minflok tuża ismek veru, se nagħtuk kodiċi għar-risposti tiegħek biex niżguraw li l-identità tiegħek tkun protetta.

Ħażna u Sigurtà tad-Data

Id-data personali tiegħek se tinħażen ofline f'verżjoni kriptata fuq hard disk estern biex niżguraw is-sigurtà tagħha. Din id-data se tkun aċċessibbli biss għat-tim tar-riċerka.

Bħala parteċipant, għandek id-dritt taħt ir-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika iktar id-dispożizzjonijiet rilevanti ta' dak ir-regolament biex taċċessa, tikkoreġi, u fejn applikabbli titlob li d-data li tikkonċernik tinqered (jew tinżamm f'forma anonimizzata).

Il-Ħtieġa u l-Użu tad-Data

Int se tkun mitlub/a taqsam biss id-data li hija neċessarja għar-riċerka. Id-data identifikabbli personali se titħassar meta ma tkunx aktar neċessarja, jiġifieri sa Settembru 2025. Id-data anonimizzata se tinżamm għal perjodu indefinit.

Jekk tagħżel li tirtira minn dan l-istudju, id-dejta kollha miġbura mill-intervista tiegħek se titħassar sakemm dan ikun possibbli teknoloġikament (pereżempju, qabel ma tiġi anonimizzata jew ippubblikata), sakemm it-tħassir tad-dejta ma jagħmilx impossibbli jew ma jimpedix serjament il-kisba tal-objetivi tar-riċerka, f'liema każ id-dejta se tinżamm f'forma anonimizzata.

Parteċipazzjoni Volontarja u Irtirar

Jekk jogħġbok kun assigurat li tirrifjuta li tipparteċipa jew li tirtira mill-istudju fi kwalunkwe ħin mhux se jinvolvi l-ebda penali jew telf ta' benefiċċji li inti intitolat/a għalihom. Il-parteċipazzjoni tiegħek hija kompletament volontarja.

Benefiċċji u Riskji tal-Parteċipazzjoni:

Il-parteċipazzjoni tiegħek hija kruċjali biex tgħin tidentifika fatturi ewlenin li jistgħu jagħmlu d-dijalisi tad-dar għażla vijabbli u benefiċjali għal pazjenti b'marda renali terminali f'Malta. Billi taqsam l-esperjenzi u l-opinjonijiet tiegħek, tkun qed tikkontribwixxi għal fehim aktar wiesa' tal-bżonnijiet u l-preferenzi li jinfluwenzaw is-servizzi tas-saħħa.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Il-parteċipazzjoni f'dan l-istudju għandha riskji minimi, li jistgħu jinkludu tensjoni psikoloġika minħabba suġġeti sensitivi. Biex jiġu mtafija dawn ir-riskji, se tiġi żgurata ambjent sikur u kunfidenzjali, se jsiru verifiki regolari biex tiġi mmonitorjata l-benessri emozzjonali waqt l-intervisti, u se jingħataw id-dettalji ta' kuntatt tas-servizzi ta' appoġġ meħtieġa.

Id-disponibbiltà biex tipparteċipa għandha tiġi indikata billi tintbagħat lura l-Formola ta' Kunsens ifirmata lir-riċerkatur. Ladarba l-formola tasal, tiġi pprovduta stedina għall-intervista. Jekk għandek xi mistoqsijiet jew teħtieġ aktar informazzjoni dwar ir-riċerka jew il-parteċipazzjoni tiegħek, tista' tikkuntattja lili jew lil Prof S. Buttigieg.

Grazzi tal-interess tiegħek li tipparteċipa f'dan l-istudju importanti. Ninsab ħerqan/a għall-kontribut siewi tiegħek u nittama li flimkien nistgħu ntejbu l-kwalità tal-kura tal-kliewi f'Malta.

Tislijiet,

_____

Matthias Azzopardi
Student ta' l-M. Sc.

Fakultà tax-Xjenzi tas-Saħħa,

Università ta' Malta

_____

Prof Sandra C Buttigieg
M.D.(Melit.),M.Sc.(Pub.Hlth.),M.B.A.(Exec.)(Melit.),Ph.D.(Aston),F.F.P.H.(UK),M.M.C.F.D.

Superviżura tar- Riċerka

Fakultà tax-Xjenzi tas-Saħħa,

Università ta' Malta

(T: +356 2340 1906)

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Participation in Interviews for Home Haemodialysis Research Project

Dear Colleague,

As my research project for the Master of Science in Health Systems Management & Leadership at the University of Malta, I will be conducting a detailed study titled **"Introduction of Home Haemodialysis in the Maltese Islands: A Needs Analysis."** [Code: FHS-2024-00090]. This project aims to explore the feasibility and desirability of implementing home haemodialysis in Malta, considering the perspectives of various stakeholders within our healthcare system.

Purpose of the Research

This research seeks to understand the potential for home haemodialysis to improve patient outcomes and operational eficiency in the Maltese healthcare context. Your insights and experiences are crucial to understanding the readiness, expectations, and potential challenges of this innovative healthcare strategy.

Interview Details

- Format: One-on-one or small group interviews, depending on availability and preference.

- Duration: Approximately 30 minutes per session.

- Medium: Interviews can be conducted in-person or via teleconference, based on your convenience.

Confidentiality and Pseudonymity

Please rest assured that all interview data will be treated with the utmost confidentiality. Details will be pseudonymised and used solely for the purpose of this academic research. No individual participant will be identifiable in any reports or publications resulting from this study. The Supervisor of the research project (Prof. S. Buttigieg [sandra.Buttigieg@um.edu.mt]) and the members of the Examination Board will have access to the coded data collected for the purpose of evaluating the project and its findings.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

In exceptional circumstances, the supervisor and examiners may have access to personal data too, for verification purposes. In case any participant wishes to know which examiner accessed their personal data, they may obtain this information by calling the provided contact number: +356 2340 1120.

Your confidentiality and pseudonymity will be assured through the use of codes. This means that instead of using your real name, we will assign a code to your responses to ensure your identity is protected.

Details of Participation

As a participant, you will be asked to take part in interviews and/or focus groups to share your perspectives on the introduction of home haemodialysis in the Maltese Islands.

Data Storage and Security

Your personal data will be stored ofline in an encrypted version on an external hard disk to ensure its security. This data will be accessible only to the research team. Anonymised data will be retained for an indefinite period.

As a participant, you have the right under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation to access, rectify, and where applicable ask for the data concerning you to be erased (or retained in anonymised form). Should you choose to withdraw, any data collected from your interview will be erased as long as this is technically possible (for example, before it is anonymised or published), unless erasure of data would render impossible or seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.

Data Necessity and Usage

You will only be asked to share data that is necessary for the research. Personally identifiable data will be deleted when it is no longer necessary, which will be September 2025.

Ethical Considerations

This study has been reviewed and approved by the relevant University of Malta ethics committee. Participation is completely voluntary, and you may withdraw at any time.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Benefits and Risks of Participation

By participating, you will contribute significantly to the shaping of future healthcare policies and practices in Malta. The findings of this study could lead to improvements in patient care and service delivery.

Participating in this study poses minimal risks, which may include potential psychological distress from sensitive topics. To mitigate these risks, a safe, confidential environment will be ensured, regular check-ins will be conducted to monitor emotional well-being during interviews, and contact details of any necessary support services will be provided.

Next Steps

Availability to participate should be indicated by returning the signed Consent Form to the researcher. Once the form is received, an interview invitation will be provided. Should you have any questions or require further information, please do not hesitate to contact me or my supervisor.

Thank you for your interest in participating in this important study. I look forward to your valuable input and hope that together, we can enhance the quality of renal care in Malta.

Matthias Azzopardi
M. Sc. Health Systems Management & Leadership Student

Faculty of Health Sciences,

University of Malta

Prof Sandra C Buttigieg
M.D.(Melit.),M.Sc.(Pub.Hlth.),M.B.A.(Exec.)(Melit.),Ph.D.(Aston),F.F.P.H.(UK),M.M.C.F.D.

Research Supervisor

Faculty of Health Sciences,

University of Malta

(T: +356 2340 1906

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Parteċipazzjoni f'Intervisti għal Proġett ta' Riċerka dwar id-Dijalisi tad-Dar

Għażiż Kollega,

Bħala parti mir-riċerka għall-*Masters* se nkun qed inwettaq studju dettaljat bl-isem ta' "Introduzzjoni tad-Dijalisi tad-Dar fil-Gżejjer Maltin: Analiżi tan-Necessitajiet." [Kodiċi: FHS-2024-00090]. Dan il-proġett għandu l-għan li jesplora l-fatibbiltà u d-dežiderabbiltà tal-implimentazzjoni tad-dijalisi tad-dar f'Malta, billi jqis il-perspetivi ta' diversi stakeholders fis-sistema tas-saħħa tagħna.

Skop tar-Riċerka

Din ir-riċerka tfittex li tifhem il-potenzjal għal dijalisi tad-dar biex ittejjeb ir-riżultati tal-pazjenti u l-effiċjenza operativa fil-kuntest tas-saħħa Malti. L-għarfien u l-esperjenzi tiegħek huma kruċjali biex nifhmu l-preparazzjoni, l-aspettativi, u l-isfidi potenzjali ta' din l-istrateġija innovativa tas-saħħa.

Dettalji tal-Intervista

- Format: Intervisti individwali jew f'gruppi żgħar, skont id-disponibbiltà u l-preferenza.

- Tul: Madwar 30 minuta kull sessjoni.

- Medju: L-intervisti jistgħu jsiru wiċċ imb wiċċ jew permezz ta' telekonferenza, skont il-konvenjenza tiegħek.

Kunfidenzjalità u Psewdonimita'

Jekk jogħġbok kun assigurat li kull informazzjoni maqsuma matul l-intervisti ser tinżamm kunfidenzjali. Id-data ser tiġi psewdonimizzatau użata biss għal skopijiet din ir-riċerka. Linji gwida etiċi streti ser jiġu segwiti biex jipproteġu l-privatezza tiegħek u l-integrità tar-riċerka. Is-Superviżura tal-proġett tar-riċerka (Prof. S. Buttigieg [sandra.Buttigieg@um.edu.mt]) u l-membri tal-Bord tal-Eżami ser ikollhom aċċess għad-data kodifikata miġbura għall-għan ta' evalwazzjoni tal-proġett u s-sejbiet tiegħu.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

F'ċirkostanzi eċċezzjonali, is-superviżur u l-eżaminaturi jista' jkollhom aċċess għad-dejta personali wkoll, għal skopijiet ta' verifika. F'każ li xi parteċipant jixtieq ikun jaf liema eżaminatur aċċessa d-data personali tiegħu, jista' jikseb din l-informazzjoni billi jċempel in-numru ta' kuntatt provdut: +356 2340 1120.

Il-kunfidenzjalità u l-psewdonimita' tiegħek se jkunu assigurati permezz tal-użu ta' kodiċijiet. Dan ifisser li minflok tuża ismek veru, se nagħtuk kodiċi għar-risposti tiegħek biex niżguraw li l-identità tiegħek tkun protetta.

Dettalji tal-Parteċipazzjoni

Bħala parteċipant, int se tkun mitlub/a tieħu sehem f'intervisti u/jew focus groups biex taqsam il-perspetivi tiegħek dwar l-introduzzjoni tad-dijaliżi fid-dar fil-Gżejjer Maltin.

Ħażna u Sigurtà tad-Data

Id-data personali tiegħek se tinħażen ofline f'verżjoni kriptata fuq hard disk estern biex niżguraw is-sigurtà tagħha. Din id-data se tkun aċċessibbli biss għat-tim tar-riċerka.

Bħala parteċipant, għandek id-dritt taħt ir-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leġiżlazzjoni nazzjonali li timplimenta u tispeċifika iktar id-dispożizzjonijiet rilevanti ta' dak ir-regolament biex taċċessa, tikkoreġi, u fejn applikabbli titlob li d-data li tikkonċernik tinqered (jew tinżamm f'forma anonimizzata). Jekk tagħżel li tirtira minn dan l-istudju, id-dejta kollha miġbura mill-intervista tiegħek se titħassar sakemm dan ikun possibbli teknoloġikament (pereżempju, qabel ma tiġi anonimizzata jew ippubblikata), sakemm it-tħassir tad-dejta ma jagħmilx impossibbli jew ma jimpedix serjament il-kisba tal-objetivi tar-riċerka, f'liema każ id-dejta se tinżamm f'forma anonimizzata.

Il-Ħtieġa u l-Użu tad-Data

Int se tkun mitlub/a taqsam biss id-data li hija neċessarja għar-riċerka. Id-data identifikabbli personali se titħassar meta ma tkunx aktar neċessarja, jiġifieri sa Settembru 2025. Id-data anonimizzata se tinżamm għal perjodu indefinit.

Konsiderazzjonijiet Etici

Dan l-istudju ġie rivedut u approvat mill-kumitat tal-etika relevanti tal-Università ta' Malta. Il-parteċipazzjoni hija kompletament volontarja, u tista' tirtira fi kwalunkwe ħin.

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Benefiċċji u Riskji tal-Parteċipazzjoni

Billi tieħu sehem, int se tikkontribwixxi b'mod sinifikanti għall-formazzjoni tal-politiki u l-pratiki tas-saħħa futuri f'Malta. Ir-rizultati ta' dan l-istudju jistgħu jwasslu għal titjib fil-kura tal-pazjenti u fil-forniment tas-servizzi.

Il-parteċipazzjoni f'dan l-istudju għandha riskji minimi, li jistgħu jinkludu tensjoni psikoloġika minħabba suġġeti sensitivi. Biex jiġu mtafija dawn ir-riskji, se tiġi żgurata ambjent sikur u kunfidenzjali, se jsiru verifiki regolari biex tiġi mmonitorjata l-benessri emozzjonali waqt l-intervisti, u se jingħataw id-dettalji ta' kuntatt tas-servizzi ta' appoġġ meħtieġa.

Id-disponibbiltà biex tipparteċipa għandha tiġi indikata billi tintbagħat lura l-Formola ta' Kunsens ifirmata lir-riċerkatur. Ladarba l-formola tasal, tiġi pprovduta stedina għall-intervista.

Jekk għandek xi mistoqsijiet jew teħtieġ aktar informazzjoni, tista' tikkuntattja lili jew lil Prof Butiegieg.

Grazzi tal-interess tiegħek li tipparteċipa f'dan l-istudju importanti. Ninsab ħerqan/a għall-kontribut siewi tiegħek u nittama li flimkien nistgħu ntejbu l-kwalità tal-kura tal-kliewi f'Malta.

Tislijiet,

_____

Matthias Azzopardi

Student ta' l-M. Sc.

Fakultà tax-Xjenzi tas-Saħħa,

Università ta' Malta

_____

Prof Sandra C Buttigieg
M.D.(Melit.),M.Sc.(Pub.Hlth.),M.B.A.(Exec.)(Melit.),Ph.D.(Aston),F.F.P.H.(UK),M.M.C.F.D.

Superviżura tar- Riċerka

Fakultà tax-Xjenzi tas-Saħħa,

Università ta' Malta

(T: +356 2340 1906)

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Patient and Caregiver Interview Guide: Home Haemodialysis Introduction

Introduction

- Brief introduction of the interviewer and the purpose of the study.

- Explanation of the interview process and assurance of confidentiality and anonymity.

- Obtain informed consent to participate in the interview.

Part 1: Background Information

1. Demographic Information

- Age, gender, and living situation (e.g., alone, with family).

- Length of time diagnosed with kidney disease and current treatment regimen.

2. Medical History

- Overview of medical history related to kidney disease and other significant health issues.

- Current dialysis regimen: frequency, duration, and mode (in-center Haemodialysis, Peritoneal Dialysis, etc.).

Part 2: Understanding of Home Haemodialysis

3. Knowledge about Home Haemodialysis

- What is your understanding of home haemodialysis?

- How did you learn about it? (e.g., healthcare provider, other patients, reading material)

4. Perceived Advantages

- What benefits do you think home haemodialysis offers over in-center dialysis?

- How do you feel about the possibility of receiving dialysis at home?

Part 3: Feasibility and Readiness

5. Home Environment Assessment

- Describe your home environment. Do you think it is suitable for home haemodialysis? Why or why not?

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

- What changes would be necessary to accommodate home haemodialysis equipment and care needs?

6. Support System

- Who are your primary caregivers? What is their understanding and willingness to manage home haemodialysis?

- Describe the support you receive from family or friends concerning your health care.

Part 4: Expectations and Concerns

7. Expected Challenges

- What concerns or fears do you have regarding the transition to home haemodialysis?

- Are there logistical, technical, or medical support concerns you foresee?

8. Training and Education Needs

- What type of training and support do you think you and your caregiver would need to manage dialysis at home?

- How confident are you in your ability to manage potential complications from home haemodialysis?

Part 5: Decision-Making and Preferences

9. Decision Factors

- What factors will influence your decision to switch to home haemodialysis (e.g., health benefits, cost, independence)?

- How do you weigh these factors in making healthcare decisions?

10. Long-Term Perspective

- How do you see home haemodialysis impacting your quality of life in the long run?

- What hopes do you have for your future health management?

Conclusion

- Recap of the discussion and opportunity for the patient/caregiver to ask questions or add additional comments.

- Thank the participant for their time and contribution to the study.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Interview Guide for Healthcare Workers (Nurses, Doctors, Technicians) in the Renal Division

Introduction

- Greet the participant and explain the purpose of the interview.

- Ensure confidentiality and inform about the voluntary nature of the interview.

- Obtain informed consent to record the interview for analysis.

Section 1: Background Information

1. Can you briefly describe your role and experience in the renal division?

2. How long have you been involved in providing care to patients with end-stage kidney disease?

Section 2: Current Experience with Renal Replacement Therapy

1. What has been your experience with the current renal replacement therapies offered in Malta (haemodialysis, peritoneal dialysis)?

2. Can you discuss any challenges you currently face with the provision of these therapies?

Section 3: Perception and Knowledge about Home Haemodialysis (HHD)

1. Are you familiar with the concept of home haemodialysis? If yes, what is your understanding of it?

2. From your perspective, what are the potential benefits of introducing HHD in Malta?

3. What challenges do you foresee in implementing HHD?

Section 4: Feasibility of Home Haemodialysis

1. Considering the current infrastructure and resources, how feasible do you think the implementation of HHD is in Malta?

2. What are the key factors that need to be addressed to facilitate the transition to HHD?

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Section 5: Training and Support

1. What type of training do you think healthcare workers need to effectively support HHD?

2. How should ongoing support and supervision be structured for patients transitioning to HHD?

Section 6: Patient Selection and Readiness

1. In your opinion, what criteria should be used to select patients for HHD?

2. How can we assess the readiness of patients and their families for HHD?

Section 7: Stakeholder Perspectives

1. How do other healthcare workers and administrators within your division view HHD?

2. Have there been any discussions or resistance concerning the shift to HHD among your colleagues?

Section 8: Long-term Implications

1. How do you view the long-term impact of HHD on patient outcomes and quality of life?

2. What do you think will be the long-term benefits and challenges for the healthcare system with HHD?

Section 9: Recommendations

1. Based on your experience, what recommendations would you make to ensure the successful implementation of HHD?

2. Are there any specific tools or resources you think would be essential for managing HHD effectively?

Conclusion

- Thank the participant for their time and insights.

- Inform them about the next steps and how the findings from the interview will be used.

- Provide contact information for any follow-up questions or concerns.

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Interview Guide for Healthcare Administrators and Policy-makers

Section 1: Introduction

- Brief introduction of the interview purpose

- Explanation of confidentiality and consent

- Overview of the interview structure

Section 2: Background Understanding and Current Perceptions

1. Current State of Renal Replacement Therapy

- Can you describe the current infrastructure for renal replacement therapy in Malta?

- How does the existing service meet the demands of patients with end-stage kidney disease?

2. Awareness of Home Haemodialysis (HHD)

- What is your understanding of home haemodialysis and its potential benefits over in-hospital dialysis?

Section 3: Feasibility of Home Haemodialysis

1. Resource Availability

- What resources (financial, human, technical) are currently available that could support the implementation of HHD?

- What are the main logistical challenges you foresee in implementing HHD?

2. Training and Education

- What training and support infrastructure is necessary for both patients and healthcare providers for HHD?

- How do you assess the readiness of healthcare staff and patients for the transition to HHD?

Section 4: Policy and Regulation

1. Policy Framework

- What current policies could influence the implementation of HHD in Malta?

- Are there any regulatory changes required to facilitate the introduction of HHD?

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

2. Stakeholder Involvement

- How can different stakeholders (patients, families, healthcare providers) be effectively involved in the policy-making process for HHD?

Section 5: Desirability and Stakeholder Perspectives

1. Advantages of HHD

- From your perspective, what are the primary advantages of introducing HHD in Malta?

- How do you think HHD could impact patient quality of life and healthcare sustainability?

2. Challenges and Concerns

- What are the potential drawbacks or challenges of HHD from a policy standpoint?

- How can these challenges be addressed?

Section 6: Long-Term Vision and Strategy

1. Future of HHD

- Where do you see the role of HHD in the future of healthcare in Malta?

- What strategic steps are necessary to integrate HHD into the mainstream healthcare system?

2. Recommendations for Implementation

- Based on our discussion, what would be your top recommendations to ensure the successful implementation of HHD?

- What are potential areas for research or further study to support HHD?

Section 7: Conclusion

- Summary of key points discussed

- Opportunity for additional comments or insights

- Thank you and next steps

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Caregiver Questionnaire (Qualitative Survey on Home Haemodialysis)

(All responses are anonymous)

Part 1: Background

1. What is your relationship to the patient?

2. How long have you been a caregiver for this patient?

Part 2: Understanding of Home Haemodialysis

4. Before today, how familiar were you with home haemodialysis?

5. Where did you first learn about home haemodialysis?

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Part 3: Caregiving and Support

6. Do you feel confident that your home could be adapted for home haemodialysis?

7. How prepared do you feel to support the patient in managing home haemodialysis?

8. What type of support do you think you would need most?

Part 4: Concerns and Expectations

9. What are your main concerns about home haemodialysis?

10. In your opinion, what could make home haemodialysis easier for caregivers like you?

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Stħarriġ għall-*Caregivers* – Dijalisi fid-Dar *(Home Haemodialysis)*

(Ir-risposti kollha huma anonimi)

Parti 1: Kura tal-Pazjent

1. X'inhi r-relazzjoni tiegħek mal-pazjent?

2. Għal kemm-il żmien ilu int kustodju għal dan il-pazjent?

Parti 2: X'taf fuq *Home Haemodialysis?*

4. Qabel illum, kemm kont familjari mal-*Home Haemodialysis*?

5. Minn fejn sirt taf l-ewwel darba dwar l-*Home Haemodialysis*?

L-Università ta' Malta

FACULTY OF HEALTH SCIENCES

Dr. Matthias Azzopardi

M. Sc. in Health Systems Management & Leadership Student

Tel: 00356 99251287
E-mail: matthias.azzopardi.05@um.edu.mt

Parti 3: Kura u Appoġġ

6. Tħossok kunfidenti li d-dar tiegħek tista' tiġi adattata għall-*Home Haemodialysis*?

7. Kemm tħossok ippreparat biex tappoġġa lill-pazjent fil-ġestjoni tal-*Home Haemodialysis*?

8. X'tip ta' appoġġ taħseb li jkollok bżonn l-iktar?

Parti 4: Tħassib u Stennijiet

9. X'inhuma l-ikbar tħassib tiegħek dwar l-*Home Haemodialysis*?

10. Fil-fehma tiegħek, x'jista' jagħmel l-Home Haemodialysis aktar faċli għall-kustodji bħalek?

REDP Form

University of Malta staff, students, or anyone else planning to carry out research under the auspices of the University, must complete this form. The UM may also consider requests for ethics and data protection review by External Applicants.

Ahead of completing this online form, please read carefully the University of Malta Research Code of Practice and the University of Malta Research Ethics Review Procedures. Any breach of the Research Code of Practice or untruthful replies in this form will be considered a serious disciplinary matter. It is advisable to download a full digital version of the form to familiarise yourself with its contents (https://www.um.edu.mt/research/ethics/resources/umdocuments/). You are also advised to refer to the FAQs (https://www.um.edu.mt/research/ethics/faqs).

Part 1: Applicant and Project Details

Applicant Details

Name:
Matthias

Surname:
Azzopardi

Email:
matthias.azzopardi.05@um.edu.mt

Applicant Status:
Student

Please indicate if you form part of a Faculty, Institute, School or Centre: *
Faculty of Health Sciences

Department: *
Department of Health Systems Management and Leadership

Principal Supervisor's Name: *
Prof. Sandra C Buttigieg

Principal Supervisor's Email: *
sandra.buttigieg@um.edu.mt

Co-Supervisor's Name:

Study Unit Code: *
HSM5011

Course Title: *
Master of Science in Health Systems Management and Leadership

Student Number: *
05035019 / 0056788M

Project Details

Title of Research Project: *

Introduction of Home Haemodialysis in the Maltese Islands: A Needs Analysis

Project description, including research question/statement and method, in brief: *

socioeconomic factors (such as income, education, and resource accessibility) will be analysed.
The study will fill in this gap in knowledge by seeking practical solutions that can enhance dialysis accessibility. It recognises the intricate nature of the research problem and will make use of both qualitative data and triangulation of that data to facilitate a

Will project involve collection of primary data from human participants?

Yes / Unsure

Explain primary data collection from human participants:

Please explain the following aspects with regard to data collection from human participants.

a. Salient participant characteristics (e.g. min-max participants, age, sex, other): *

Patients with end-stage kidney disease (ESKD) in the Maltese Islands, with diverse support structures, who fall within predetermined inclusion criteria. Healthcare personnel, management, and policymakers. Healthcare workers will include renal nurses, physicians, and technicians. All participants will be adults (18 years of age),

b. How will they be recruited (e.g. sampled, selected, contacted, etc.): *

A census of all the patients in end-stage kidney disease (c.250) will be offered the opportunity to participate in the study via the use of one or more intermediaries. This being a qualitative study, if sufficient data to extract themes is attained, recruitment may be stopped at an earlier stage. Recruitment will be opt-in, allowing

c. What they will be required to do and for how long: *

Data collection will take place in the form of one-to-one interviews and focus groups It is envisaged that each interview will take c.30-60 mins. Focus group discussions will range from 1-2 hours.

d. If inducements/rewards/compensation are offered: *

No inducements, rewards or compensation will be offered.

e. How participants/society may benefit: *

The introduction of HHD in the Maltese Islands is anticipated to be a cost-efficient healthcare strategy, leading to an increase in the availability of dialysis slots. It is hypothesised to reduce the workload on renal unit staff and enhance the quality of care.

f. Is the participant's identity recorded at any stage of the research (e.g. in consent forms, records, publications): *

Each participant identity will be pseudonymised and given a unique identification number, different and unrelated to their identity number. Names or other distinguishing identifiers will not be taken or stored in the data collection sheet.

g. The manner in which you will manage and store the data and records (including consent forms): *

All personal data shall be password encrypted and stored offline in an encrypted version on an external hard disk. The only people with access to the data will be myself, my supervisor (and possible co-supervisor), and the Board of Examiners.

Will project involve collection of primary data from animals (live non-human vertebrates/cephalopods, their foetuses and larvae, their tissue/samples and/or dead specimens of these animals)?

No

Part 2: Self Assessment and Relevant Details

In what follows, all questions have been answered as "No or Not Applicable" by default. Please mark "Yes or Unsure" to any of the issues that may apply to your research. In such cases, your research proposal presents potential issues in the domain of research ethics and/or data protection. Therefore, you are kindly asked to elaborate upon the specific issue/s you indicate, and you will need to seek F/REC permission before data collection.

Human Participants

Skip questions 1-10 if your project does NOT involve primary data collection from human participants (or their tissue/samples).

1. Risk of harm to participants:

Are your participants at risk of harm? (Physical, psychological, legal, economic, social, etc.)

Yes / Unsure

Please explain: i. whether and how participants risk any harm (physical, psychological, legal economic or social) by participating in the research; ii. why such risks are unavoidable; iii. what safeguards you have taken to minimise the risk. *

Risks of harm to human participants may include breaches of confidentiality, participant distress when discussing personal experiences, and data bias. To mitigate these risks, the following measures will be taken:

2. Physical intervention:

Does your research involve non-harmful physical intervention on participants which may raise ethical concerns in your discipline?

No / N.A.

3. Vulnerable participants:

Do you include participants who, in your study or discipline, would be considered vulnerable or may be more at risk of being in vulnerability than others (e.g. children, persons who are older, with dementia, patients, subject to discrimination, with disabilities, with mental health conditions, unable to give consent, in prostitution, incarcerated, substance abusers, economically or educationally disadvantaged or minorities)?

Yes / Unsure

Please explain: i. the nature of the vulnerability; ii. what safeguards will be taken to protect vulnerable participants (e.g. by not stigmatising participants, not putting undue pressure, implementing safeguards while processing consent, providing contact details for professional help should this be required, safeguarding privacy, providing compensation, etc. If participants are unable to give consent, please explain how you intend to obtain their assent; if this is not possible, please explain why. *

In this study End-Stage Kidney Disease (ESKD) patients will be recruited. These patients face multiple vulnerabilities due to their condition and treatment. Physically, they are often weak and experience fatigue and pain, which may hinder participation. Emotionally and psychologically, chronic illness acts as a stressor,

4. Identifiable participants:

Are there participants in your research whose identity may be revealed in your research data, even though they have not given explicit consent to be so identified/attributed?

No / N.A.

5. Special Categories of Personal Data (SCPD):

Do you plan to collect SCPD, which, for identifiable participants (in records, data and/or publication), reveals race or ethnic origin, political opinions, religious or philosophical beliefs, membership in a trade union, genetic or biometric data that may uniquely identify a natural person, health, sex life and/or sexual orientation?

Yes / Unsure

Which of the following data categories are collected, if any? i. race and ethnic origin; ii. political opinions; iii. religious and philosophical beliefs; iv. trade union memberships; v. health status; vi. sex life or sexual orientation; vii. genetic information; viii. biometric data that may uniquely identify a natural person. Please describe. Please submit a Data Management Plan. *

In carrying out a qualitative study on the introduction of home haemodialysis in the Maltese islands by assessing stakeholder perspectives, patients will be asked to provide details on their medical history, condition, and treatment, which directly pertains to their health status.

6. Human tissue/samples:

Will your research involve the collection of human tissue/samples?

No / N.A.

7. Withheld info assent/consent:

Do you plan to withhold information from potential participants regarding the nature of the research when you seek to obtain assent/consent?

No / N.A.

8. 'opt-out' recruitment:

Will you use the 'opt-out' instead of the 'opt-in' method of obtaining consent when recruiting participants (i.e. will any participants be included in your study without providing explicit consent)?

No / N.A.

9. Deception in data generation:

Do you plan to actively provide false/misleading information or passively withhold information during the process of data generation (e.g. experiments, use of placebos, scenarios, games)?

No / N.A.

10. Incidental findings:

Could your research generate incidental findings that may need to be communicated to participants or others?

No / N.A.

Unpublished secondary data

Answer questions 11-13 if your research involves the use of secondary data. Otherwise skip to question 14.

11. Human:

Was the data collected from human participants?

No / N.A.

12. Animal:

Was the data collected from animals (live non-human vertebrates/cephalopods, their foetuses and larvae, their tissue/samples and/or dead specimens of these animals)?

No / N.A.

13. No written permission:

Is written permission from the data controller of the original data still to be obtained?

No / N.A.

Animals

Answer questions 14 - 16 if your project involves primary data collection from animals (non-human vertebrates and cephalopods or their foetuses or larvae) or their tissue/samples. Otherwise skip to question 17.

14. Live animals, lasting harm:

Does your research involve taking live animals out of their natural habitat for use in procedures or where such removal may cause the animals lasting harm?

No / N.A.

15. Live animals, harm:

Is there a risk that your research causes harm to live animals?

No / N.A.

16. Source of dead animals, illegal:

Does your research involve the use of dead animals (or their tissue/samples) that have not been acquired legally or from a legal source?

No / N.A.

General Considerations

These questions are to be considered for all projects.

17. Cooperating institution:

If you need permission from a cooperating institution, do you require F/REC approval prior to approaching the institution?

No / N.A.

18. Risk to researcher/s:

Does this research expose any members of the research team to any significant foreseeable risk that would require precautionary measures over and above those typically required in their line of work?

No / N.A.

19. Risk to environment:

Is there significant foreseeable risk that your research can cause harm to the environment?

No / N.A.

20. Commercial sensitivity:

Does your research make use of data that may be commercially sensitive?

No / N.A.

Other Potential Risks

Other potential risks for research ethics and data projection may arise from conflict of interest; harvesting social media data; the involvement of low income and/or lower middle income countries; the import and/or export of records, data, materials and specimens; the need for special permits/licenses to employ specific constructs/tests; the researcher/s having a dual role; and/or the dual use/misuse of research, among other. Applicants are advised to refer to the FAQs in case of doubt (https://www.um.edu.mt/research/ethics/faqs).

21. Other potential risks:

Does your research run other potential ethical or data protection risks?

No / N.A.

22. Official statement: Do you require an official statement from the F/REC that this submission has abided by the UM's REDP procedures?

Please note that answering "Yes / Unsure" here means that you may not start data collection until you receive F/REC approval. *You may also request a formal letter at a later date if you need it for publication/funding purposes.*

No / N.A.

Part 3: Submission

Which F/REC are you submitting to? *

Faculty applicants will submit automatically to the Faculty FREC. Non-Faculty applicants may refer to the UREC webpages and seek guidance from their Institute, Centre or School to identify which F/REC they should apply to.

Faculty of Health Sciences

Attachments:

Please indicate which of the following materials you are attaching. Failure to provide these, where relevant, risks delaying approval to proceed with the research. Materials should be attached below. Students may be required to produce their DRAFT letters of request ahead of sending to cooperating institutions and to obtain their supervisor's signature on consent and assent forms.

Researcher Actions

Submit REDP form

Draft/submitted forms

Account

Logout

- Research_Proposal_FINAL_To_Submit_to_FREC_v6_final.pdf (size: 471.6 KB, uploaded on: 23/04/2024 08:48:34)
- Research_Proposal_Summary.pdf (size: 146.0 KB, uploaded on: 23/04/2024 08:48:35)
- Ing_Attard_Montalto_Approval_of_Research_Proposal.pdf (size: 644.3 KB, uploaded on: 23/04/2024 08:48:38)
- Mr_Debono_-_Research_Project_Approval.jpg (size: 274.5 KB, uploaded on: 23/04/2024 08:48:40)
- Ms_C_Damato_Endorsement_of_Research_Project.pdf (size: 418.8 KB, uploaded on: 23/04/2024 08:48:42)
- Prof_Fava_Endorsement.pdf (size: 226.6 KB, uploaded on: 23/04/2024 08:48:43)
- Intermediary_Signed_Consent_1.jpg (size: 196.4 KB, uploaded on: 23/04/2024 08:48:44)
- Intermediary_Signed_Consent_2.jpg (size: 192.3 KB, uploaded on: 23/04/2024 08:48:45)
- DPO_Permission.pdf (size: 1.0 MB, uploaded on: 23/04/2024 08:48:52)
- Declaration_logo.pdf (size: 258.6 KB, uploaded on: 23/04/2024 08:48:53)
- Interview_Guide_for_Healthcare_Administrators_and_Policy-makers_logo.pdf (size: 229.2 KB, uploaded on: 23/04/2024 08:48:54)
- Interview_Guide_for_Healthcare_Workers_ENG_logo.docx.pdf (size: 193.3 KB, uploaded on: 23/04/2024 08:49:00)
- Interview_Guide_for_Healthcare_Workers_MLTlogo.pdf (size: 199.0 KB, uploaded on: 23/04/2024 08:49:02)
- Patient_and_Caregiver_Interview_Guide_MLTlogo.pdf (size: 246.4 KB, uploaded on: 23/04/2024 08:49:07)
- Patient_and_Caregiver_Interview_Guide_ENGlogo.pdf (size: 236.0 KB, uploaded on: 23/04/2024 08:49:09)
- MDH_Legal_Team_Approval.pdf (size: 248.2 KB, uploaded on: 16/05/2024 21:48:44)
- Data_Management_Plan.pdf (size: 177.9 KB, uploaded on: 16/05/2024 21:48:45)
- Office_of_the_CEO_Approval.pdf (size: 276.3 KB, uploaded on: 21/05/2024 19:51:15)
- Consent_Form_for_Participation_HCWs__Admin_ENGlogo.pdf (size: 276.2 KB, uploaded on: 16/08/2024 17:01:02)
- Consent_Form_for_Participation_HCWs__Admin_MLTlogo.pdf (size: 322.8 KB, uploaded on: 16/08/2024 17:01:04)
- Consent_Form_for_Participation_Patients_ENGlogo.pdf (size: 288.6 KB, uploaded on: 16/08/2024 17:01:05)
- Consent_Form_for_Participation_Patients_MLTlogo.pdf (size: 307.3 KB, uploaded on: 16/08/2024 17:01:07)
- Information_Letter_to_HCW_Admin_and_Policymakers_ENGlogo.pdf (size: 248.7 KB, uploaded on: 16/08/2024 17:01:08)
- Information_Letter_to_HCW_Admin_and_Policymakers_MLTlogo.pdf (size: 284.7 KB, uploaded on: 16/08/2024 17:01:10)
- Information_Letter_to_Patients_ENGlogo.pdf (size: 245.8 KB, uploaded on: 16/08/2024 17:01:11)
- Information_Letter_to_Patients_MLTlogo.pdf (size: 278.1 KB, uploaded on: 16/08/2024 17:01:13)

*Please produce these materials in English and/or Maltese and/or any other relevant language (or equivalent text that may be communicated orally for those who do not read).

Researcher Actions

Submit REDP form

Draft/submitted forms

Account

Logout

- [x] Information and/or recruitment letter*
- [x] Consent forms (adult participants)*
- [ ] Consent forms for legally responsible parents/guardians, in case of minors and/or adults unable to give consent*
- [ ] Assent forms in case of minors and/or adults unable to give consent*
- [x] Data collection tools (interview questions, questionnaire etc.)
- [x] Data Management Plan
- [ ] Data controller permission in case of use of unpublished secondary data
- [x] Licence/permission to use research tools (e.g. constructs/tests)
- [ ] Any permits required for import or export of materials or data
- [x] Letter granting institutional approval for access to participants
- [x] Institutional approval for access to data
- [x] Letter granting institutional approval from person directly responsible for participants
- [x] Other

Please feel free to add a cover note or any remarks to F/REC

If this is a re-submission of a Form to F/REC, please include previous form reference number. Please indicate if you require written approval for institutional/funding purposes. Please include reference to project grant and/or any previous ethics/data protection approval of related parent project. Please elaborate on any additional attachments you are providing.

Declarations: *

- [x] I hereby confirm having read the University of Malta Research Code of Practice and the University of Malta Research Ethics Review Procedures.
- [x] I hereby confirm that the answers to the questions above reflect the contents of the research proposal and that the information provided above is truthful.
- [x] I hereby give consent to the University Research Ethics Committee to process my personal data for the purpose of evaluating my request, audit and other matters related to this application. I understand that I have a right of access to my personal data and to obtain the rectification, erasure or restriction of processing in accordance with data protection law and in particular the General Data Protection Regulation (EU 2016/679, repealing Directive 95/46/EC) and national legislation that implements and further specifies the relevant provisions of said Regulation.

Applicant Signature: *

Write your full name here. By doing so and submitting this form you are effectively signing the declaration.

Matthias Azzopardi

Date of Submission: *

16/08/2024

If applicable: Date collection start date

Please insert envisaged date of data collection.

01/06/2024

Administration

REDP Application ID

FHS-2024-00090

Current Status

Approved

Audit Trail

Researcher Actions

Submit REDP form

Draft/submitted forms

Account

Logout

Researcher Actions

Submit REDP form

Draft/submitted forms

Account

Logout

23/04/2024 09:01
Matthias Azzopardi
Submitted by researcher

23/04/2024 16:21
Sandra C Buttigieg
Form set to Endorsed by supervisor

16/05/2024 20:19
Matthias Azzopardi
Form withdrawn by researcher

21/05/2024 19:53
Matthias Azzopardi
Submitted by researcher for review

21/05/2024 20:02
Sandra C Buttigieg
Form set to Endorsed by supervisor

17/06/2024 20:52
Matthias Azzopardi
Form withdrawn by researcher

17/06/2024 22:47
Matthias Azzopardi
Submitted by researcher for review

19/06/2024 08:16
Matthias Azzopardi
Form withdrawn by researcher

19/06/2024 08:18
Matthias Azzopardi
Submitted by researcher for review

26/06/2024 14:40
Matthias Azzopardi
Form withdrawn by researcher

26/06/2024 14:40
Matthias Azzopardi
Submitted by researcher for review

26/06/2024 14:49
Sandra C Buttigieg
Form set to Endorsed by supervisor

16/08/2024 16:32
Matthias Azzopardi
Form withdrawn by researcher

16/08/2024 16:32
Matthias Azzopardi
Form withdrawn by researcher

16/08/2024 16:32
Matthias Azzopardi
Form withdrawn by researcher

16/08/2024 16:34
Matthias Azzopardi
Submitted by researcher for review

Researcher Actions

Submit REDP form

Draft/submitted forms

Account

Logout

16/08/2024 16:58
Matthias Azzopardi
Form withdrawn by researcher

16/08/2024 17:01
Matthias Azzopardi
Submitted by researcher for review

18/08/2024 22:23
Sandra C Buttigieg
Form set to Endorsed by supervisor

20/08/2024 12:02
Research Ethics HEALTHSCI
Approved by F/REC

If a submitted application needs to be amended, it can be withdrawn, edited, and resubmitted, and it will retain the same reference number. There is no need to submit a new application.

L-Università ta' Malta

Matthias Azzopardi <matthias.azzopardi.05@um.edu.mt>

FHS-2024-00090 Matthias Azzopardi

Research Ethics HEALTHSCI <research-ethics.healthsci@um.edu.mt> 8 August 2024 at 12:44
To: Matthias Azzopardi <matthias.azzopardi.05@um.edu.mt>
Cc: Sandra C Buttigieg <sandra.buttigieg@um.edu.mt>, Paulann Grech <paulann.grech@um.edu.mt>

Dear Matthias,

Further to the correspondence below, please note that UREC-DP has reviewed your application. Approval is granted **on condition** that the following issues are addressed by the researcher and verified by the FREC before the research commences:

1. Participant Information Sheet/Consent Form

1.1. The description of the study should be removed from the Consent Form. This is done in case of a breach. For instance the following should be removed: *The interview will involve questions about your experience, opinions, and insights related to the provision of renal replacement therapy and the potential for home haemodialysis.*

1.2. The Consent Form or Info Sheet should include the following statement in relation to what is done with the data gathered about/from participants who withdraw their consent, since this is missing (except for audio recordings in the Declaration Form):

Should you choose to withdraw, any data collected from your interview will be erased as long as this is technically possible (for example, before it is anonymised or published), unless erasure of data would render impossible or seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.

1.3. The researcher mentions potential 'minimal risks', yet does not provide much details about what risks are foreseen. The researcher should also provide information on how these risks can be mitigated e.g. contact details of support services if risks include psychological distress.

2. Miscellaneous

2.1. Data collected should not be in excess of what is required for the study. In the consent form, the researcher asks for the participants' email. Is this truly required to reach the study objectives? If so, the researcher should include justification, but if not, the researcher should remove this request.

Please forward the **amended documents with track changes** **as a reply to all on the same email thread** to be approved oBo FREC. **Once the FREC has verified that all the issues raised above have been addressed, you may proceed with your study.**

Please forward me:

1. A soft copy of the documents a), b) and c) **merged in ONE pdf document**:
   a) the revised pages only made in Word using track changes.
   b) the endorsement email from your supervisor.
   c) the endorsement email from Prof Paulann Grech.

2. An updated soft copy of the amended document(s) only **(without track changes)**.

by not later than **Monday, 19th August 2024.**

ATTENTION:
In order to amend your previously submitted URECA Form, you need to withdraw it first. Then you can access the form in question from the “Draft/Submitted forms” section and amend it accordingly. Every time you “submit” the form, this needs to be endorsed by the supervisor (if any). Please make sure that any updated appendices forwarded to FREC are also attached to the URECA Form, on the URECA portal, without track changes. Once the URECA Form is updated, your application status will be set to "Approved".

Thanks and Regards,
Christabel

L-Università ta' Malta

Christabel Vella | Administration Specialist
B.A. (Hons) in Maltese

FREC Secretary
Faculty of Health Sciences
Room 6, Block A, Level 1
+356 2340 1575

[Quoted text hidden]

L-Università ta' Malta

Matthias Azzopardi <matthias.azzopardi.05@um.edu.mt>

RE: Master's Research Project

Data Protection at MHA - MDH <datapro.mdh@gov.mt> 17 April 2024 at 07:17
To: Matthias Azzopardi <matthias.azzopardi.05@um.edu.mt>
Cc: Young Sharon at MHA - MDH <sharon.young@gov.mt>, Data Protection Approval Form at MHA - MDH <dpaform.mdh@gov.mt>, Azzopardi Matthias at MHA - MDH <matthias.azzopardi@gov.mt>, Sandra C Buttigieg <sandra.buttigieg@um.edu.mt>

Dear Dr Azzopardi

On the basis of the documentation you submitted**,** **from MDH data protection point of view** you have been cleared to proceed with your study titled ***Introduction of Home Haemodialysis in the Maltese Islands: A Needs Analysis*** provided that:

1. Publications and any other requirements including recognition / obligations towards MDH will be discussed with MDH legal office.

2. You obtain approval from MDH CEO (ceo.mdh@gov.mt - please provide the relevant documents including Mr Chris Attard Montalto's, Ms Carmen D' Amato's and Prof Stephen Fava's approval, approval from MDH legal office and this clearance letter).

- Your intermediaries to approach potential participants on your behalf are *Mr Reuben Formosa – Senior Practice Nurse and Ms Charmaine Schembri – Charge Nurse; both working at the Renal Unit within the Department of Medicine, MDH*

- Your potential participants to attend your interviews are *Patients (not their relatives or anyone else) over the age of 18 years who are receiving a service at the Renal Unit within the Department of Medicine, MDH and Staff Nurses and Doctors who work at the Renal Unit within the Department of Medicine, MDH and Technicians who work at the Biomedical Engineering Directorate, MDH*

-

-

All data stored must be anonymized and in no way should you retain any personal details you obtain from your research and these should be destroyed at the end of your study and /or if any of your participants decides to withdraw. Remember that participants reserve the right to be forgotten.

Anonymisation and Data minimisation

Participant consent forms must be separated from the interview answers at source, meaning that there will be no correlation between one and the other that will indicate how participants replied.

ALL data presented to your supervisors / tutors or examiners or any other personnel from UOM or anyone else must be already anonymized; meaning that you must not divulge to anyone the identity of your participants and / or how they replied. If any participant wants to enquire who may have accessed personal data for verification purposes (in exceptional circumstances), one may contact 23401120.

Consent Criteria

This clearance does not allow viewing of medical records nor access to Health Information Systems / Medical Records.

All your participants must be reached and approached through the above- mentioned intermediaries when physically at MDH grounds (for patients) and through the gov email (for Nurses, Doctors and Technicians) and NOT via postal services, telephone or any other means. You cannot be handed any contact details of potential participants, otherwise consent would be bypassed.

Potential participants must be approached by the above- mentioned intermediaries for invitation and not directly by you. You can approach only after they accept.

Personal identifiable data such as signed consent forms or pseudonym lists are not to be sent via email (not even relayed to yourself), replicated and/or uploaded in any server, cloud storage, site or any other media given that participants will not consent any service provider to store their personal identifiable data.

Audio recordings must be strictly accessed and listened only by you (not even by your tutors, supervisors or any personnel from UOM) and that all data (including transcripts) presented to UOM must be completely anonymised. Such recordings are not to be sent via email, replicated and/or uploaded in any server, cloud storage, site or any other media. Audio recordings must be destroyed after the conversation will be transcribed or if a participant decides to withdraw from your study.

Transcription software shall be used offline.

Video recordings and photography are not allowed for this research.

If in agreement, the interview shall take place online (for staff) only after explicit written consent will be obtained with the online contact details that will be handed to you directly by the participant and not through another person.

During the online session you shall **only record the audio stream** and not the audio – visual stream given that you declared that video recordings will not be carried out.

Email approach for Staff

This clearance does not allow you to communicate with participants given that they will only be approached by the above- mentioned intermediaries through the gov email.

The above- mentioned intermediaries must approach potential participants only through the gov mail given that they will be representing MDH. Personal email accounts must not be used.

This clearance does not cover the above- mentioned intermediaries to approach potential participants through social media or any other means. MDH clearance is applicable for MDH grounds and not for public domains or any other spheres that are not under MDH's responsibility.

Potential participants for this approach are staff (Nurses, Doctors and Technicians) working at MDH; not staff or any other public servant who is not under the responsibility of MDH's Data Controller.

The above- mentioned intermediaries cannot obtain any email addresses lists specifically for your research otherwise personal data would be processed without consent. Instead, your intermediaries must reach potential participants from his / her already contacts.

When the above- mentioned intermediaries will send the mail shot to invite potential participants, the list of recipients should be in **Bcc** not ***To*** or ***Cc***.

Clarifications

This clearance does not cover ethical approval.

Your submitted documentation must remain unchanged.

All documents presented to your participants must include UOM's logo.

This clearance does not allow verbal consent.

What was declared during this clearance process is what you will abide to.

You must abide with all the articles of the GDPR (EU) 2016 / 679 throughout the data collection process and thereafter.

You are requested to submit a copy of your findings to this office at the end of your study.

This clearance covers your research to be carried out only within the Department of Medicine, MDH and not in any other department / institution such as Primary Healthcare, GGH, MHS, SVPR, DHIR or any other institution / department that doesn't form part of MDH Data Controller.

It is understood that *HCM, Admin and Policymakers* form part of the Nursing, Medical and Technical potential participants whom you will be interviewing.

It is understood that the term *Care Giver* refers to the Nursing and Medical professions whom you will be interviewing and not to the patients' relatives or anyone else. This clearance cannot cover the relatives or anyone else given that these Data Subjects are not within our Controllership.

Please communicate with Mr Reuben Formosa and with Ms Charmaine Schembri to present this clearance email.

To sign the data protection form, please contact Ms Graziella Aquilina through dpaform.mdh@gov.mt *to provide the following:*

1. *This clearance email in PDF – to provide in PDF*
2. *MDH Legal Office approval in PDF - pending*
3. *MDH CEO's approval in PDF - pending*
4. *The name of the Chairperson and Directors who approved your research -Prof Stephen Fava, Ms Carmen D' Amato and Mr Chris Attard Montalto*
5. *The period of data collection – June 2024 (after you and Prof Sandra Buttigieg will sign the DP form) – January 2025*
6. *Title of your research - Introduction of Home Haemodialysis in the Maltese Islands: A Needs Analysis*
7. *Your ID number and Prof Sandra Buttigieg's: - pending*

This form must be signed by your good self and by Prof Sandra Buttigieg before starting. You will both receive an email from adobe sign to sign electronically.

In summary – next step

1. Obtain approval from MDH Legal Office through legal-office.mdh@gov.mt
2. Obtain approval from MDH CEO through ceo.mdh@gov.mt
3. Sign the Data Protection form at Ms Aquilina through dpaform.mdh@gov.mt (please provide the above seven points)

[Quoted text hidden]

image001.jpg
24K

L-Università ta' Malta

Matthias Azzopardi <matthias.azzopardi.05@um.edu.mt>

Research Project Approval

Fenech Carol 1 at MHA - MDH <carol.fenech.1@gov.mt> 21 May 2024 at 11:03
To: Matthias Azzopardi <matthias.azzopardi.05@um.edu.mt>, Sandra C Buttigieg <sandra.buttigieg@um.edu.mt>
Cc: CEO at MHA - MDH <ceo.mdh@gov.mt>, Gatt Cherise at MHA- Contractors <cherise.gatt@contractors.gov.mt>

Dear Matthias,

On behalf of Ing. Keith Attard, CEO, Mater Dei Hospital, your study titled "***"Introduction of Home Haemodialysis in the Maltese Islands: A Needs Analysis."*** is hereby approved.

Kindly keep to the guidelines provided and as ethical clearance is sought.

Best regards,

Carol

Carol Fenech
Assistant Director and Coordinator for European Reference Networks
Admin- Office Of The CEO
MHA-Mater Dei Hospital

t: 25454102 **e:** carol.fenech.1@gov.mt
https://health.gov.mt

MINISTRY FOR HEALTH AND ACTIVE AGEING
Mater Dei Hospital, Triq Id-Donaturi Tad-Demm,
Msida, Malta

From: Matthias Azzopardi <matthias.azzopardi.05@um.edu.mt>
Sent: Monday, May 20, 2024 8:56 PM
To: Fenech Carol 1 at MHA - MDH <carol.fenech.1@gov.mt>; Sandra C Buttigieg <sandra.buttigieg@um.edu.mt>
Subject: FW: Research Project Approval

[Quoted text hidden]

image001.jpg
24K